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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1280

[Document No. AMS–LP–19–0093]

RIN 0581–AC06

Lamb Promotion, Research, and Information Order; Activity Changes

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rulemaking revises the Lamb Promotion, Research, and Information Order (Order), requiring market agencies (*e.g.,* commission merchant, auction market, livestock market) in the business of receiving lambs to collect and remit on behalf of the producer, feeder, or seedstock producer, the ''live-weight'' assessment on ovine animals sold and the ''price-per-head'' assessment owed by the first handler when lambs are sold through these channels. Market agencies are required to remit the full assessment to the American Lamb Board (also known as the Lamb, Promotion, Research, and Information Board (Board)) when ovine animals are sold. This rulemaking includes technical amendments to the Order, correcting references to assessment rates that were inadvertently not updated during the previous amendment to the Order.

DATES:

Effective date: January 21, 2022.

Delayed enforcement date: Enforcement of the market agency assessment remittance procedures is delayed until March 22, 2022.

FOR FURTHER INFORMATION CONTACT: Jason Julian, Agricultural Marketing Specialist, Research and Promotion Division, Livestock and Poultry Program, AMS, USDA; Telephone: (202) 731–2149; or Email: *jason.julian@usda.gov.*

SUPPLEMENTARY INFORMATION: Under the Order (7 CFR part 1280), which became effective April 11, 2002, the Board administers a nationally coordinated program of research, development, and promotion activities designed to strengthen the position of, and to develop and expand the markets for, ovine animals and ovine products. The program is financed by producers, feeders, and seedstock producers (*i.e.,* producers) who pay an assessment of seven-tenths of a cent ($0.007) per pound on all live lambs sold. Additionally, first handlers or exporters, pay $0.42 per head on ovine animals purchased for slaughter.

The Order currently mandates that assessments be collected from producers or feeders for the sale of live lambs, and that the assessment be forwarded to the subsequent purchaser (if applicable) until remitted by a first handler or exporter. That first handler or exporter is responsible for submitting both the producer or feeder's assessment and the first handler or exporter's assessment and volume report to the Board. The collection process is known as a ''pass-through'' assessment. Since the initial Order was established, industry markets have evolved; non-traditional first handlers, such as ethnic processors (butcher shops) and farmers market processors now participate to a larger degree in the purchasing and processing of lamb and lamb products. However, based on information about lamb sales from market agencies, the Board believes many non-traditional first handlers are not remitting assessments, as required by the Order. The Board, in turn, is not capturing all assessments paid by producers and feeders. Over the years, Board staff has worked to collect the owed lamb assessments from the nontraditional buyers, with limited success.

On January 23, 2019, the Board approved a motion to request the Secretary of Agriculture (Secretary) amend the assessment collection procedures and update corresponding sections of the Order. The revisions to the assessment collection procedures require market agencies to collect the full assessment, including the first handler assessment portion, for remittance to the Board. The assessment collection change only impacts lambs sold through market agencies. Other modes of sale, such as traditional markets (*e.g.,* first handler purchases from a producer or feeder, independent of a market agency) will continue to use the pass-through assessment collection process. *Examples 1* and *2* below show the current assessment collection processes when lambs are sold through a market agency:

Example 1—Existing Procedures—Producer sells lambs at market agency to a first handler: The producer pays the assessment to the market agency who passes the assessment through to the first handler. The first handler remits the live-weight (LW) and price-per-head (PH) assessments to the Board along with a Remittance Report form. This example is depicted in Figure 1.

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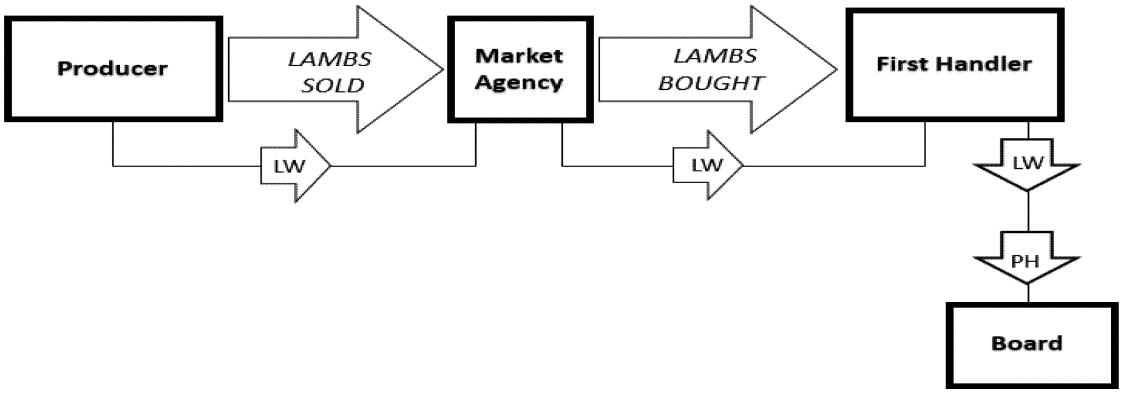
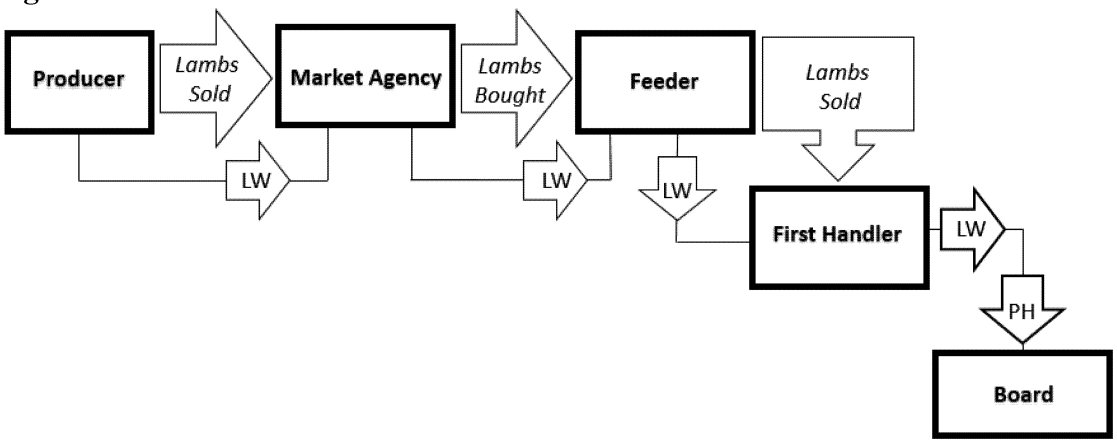
Figure 1.



Example 2—Existing Procedures—Producer sells lambs at market agency to a feeder. At a later date, the feeder sells the same lambs to a first handler (via traditional sales/non-market agency): The producer pays the live-weight assessment (LW) to the market agency, who passes the assessment through to the feeder. At a later date, the feeder sells the same lambs to a first handler, where the LW assessment passes-through to the first handler, who remits the LW assessment and the PH assessment to the Board. This example is depicted in Figure 2.

Figure 2.

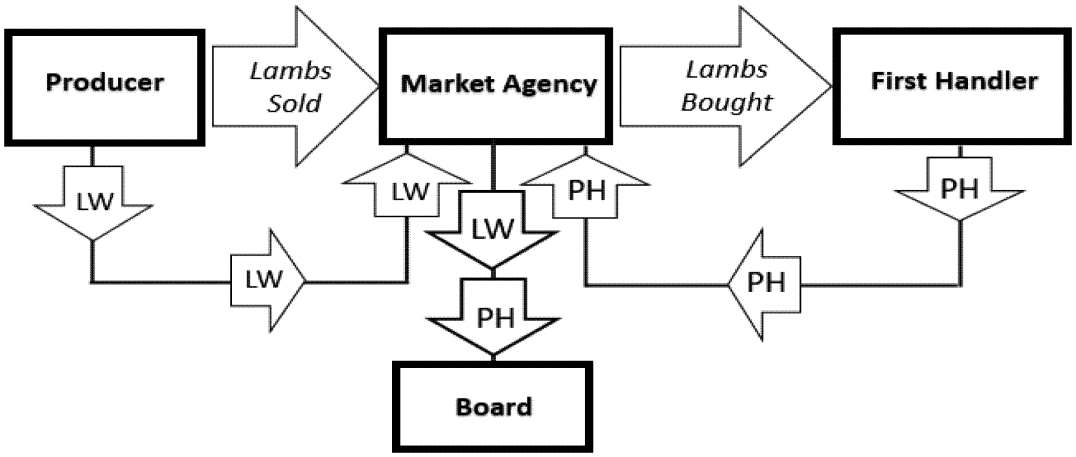


Under the proposed rule, existing procedures in *Example 1* above would stay the same and existing procedures in *Example 2* above, would be replaced as shown in the following three scenarios.

Under this final rule, existing procedures in *Example 1* and *Example 2* will be replaced as shown in the following three scenarios.

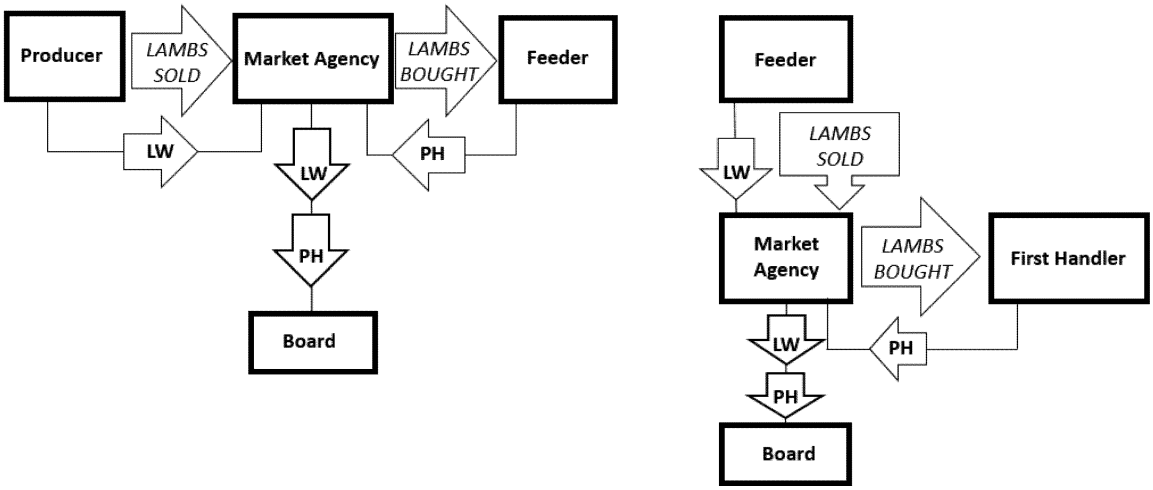
Example 3—Revised Procedure—Producer sells lambs at market agency to first handler: Under this final rule, the market agency collects the LW assessment from the producer and the PH assessment from the first handler and remits both assessments to the Board. This example is depicted in Figure 3.

Figure 3.



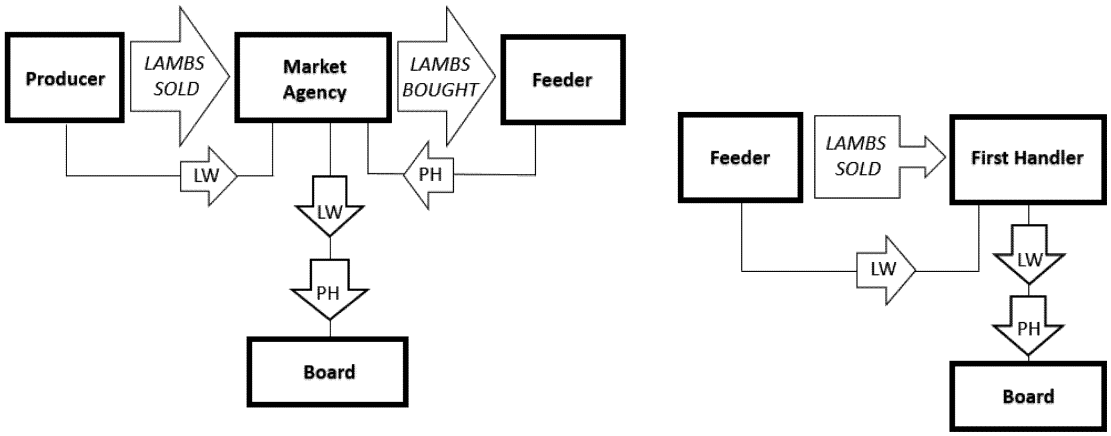
Example 4—Revised Procedure—Producer sells lambs at market agency to a feeder. At a later date, the feeder brings the same lambs to a market agency to sell to a first handler: The producer pays the LW assessment to the market agency. The feeder pays the PH assessment to the market agency, which remits both assessments to the Board (LW and PH). At a later date, when the feeder sells the same lambs at market agency, the feeder pays the LW assessment to the market agency, and the first handler pays the PH assessment to the market agency, which remits both assessments to the Board (LW and PH). Since the feeder was initially charged the PH assessment (first handler's assessment) and then paid the total LW assessment (lambs sold at market agency to the first handler), the feeder is eligible for a refund on the original PH assessment (initial first handler's assessment) and the difference between the total LW assessment and the producer's LW assessment. If the feeder were to exercise this option to recoup the two assessments, the feeder completes the Lamb Assessment Refund, form LP–85, and files with the Board to receive a refund. This example is depicted in Figure 4.

Figure 4.



Example 5—Revised Procedure—Producer sells lambs at a market agency to a feeder. At a later date, the feeder sells the lambs to a first handler (via traditional market/non-market agency sale): The producer pays the LW assessment to the market agency. Additionally, the feeder pays the PH assessment to the market agency, which remits both assessments to the Board (LW and PH). At a later date, when the feeder sells the lambs to a first handler (via traditional market/non-market agency sale), the feeder pays the LW assessment to the first handler, who remits the LW assessment and the PH assessment to the Board. The feeder is eligible for refunds on the original PH assessment paid (first handler assessment) and the difference between the total LW assessment and the producer's original LW assessment. If the feeder were to exercise this option to recoup the two assessments, the feeder completes the Lamb Assessment Refund, form LP–85, and files with the Board to receive a refund. This example is depicted in Figure 5.

Figure 5.



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The amended collection process is estimated to generate approximately $500,000 in new revenue, or approximately 20 percent of the Board's annual budget, based on 2019 production levels (pre-COVID 19). The Board's budget is based on the amount of assessments collected on an annual basis, voluntary contributions, and revenue derived from the investment of funds.

This final rule also adds a definition for *market agency* and makes technical corrections to the regulations that remove references to obsolete assessment rates. Finally, references to Order administration prior to appointment of the Board are removed.

The Commodity Promotion, Research, and Information Act of 1996 (Act) (7 U.S.C. 7413) provides for the creation of, and amendments to, the Order. The Order provides in § 1280.210 that the Board shall have the powers and duties to recommend to the Secretary such amendments to the Order as the Board considers appropriate.

Revisions

This final rule revises § 1280.101 to consolidate definitions listed in § 1280.101 through § 1280.129 and to establish a definition for *market agency.* Sections 1280.102 through 1280.129 are removed. This change alphabetizes and consolidates the definitions into one section, to simplify any future revisions to the Definitions Section.

This final rule revises § 1280.217(a) to reflect the current assessment rate of seven-tenths of a cent ($.007) per pound of live lambs sold. This corrects the reference to an obsolete assessment rate. Additionally, this final rule incorporates the last three sentences from current § 1280.217(e) into § 1280.217(a), maintaining the right of the Board to raise or lower the assessment rate. Section 1280.217(e) will be removed.

This final rule revises § 1280.217(c) to reflect the current first handler assessment rate and make a conforming change to reflect the elimination of § 1280.217(e). Additionally, a reference in § 1280.217(c) to the assessment rate in § 1280.217(e) is revised to reference the assessment rate in corrected § 1280.217(a).

This final rule revises § 1280.217(d) requiring market agencies to collect and remit the producer, seedstock producer, feeder, or first handler assessments to the Board. Additionally, § 1280.217(d), provides that lamb feeder farms who pay assessments twice may request a refund by completing and submitting the Lamb Assessment Refund, form LP–85, to the Board. This final rule removes § 1280.217(g), as it is no longer applicable, and makes conforming changes. Additionally, this final rule redesignates § 1280.217(f) as § 1280.217(e) and § 1280.217(h) as § 1280.217(f).

This final rule revises § 1280.218 to reference the assessment rate established in § 1280.217(a). This final rule revises § 1280.218 to change assessment due dates from ''time of export'' to ''the 15th day of the month following the month in which the lambs were purchased for slaughter and export or live export.'' This aligns with the current process for the collection of assessments listed in § 1280.220.

This final rule revises § 1280.220(a) and provides that market agencies, as well as first handlers and exporters, are responsible for collecting and remitting assessments to the Board.

This final rule makes a conforming change to § 1280.402(b) requiring market agencies to collect and remit assessments to the Board, to reflect the revision in § 1280.217(d).

Finally, this final rule revises § 1280.402(e)(1) by removing, ''. . . if a first handler markets lambs or lamb products directly to consumers, in order to avoid late payment charges.'' This phrase, which is not applicable here, was placed in this section inadvertently and should be removed.

Comments

The Agricultural Marketing Service (AMS) received 11 submissions to the proposed rule, 3 of the submissions contained multiple comments to the proposed rule.

Comment: One comment from an individual agreed with the proposed rule.

AMS Response: No response.

Comment: One comment received from an individual stated, ''go lambs.''

AMS Response: No response.

Comment: One comment received by a livestock sales association was against the proposed rule, stating that ''. . . requiring only transactions by marketing agencies, exporters, and first handlers to collect and remit the assessments, much of the volume currently conducted by marketing agencies will move away. This volume as well as volume currently conducted by other entities and individuals, will not be subject to collection and remittance of checkoff funds.''

AMS Response: Traditional lamb sales (first handler purchases from a producer or feeder, independent of a market agency) will still be subject to the current assessment remittance procedures via the pass-through collection process. Additionally, the Board performs monthly compliance checks and random onsite audits to determine potential sellers and buyers who are not remitting their assessments. Lastly, if the Board is made aware of new processing facilities or individuals who are selling or buying lambs, they

will notify such individuals of their requirements to remit assessments and will perform onsite audits, if needed. These efforts assist in ensuring that all appropriate entities and individuals who are subject to collection and remittance of checkoff funds are following the requirements of the Act and Order.

Comment: One comment received by a national trade association for livestock auction markets, stated that ''If auction markets are going to be made mandatory collection points, then all participants should be made to follow the rules of the checkoff through the pass-through and remittance requirements. The Board, through their partnership with the U.S. Department of Agriculture (USDA), AMS, should prioritize finding solutions to help those currently not participating in the process to come into compliance.

AMS Response: Anyone who sells or buys domestic lamb or lamb products in the United States of America, is required by law to pay the price-per-pound and price-per-head assessments. In order to reduce assessment delinquency rates or non-payment of assessment rates, the Board proposed market agencies collect the assessments at the point of sale/purchase. The collection of assessments at the market agency level will be a solution to those who do not currently participate in the assessment remittance process at the market agency level. Individuals who do not remit their assessments or who are late in the pass-through remittance process will continue to be subject to the Board's Compliance Department. Additionally, the Board performs monthly compliance checks and random onsite audits to determine potential sellers and buyers who are not remitting their assessments. Lastly, if the Board is made aware of new processing facilities or individuals who are selling or buying lambs, they will notify such individuals of their requirements to remit assessments and will perform onsite audits, if needed. These efforts assist in ensuring that all appropriate entities and individuals who are subject to collection and remittance of checkoff funds are following the requirements of the Act and Order.

Comment: One comment received was concerned that ''If the reason for making these changes are because first handlers are not remitting assessments to the Board now, it cannot be assumed they would disclose to the market agency they are the first handler and have the assessment deducted after the amendment.''

AMS Response: Under the final rule, anyone purchasing lambs at a market agency will be required to pay the $0.42 per-head-assessment rate on ovine animals, regardless if the buyer discloses that they are a first handler or not. Currently, there is no requirement in the Order for disclosing first handler status.

Comment: One comment received was concerned with implementation costs of the proposed rule. Another commenter was concerned with implementation costs of the proposed rule as well as the technical training of market agency staff on how to perform assessment collection procedures.

AMS Response: The Board will cover the costs of upgrades to each respondent's existing computer software system (at an estimated cost of $500 per respondent) and provide hands-on training to amend the collection and remittance process. Once this final rule is implemented, the Board will perform educational outreach to the market agencies to educate them on the new collection and remittance process. The outreach efforts will also consist of mailed educational materials and training webinars, which is estimated to cost $5 per respondent.

Comment: One commenter asked for flexibility on the frequency of assessment remittances to ''relieve the burden of constant documentation and remittance on markets, particularly those who do not regularly sell small ruminants at their businesses.'' Additionally, another commenter from an advocacy alliance group stated that ''if market agencies already have low sales volume, it is the position of the alliance that AMS ought to be lifting burdens, rather than adding to them.''

AMS Response: Due to the above comments, AMS reopened the comment period on two separate occasions [86 FR 10459 and 86 FR 24513] to encourage additional input on:

1. What level or threshold should AMS consider as a low-volume market agency that might be eligible for additional flexibility?

2. Approximately how many market agencies would fit into such a category?

3. How would this type of flexibility reduce regulatory burden for those market agencies?

Unfortunately, during the two additional comment periods, no data was provided to AMS to define a low-volume market agency. Should such data be provided at a later date, AMS would consider defining a low-volume market agency in hopes of alleviating the burden to said agencies. However, the final rule does allow for flexibility in the remittance process as auction markets only need to complete a remittance form when lambs were sold in the previous month. For those markets that do not sell lambs each month, this offers flexibility in the remittance of assessments. For example, seasonal market agencies, who facilitate the selling and buying of lambs for 3 months out of the year, will only be required to collect and remit assessments for those 3 months.

Comment: One commenter was concerned that the proposed rule could ''create an incentive for sellers of sheep to choose to market their livestock outside of a public auction environment through other private channels (*e.g.,* livestock dealers or direct sales) to skirt around checkoff requirements.''

AMS Response: Traditional lamb sales (first handler purchases from a producer or feeder, independent of a market agency) will still be subject to the current assessment remittance procedures via the pass-through collection process.

Multiple commenters responding to the proposed rule submitted comments that were outside the scope of this particular rulemaking. For example, one commenter suggested that Research and Promotion Programs should be voluntary in nature, instead of mandatory. Two commenters responded to the proposed rule in what appeared to be Slovakian language. When translated, the comments mentioned a cleaning company and the services they provided. Three commenters made disparaging remarks about the U.S. Government. Accordingly, AMS is making no changes to the final rule based on these comments.

Executive Orders 12866 and 13563

AMS is issuing this final rule in conformance with Executive Orders (E.O.) 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from E.O. 12866 review.

Executive Order 12988

This final rule has been reviewed under E.O. 12988, Civil Justice Reform. It is not intended to have a retroactive

effect. Section 524 of the Act provides that it shall not affect or preempt any other Federal or State law authorizing promotion or research relating to an agricultural commodity.

Under section 519 of the Act (7 U.S.C. 7418), a person subject to an order may file a written petition with USDA stating that an order, any provision of an order, or any obligation imposed in connection with an order, is not established in accordance with the law, and request a modification of an order or an exemption from an order. Any petition filed challenging an order, any provision of an order, or any obligation imposed in connection with an order, shall be filed within 2 years after the effective date of an order, provision, or obligation subject to challenge in the petition. The petitioner will have the opportunity for a hearing on the petition. Thereafter, USDA will issue a ruling on the petition. The Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall have the jurisdiction to review a final ruling on the petition, if the petitioner files a complaint for that purpose not later than 20 days after the date of the entry of USDA's final ruling.

Executive Order 13175

This final rule has been reviewed under E.O. 13175—Consultation and Coordination with Indian Tribal Governments. E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on: (1) Policies that have tribal implication including regulation, legislative comments, or proposed legislation; and (2) other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

AMS has assessed the impact of this final rule on Indian tribes and determined that this rule will not have tribal implications that require consultation under E.O. 13175. Additionally, AMS hosts a quarterly teleconference with tribal leaders where matters of mutual interest regarding the marketing of agricultural products are discussed. Information about the final rule was shared with tribal leaders during a quarterly conference call. AMS will continue to work with the USDA Office of Tribal Relations to ensure meaningful consultation is provided as needed with regards to the regulations.

Regulatory Flexibility Act

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), AMS has performed a RFA review regarding the impact of the final rule on small entities. The purpose of RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly burdened. AMS determined that small businesses will not be unduly burdened.

The North American Industry Classification System (NAICS) code for sheep farms is 112410. The Small Business Association (SBA) size classification for this industry limits the number of employees for a small business to 100 people. Based on industry response, almost all lamb farms employ fewer than 100 people; in fact, almost all lamb farms employ less than 15 people. The majority of lamb farms are considered small businesses.

According to the 2017 Census of Agriculture (AC–17–A–51), there were 60,675 farms that sold sheep and lambs. This number includes sheep and lambs raised for dairy, wool, and meat. This final rule focuses only on those lambs raised for meat. The census does not break down the data to the level of lamb feeder farms. Therefore, AMS has worked with industry stakeholders to understand the makeup of the industry. According to lamb industry estimates, of those 60,675 farms, 500 farms are considered feeder farms that raise lambs for meat. Additionally, the lamb industry estimates that of those 500 feeder farms, approximately 10 percent, or 50 of those feeder farms, could potentially purchase/sell their lambs at market agencies. The remainder of the feeder farms sell lambs directly to a first handler. Therefore, AMS has concluded that the number of feeder farms that raise lambs for meat that will be financially impacted by this final rule will not be considered substantial.

This final rule does not increase the assessment rates under the Order, thus no new economic burden is placed on producers, feeders, seedstock producers, or first handlers for sales that take place outside of market agencies, as that process for paying assessments will not change. When a sale takes place at a market agency, no new burden will be placed on producers or seedstock producers, regardless of size, as they will continue to pay their assessments to the market agency. No new burden will be placed on first handlers of any size as they will remit assessments to the market agency instead of the Board.

However, the final rule will place a burden on feeder farms who pay assessments twice, having to seek reimbursement for two assessments paid for the same lambs by filling out a Lamb Assessment Refund form. However, AMS concluded that this impact will not be considered substantial. Under this final rule, a lamb feeder farm could potentially pay assessments twice in scenarios 4 and 5 described above and will need to fill out a refund form after selling the lambs through a market agency to recoup the twice-paid assessment. This paperwork burden is described in detail in the Paperwork Reduction Act section of this final rule. During the initial 60-day comment period [85 FR 62617], AMS sought comments on whether the limited data available is representative of industry lamb numbers and what alternative data sources, if any, were available to further refine this analysis. Unfortunately, no data existed.

This final rule does require market agencies to report and collect assessments from producers, feeders, seedstock producers, and first handlers; and remit to the Board, thus placing a new burden on market agencies to collect and remit assessments for the sale and purchase of lambs.

NAICS code for marketing agencies is 424520. Firms in the 424-sector classification are defined as large or small depending on the number of employees rather than sales values. SBA size classification for this industry limits the number of employees for a small business to 100. Data on employee numbers for this industry is available from the U.S. Department of Commerce, Census Bureau. The most recent available data to determine the size of firms in the industry is from the 2012 Economic Census. According to the data, the vast majority of the firms (666 of 668 total firms) are small businesses. According to industry, of the 666 existing firms, approximately 300 market agencies that sell lambs will be impacted by this final rule. Currently, 50 full-time market agencies are voluntarily collecting and remitting producer assessments to the Board; however, they are not collecting and remitting first handler assessments. Additionally, 250 seasonal market agencies are not collecting and remitting either of the assessments to the Board.

The Board provided AMS an estimate that all 50 full-time market agencies currently utilize computer software in their information collection and billing processes. Therefore, implementation costs will consist of upgrades to each respondent's existing computer software system and hands-on training to amend

the collection and remittance process, at an estimated cost of $500 per respondent that will be paid for by the Board. Thus, lessening the burden on the markets. Additionally, the Board has provided an estimate to AMS that a large majority of the 250 seasonal market agencies currently perform their information collection and billing process utilizing computer software programs. Due to seasonal sales and low sheep volume sales per respondent, AMS anticipates that the seasonal markets will be able to utilize existing computer software systems or existing hard-copy tracking procedures for the new collection and remittance process. Once this final rule is implemented, the Board will perform educational outreach to the seasonal market agencies to educate them on the new collection and remittance process. The outreach efforts will consist of mailed educational materials and training webinars to limit the burden on auction managers to train personnel, which is estimated will cost $5 per respondent. Once the computer software is installed and the outreach efforts have been completed, the physical submission of the assessments to the Board will be the only burden on market agencies, which is considered a minor burden. However, the option to electronically remit the owed assessments to the Board is available, which will further reduce the burden. AMS considered the economic effect of this action on small entities and has determined that this final rule, while imposing new administrative burdens on market agencies and some feeder farms, will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

The information collection and recordkeeping requirements that are imposed by the Order have been approved previously under OMB control number 0581–0093. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, subchapter I).

The existing form (LP–81) will be amended to require data for the total lambs sold/slaughtered, to effectively carry out the requirements of the program, and its use is necessary to fulfill the intent of the Act. The Board will supply such information for data processing software and/or technical expertise to train market agency staff on how to complete the information collection and remittance process. The lamb information collection and remittance form will be simple, easy to understand, and will place as small a burden as possible on the person required to file the information.

The timing and frequency of collecting the revised information are intended to meet the needs of the industry while minimizing the amount of work necessary to fill out the required reports. In addition, the information that will be included on this form is not available from other sources because such information relates specifically to individual market agencies who are reporting information subject to the provisions of the Act. There is no practical method for collecting the required information without the use of these forms.

Information collection requirements that are in this proposal include:

Title: LP–81—Lamb Promotion, Research, and Information Board Remittance Report form.

OMB Number: 0581–0093.

Type of Request: Amended collection.

Abstract: The information collection requirements are essential to carry out this rule.

The Order authorizes the collection of assessments from lamb producers, feeders, seedstock producers, and first handlers. Under this final rule, market agencies are required to collect and remit assessments, while the collection and remittance process remains unchanged for lamb sales independent of market agencies. This final rule requires assessment-related records, including the Remittance Report form, be retained for at least 2 years beyond the fiscal year of their applicability. This is consistent with the current recordkeeping requirements of the program. Two hundred fifty of the 300 market agency respondents operate on a seasonal basis. It is estimated that these market agencies will complete three responses per respondent, as assessments are submitted monthly and a typical season consists of 3 months. The additional 50 market agency respondents operate on a full-time basis. These market agencies will complete an estimated 12 responses per year per respondent, as assessments are submitted monthly.

The design of this form has been carefully reviewed and every effort has been made to minimize any unnecessary recordkeeping costs or requirements, including efforts to utilize information already submitted under other lamb programs administered by USDA. The form will be available through the Board or USDA. The information collection will be used only by authorized Board employees and representatives of USDA, including AMS staff.

(1) The request for approval of the amended information collection is as follows: Form LP–81, Lamb Promotion, Research, and Information Board Remittance Report form.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 1 hour per lamb sale or purchase via market agency.

Respondents: Lamb Market Agencies.

Estimated Number of Respondents: 800 (includes 300 new respondents—50 monthly and 250 seasonal).

Estimated Number of Responses per new Respondent per year: 12 (monthly respondents $12 \times 550 = 6{,}600$ responses; and seasonal respondents $1 \times 250 = 250$ responses).

Estimated Total Annual Burden on Respondents: 6,850 hours (includes 850 new burden hours annually).

The total annual estimated cost for market agencies in providing the information to the Board is $125,150 (Increase in response total $850 \times \$18.27 = \$15{,}529.50$; grand total is $6{,}850 \times \$18.27 = \$125{,}149.50$). This total has been estimated by multiplying 850 total burden hours by $18.27, the estimated wage rate of respondents. AMS used the hourly wage of farmworkers, farm, ranch, and aquaculture animals as obtained from the U.S. Bureau of Labor Statistics, Occupational Employment and Wages, published May 2018. This publication can be found at the following website: *https://www.bls.gov/oes/current/oes_nat.htm.*

The average hourly wage rate of $13.87 with an additional 31.7 percent to account for benefits and compensations, for an hourly wage of $18.27, was used to calculate annual cost. Costs of benefits and compensation guidance were provided by Bureau of Labor Statistics News Release issued December 14, 2018.

To offset startup costs associated with the new collection and remittance process, the Board will allocate approximately $500 per full-time market agency respondent to upgrade their computer software programs and to provide staff training for the new collection and remittance procedures (50 full-time market agencies $\times$ $500 = $25,000). Additionally, the Board will provide educational training materials and will host training webinars with seasonal market agency staff on the new collection and remittance process. The Board will allocate approximately $5 for the educational materials and webinar training costs per seasonal market agency respondent (250 seasonal market agencies $\times$ $5 = $1,250).

This final rule also announces that AMS sought approval for a new information collection and recordkeeping requirement that is imposed under the Order. The new

information collection has been submitted to OMB for approval.

The ''Lamb Feeder Checkoff Refund'' form will require the minimum information necessary to effectively carry out the requirements of the program, and its use is necessary to fulfill the intent of the Act. Such information can be supplied without data processing equipment or outside technical expertise. In addition, there are no additional training requirements for individuals filling out reports and requesting a refund from the Board. The form will be simple, easy to understand, and place as small a burden as possible on the person required to file the information.

The timing and frequency of collecting information are intended to meet the needs of the industry while minimizing the amount of work necessary to fill out the required reports. In addition, the information to be included on this form is not available from other sources because such information relates specifically to individual market agencies who are subject to the provisions of the Act. Therefore, there is no practical method for collecting the required information without the use of these forms.

Information collection requirements that are included in this proposal include:

Title: LP–85—Lamb Assessment Refund Form.

OMB Number: 0581–0325.

Type of Request: New collection.

Abstract: The information collection requirements are essential to carry out this final rule.

The Order authorizes the collection of assessments from lamb producers, feeders, seedstock producers, and first handlers. Under this final rule, market agencies are required to collect and remit assessments for the purchase and sale of lambs, while the collection and remittance process remain unchanged when sales occur independent of market agencies. This final rule requires assessment-related records to be retained for at least 2 years beyond the fiscal year of their applicability. This is consistent with the current recordkeeping requirements of the program. According to the 2017 Census of Agriculture (AC–17–A–51), there were 60,675 farms that sold lambs. The census does not breakdown the data to the level of feeder farms. Therefore, AMS has worked with industry to understand the makeup of the industry. Of those farms, the lamb industry estimated that 500 are considered feeder farms. Additionally, the lamb industry estimates that of those 500 feeder farms, approximately 10 percent, or 50, of those feeder farms purchase or sell lambs at market agencies. The estimated time for each respondent to complete the Lamb Feeder Checkoff Refund form is 15 minutes. The estimated total hours for all respondents to complete the form is 150 hours (*i.e.,* 50 respondents multiplied by one quarter of an hour to complete the form per respondent multiplied by 12 forms being filled out per year, per respondent). The estimated total cost of requesting a refund from the Board, for all respondents, will be $2,740.50. The total cost has been estimated by multiplying the total hours for respondents to complete the form (150 hours) by $18.27, which is what AMS used for the hourly wage of farmworkers, farm, ranch, and aquaculture animals, as obtained from the U.S. Bureau of Labor Statistics, Occupational Employment and Wages, published May 2018. This publication can be found at the following website: *https://www.bls.gov/oes/current/oes_nat.htm.*

Based on the average hourly wage rate of $13.87 with an additional 31.7 percent to account for benefits and compensations, for an hourly wage of $18.27 was used to calculate annual cost. Costs of benefits and compensation guidance was provided by Bureau of Labor Statistics News Release issued December 14, 2018.

The design of this form has been carefully reviewed, and every effort has been made to minimize any unnecessary recordkeeping costs or requirements, including efforts to utilize information already submitted under other lamb program administered by USDA. The form will be available through the Board or USDA. The information collection will be used only by authorized Board employees and representatives of USDA, including AMS staff.

(2) The request for approval of the new information collection is as follows: Form LP–85, Lamb Feeder Checkoff Refund form.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 15 minutes per lamb purchase/sale by a feeder at a market agency.

Respondents: Feeder farms who sell lambs at market agencies.

Estimated Number of Respondents: 50.

Estimated Number of Responses per Respondent per Year: 12.

Estimated Total Annual Burden on Respondents: 150 hours.

Total Cost: $2,740.50.

List of Subjects in 7 CFR Part 1280

Administrative practice and procedure, Advertising, Agricultural research, Meat and meat products, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service amends 7 CFR part 1280 as follows:

PART 1280—LAMB PROMOTION, RESEARCH, AND INFORMATION ORDER

■ 1. The authority citation for part 1280 continues to read as follows:

Authority: 7 U.S.C. 7411–7425 and 7 U.S.C. 7401.

■ 2. Section 1280.101 is revised to read as follows:

§ 1280.101 Definitions

Act means the Commodity Promotion, Research, and Information Act of 1996 (7 U.S.C. 7411–7425; Public Law 104–127; 110 Stat. 1029, as amended), or any amendments thereto.

Board means the Lamb Promotion, Research, and Information Board established pursuant to § 1280.201.

Certified organization means any organization which has been certified by the Secretary pursuant to this part as being eligible to submit nominations for membership on the Board.

Conflict of interest means a situation in which a member or employee of a Board has a direct or indirect financial interest in a person that performs a service for, or enters into a contract with, a Board for anything of economic value.

Department means the United States Department of Agriculture.

Exporter means any person who exports domestic live lambs from the United States.

Feeder means any person who acquires ownership of lambs and feeds such lambs in the U.S. until they reach slaughter weight.

First handler means the packer or other person who buys or takes possession of lambs from a producer or feeder for slaughter, including custom slaughter. If a producer or feeder markets lamb products directly to consumers, the producer or feeder shall be considered a first handler with respect to such lambs produced by the producer or feeder.

Fiscal period and marketing year mean the 12-month period ending on December 31 or such other consecutive 12-month period as shall be recommended by the Board and approved by the Secretary.

Information means information and programs that are designed to increase efficiency in producing lambs, to

maintain and expand existing markets, and to develop new markets, marketing strategies, increased market efficiency, and activities that are designed to enhance the image of lamb and lamb products on a national or international basis. These include:

(1) Consumer information, which means any action taken to provide information to, and broaden the understanding of, the general public regarding the consumption, use, and nutritional attributes of lamb and lamb products; and

(2) Industry information, which means information and programs that will lead to the development of new markets, new marketing strategies, or increased efficiency for the lamb industry, and activities to enhance the image of lamb.

Lamb means ovine animals of any age, including ewes and rams.

Lamb products means products produced in whole or in part from lamb, including pelts, and excluding wool and wool products.

Market agency means commission merchant, auction market, or livestock market in the business of receiving lambs or lamb products for sale or purchase on commission for or on behalf of a producer, feeder, seedstock producer, or first handler.

Order means an Order issued by the Secretary under § 514 of the Act that provides for a program of generic promotion, research, and information regarding agricultural commodities authorized under the Act.

Part means the Lamb Promotion, Research, and Information Order and all rules and regulations issued pursuant to the Act and the Order. The Order shall be a subpart of the Part.

Person means any individual, group of individuals, partnership, corporation, association, cooperative, or any other legal entity.

Producer means any person who owns and produces lambs in the United States for sale.

Producer information means activities designed to provide producers, feeders, and first handlers with information relating to production or marketing efficiencies, development of new markets, program activities, or other information that would facilitate an increase in the demand for lamb or lamb products.

Promotion means any action, including paid advertising and the dissemination of culinary and nutritional information and public relations with emphasis on new marketing strategies, to present a favorable image of U.S. lamb products to the public for the purpose of improving the competitive position of U.S. lamb and lamb products in the marketplace and to stimulate sales.

Referendum means a referendum to be conducted by the Secretary pursuant to the Act whereby producers, feeders, first handlers, and exporters shall be given the opportunity to vote to determine whether the continuance of this subpart is favored by a majority of eligible persons voting and a majority of volume voting.

Research means any type of test, study, or analysis designed to advance the image, desirability, use, marketability, production, product development, or quality of lamb or lamb products.

Secretary means the Secretary of Agriculture of the United States or any other officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in the Secretary's stead.

Seedstock producer means any lamb producer in the U.S. who engages in the production and sale of breeding replacement lambs or semen or embryos.

State means each of the 50 States and the District of Columbia.

Suspend means to issue a rule under § 553 of title 5 U.S.C., to temporarily prevent the operation of an Order or part thereof during a particular period of time specified in the rule.

Terminate means to issue a rule under § 553 of title 5 U.S.C., to cancel permanently the operation of an Order or part thereof beginning on a date certain specified in the rule.

Unit means each State, group of States, or class designation (producers, feeders, first handlers, or seedstock producers) that is represented on the Board.

United States means collectively the 50 States and the District of Columbia.

Wool means fiber from the fleece of a lamb.

Wool products mean products produced, in whole or in part, from wool and products containing wool fiber, excluding pelts.

§§ 1280.102 through 1280.129 [Removed and Reserved]

■ 3. Remove and reserve §§ 1280.102 through 1280.129.

■ 4. Section 1280.217 is amended by:

■ a. Revising paragraphs (a), (c), and (d);

■ b. Removing paragraphs (e) and (g); and

■ c. Redesignating paragraphs (f) and (h) as paragraphs (e) and (f), respectively.

The revisions read as follows:

§ 1280.217 Lamb purchases.

(a) Except as prescribed by regulations approved by the Secretary, each first handler or exporter making payment to a producer, seedstock producer, or feeder for lambs purchased from such producer, seedstock producer, or feeder shall collect an assessment from the producer, seedstock producer, or feeder. Each producer, seedstock producer, or feeder shall pay such assessment to the first handler or exporter, at the rate of seven-tenths of a cent ($.007) per pound of live lambs sold. The rate of assessment may be raised or lowered no more than twenty-hundredths of a cent ($0.002) in any one year. The Board may recommend any change in the assessment rate to the Department. Prior to a change in the assessment rate, the Department will provide notice by publishing in the **Federal Register** any proposed changes with interested parties allowed to provide comment.

* * * * *

(c) Each person processing or causing to be processed lambs or lamb products of that person's own production and marketing such lambs or lamb products, shall pay an assessment on such lambs or lamb products on the live weight of the lamb at the time of slaughter at the rate established in subparagraph (a) of this section. In addition, pursuant to § 1280.108, such an individual is considered a first handler and is required by § 1280.219 to pay an additional assessment of $0.42 per head. As the first handler, the individual must remit the total amount of assessments to the Board.

(d) A market agency shall collect an assessment from the producer, seedstock producer, feeder, or first handler and remit the collected assessment to the Board. Any person who pays more than one assessment on the same lamb may be eligible for a refund by submitting a request on a form provided by the Board.

* * * * *

■ 5. Section 1280.218 is revised to read as follows:

§ 1280.218 Exporter.

Each person exporting live lambs or lamb products, including an exporter directly exporting his or her own lambs or lamb products, shall remit to the Board an assessment at the rate established in § 1280.217(a) by the 15th day of the month following the month in which the live lambs were purchased for slaughter and export or live export.

■ 6. Section 1280.220 is amended by revising paragraph (a) to read as follows:

§ 1280.220 Collections.

(a) Each first handler, market agency, and exporter responsible for the collection of assessments under this subpart shall remit assessments to the Board by the 15th day of the month following the month in which the lambs were purchased for slaughter or export.

* * * * *

■ 7. Section 1280.402 is amended by revising paragraphs (b) and (e)(1) to read as follows:

§ 1280.402 Assessments.

* * * * *

(b) *Market agency.* A market agency will be required to collect an assessment from the producer, feeder, seedstock producer, or first handler and remit the collected assessment to the Board.

* * * * *

(e) * * *

(1) Assessments shall be remitted to the Lamb Promotion, Research, and Information Program, c/o the Secretary at USDA, 23029 Network Place, Chicago, Illinois 60673–1230, with a ''Monthly Remittance Report'' form not later than the 15th day of the following month in which lambs or lamb products were purchased for slaughter or export, or marketed.

* * * * *

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2021–27467 Filed 12–21–21; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

8 CFR Part 214

RIN 1615–AC61

Modification of Registration Requirement for Petitioners Seeking To File Cap-Subject H–1B Petitions, Implementation of Vacatur

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Final rule; withdrawal.

SUMMARY: This final rule withdraws the ''Modification of Registration Requirement for Petitioners Seeking to File Cap-Subject H–1B Petitions,'' final rule issued on January 8, 2021, because that rule has been vacated by a Federal district court.

DATES: The Department of Homeland Security is withdrawing the final rule published January 8, 2021 (86 FR 1676), which was delayed by the final rule published February 8, 2021 (86 FR 8543), as of December 22, 2021.

FOR FURTHER INFORMATION CONTACT: Charles L. Nimick, Chief, Business and Foreign Workers Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 5900 Capital Gateway Drive, Mail Stop 2090, Camp Springs, MD 20588–0009. Telephone Number (240) 721–3000 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

I. Background and Basis for Removal of Regulations

On January 8, 2021, after going through notice and comment rulemaking, the Department of Homeland Security (DHS) issued a final rule titled ''Modification of Registration Requirement for Petitioners Seeking To File Cap-Subject H–1B Petitions'' (''H–1B Selection Final Rule'').[1] The rule was scheduled to go into effect on March 9, 2021. On February 8, 2021, DHS issued a final rule delaying the effective date of the H–1B Selection Final Rule to December 31, 2021.[2] On March 19, 2021, Plaintiffs in ongoing litigation moved to file an amended complaint in the U.S. District Court for the Northern District of California adding the H–1B Selection Final Rule to the list of challenged agency actions,[3] which the court granted leave to file on April 15, 2021.[4] Following several months of litigation, on September 15, 2021, the court vacated the H–1B Selection Final Rule and remanded the matter to DHS.[5]

DHS intends to comply with the court's decision vacating the H–1B Selection Final Rule. Therefore, since regulatory changes promulgated through the H–1B Selection Final Rule are scheduled to be codified in the Code of Federal Regulations (CFR) at 8 CFR 214.2 on the rule's new effective date, December 31, 2021, DHS is issuing this rule to withdraw the vacated H–1B Selection Final Rule.

DHS is not required to provide notice and comment or delay the effective date of this rule because this rule simply implements the court's vacatur of the H–1B Selection Final Rule and ensures that the vacated regulatory provisions are not codified in CFR. Following the vacatur, the changes made by the H–1B Selection Final Rule do not have any legal effect.

Moreover, good cause exists here for forgoing notice and comment and a delayed effective date even if those procedures were otherwise required. Notice and comment and a delayed effective date are unnecessary for the implementation of the court's order vacating the rule and would be impracticable in light of the agency's immediate need to implement the final judgment. *See* 5 U.S.C. 553(b)(B), (d). Furthermore, DHS believes that delaying this ministerial act would be contrary to public interest because it could lead to vacated regulatory provisions being codified and significant confusion among the regulated public regarding the administration of the fiscal year (FY) 2023 H–1B numerical allocations, generally known as the ''H–1B cap,'' which is likely to begin in early March 2022.[6]

DHS has concluded that each of those three reasons—that notice and comment and a delayed effective date are unnecessary, impracticable, and contrary to the public interest—independently provides good cause to bypass any otherwise applicable requirements of notice and comment and a delayed effective date.

II. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521, DHS is required to submit to the Office of Management and Budget (OMB), for review and approval, collections of information and changes to collections of information. The following information collections are impacted by the vacatur. DHS is withdrawing the

[1] *Modification of Registration Requirement for Petitioners Seeking To File Cap-Subject H–1B Petitions,* 86 FR 1676 (Jan. 8, 2021).

[2] *Modification of Registration Requirement for Petitioners Seeking To File Cap-Subject H–1B Petitions; Delay of Effective Date,* 86 FR 8543 (Feb. 8, 2021).

[3] *See Chamber of Commerce of the United States of America et al.* v. *United States Department of Homeland Security, et al.,* No. 4:20–cv–07331 (N.D. Cal. March 19, 2021) (Amended Complaint).

[4] *See Chamber of Commerce of the United States of America et al.* v. *United States Department of Homeland Security, et al.,* No. 4:20–cv–07331 (N.D. Cal. Apr. 15, 2021) (Order Permitting Supplementation of Complaint and Extending Deadline to Submit Joint Case Management Conference Statement).

[5] *See Chamber of Commerce of the United States of America et al.* v. *United States Department of Homeland Security, et al.,* No. 4:20–cv–07331 (N.D. Cal. Sep. 15, 2021) (Order Granting Pl.'s Motion for Summary Judgment and Denying Def.'s Cross-Motion for Summary Judgment; Judgment). On November 12, 2021 a notice of appeal was filed in the case. On November 30, 2021, the government filed a motion to voluntarily dismiss the appeal, and the appeal was dismissed on December 2, 2021. The district court's judgment is final.

[6] *See* 8 CFR 214.2(h)(8)(iii)(A)(*3*) (explaining that the annual initial registration period will start at least 14 calendar days before the earliest date on which H–1B cap-subject petitions may be filed, consistent with 8 CFR 214.2(h)(2)(i)(I). For the FY 2023 H–1B numerical allocations, the earliest date that H–1B cap-subject petitions may be filed is April 1, 2022, such that registration is likely to commence in early March 2022).

changes to these information collection instruments associated with the H–1B Selection Final Rule.

U.S. Citizenship and Immigration Services (USCIS) Form I–129

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Petition for a Nonimmigrant Worker.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection: I–129; USCIS.*

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for profit. USCIS uses the data collected on this form to determine eligibility for the requested nonimmigrant petition and/or requests to extend or change nonimmigrant status. An employer (or agent, where applicable) uses this form to petition USCIS for a noncitizen to temporarily enter as a nonimmigrant. An employer (or agent, where applicable) also uses this form to request an extension of stay or change of status on behalf of the noncitizen worker. The form serves the purpose of standardizing requests for nonimmigrant workers and ensuring that basic information required for assessing eligibility is provided by the petitioner while requesting that beneficiaries be classified under certain nonimmigrant employment categories. It also assists USCIS in compiling information required by Congress annually to assess effectiveness and utilization of certain nonimmigrant classifications. USCIS also uses the data to determine continued eligibility. For example, the data collected is used in compliance reviews and other inspections to ensure that all program requirements are being met.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* I–129 is 294,751 and the estimated hour burden per response is 2.34 hours; the estimated total number of respondents for the information collection E–1/E–2 Classification Supplement to Form I–129 is 4,760 and the estimated hour burden per response is 0.67 hours; the estimated total number of respondents for the information collection Trade Agreement Supplement to Form I–129 is 3,057 and the estimated hour burden per response is 0.67 hours; the estimated total number of respondents for the information collection H Classification Supplement to Form I–129 is 96,291 and the estimated hour burden per response is 2 hours; the estimated total number of respondents for the information collection H–1B and H–1B1 Data Collection and Filing Fee Exemption Supplement is 96,291 and the estimated hour burden per response is 1 hour; the estimated total number of respondents for the information collection L Classification Supplement to Form I–129 is 37,831 and the estimated hour burden per response is 1.34 hours; the estimated total number of respondents for the information collection O and P Classifications Supplement to Form I–129 is 22,710 and the estimated hour burden per response is 1 hour; the estimated total number of respondents for the information collection Q–1 Classification Supplement to Form I–129 is 155 and the estimated hour burden per response is 0.34 hours; the estimated total number of respondents for the information collection R–1 Classification Supplement to Form I–129 is 6,635 and the estimated hour burden per response is 2.34 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection of information is 1,072,810 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $70,681,290.

USCIS H–1B Registration Tool

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* H–1B Registration Tool.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* OMB–64; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for profit. USCIS will use the data collected through the H–1B Registration Tool to select a sufficient number of registrations projected as needed to meet the applicable H–1B cap allocations and to notify registrants whether their registrations were selected.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of business or other for-profit respondents for the information collection H–1B Registration Tool is 35,500 with an estimated 3 responses per respondents and an estimated hour burden per response of 0.5 hours. The estimated total number of attorney respondents for the information collection H–1B Registration Tool is 4,500 with an estimated 38 responses per respondents and an estimated hour burden per response of 0.5 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection of information is 138,750 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $0.

List of Subjects in 8 CFR Part 214

Administrative practice and procedure, Aliens, Cultural exchange program, Employment, Foreign officials, Health professions, Reporting and recordkeeping requirements, Students.

PART 214—NONIMMIGRANT CLASSES

■ Accordingly, the amendments to 8 CFR part 214, published in the **Federal Register** on January 8, 2021 (86 FR 1676), which were to take effect on December 31, 2021 (86 FR 8543, February 8, 2021), are withdrawn as of December 22, 2021.

Alejandro N. Mayorkas,

Secretary of Homeland Security.

[FR Doc. 2021–27714 Filed 12–21–21; 8:45 am]

BILLING CODE 9111–97–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 701

RIN 3133–AF15

Temporary Regulatory Relief in Response to COVID–19—Extension

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule and temporary final rule; extension.

SUMMARY: The NCUA Board (Board) is further extending its temporary final rule, which modified certain regulatory requirements to help ensure that federally insured credit unions (FICUs) remain operational and can address economic conditions caused by the COVID–19 pandemic. The temporary final rule issued by the Board in April 2020 temporarily raised the maximum aggregate amount of loan participations that a FICU may purchase from a single originating lender to the greater of $5,000,000 or 200 percent of the FICU's net worth. The rule also temporarily

suspended limitations on the eligible obligations that a Federal credit union (FCU) may purchase and hold. In addition, given physical distancing practices necessitated by COVID–19, the rule also tolled the required timeframes for the occupancy or disposition of properties not being used for FCU business or that have been abandoned. The temporary amendments were originally scheduled to expire on December 31, 2020. The Board subsequently extended their effectiveness until December 31, 2021. Due to the continued impact of COVID–19, the Board has decided it is necessary to further extend the effective period of these temporary modifications until December 31, 2022.

DATES: This rule is effective December 22, 2021 except for the amendment to § 701.23 in instruction 3.b., which is effective April 1, 2022. The expiration date of the temporary final rule published on April 21, 2020 (85 FR 22010), and extended by final rule published on December 22, 2020 (85 FR 83405), is further extended through December 31, 2022.

FOR FURTHER INFORMATION CONTACT: *Policy and Analysis:* Victoria Nahrwold, Office of Examination and Insurance, at (703) 548–2633; *Legal:* Ariel Pereira, Senior Staff Attorney, Office of General Counsel, at (703) 518–6540; or by mail at: National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314.

SUPPLEMENTARY INFORMATION:

I. Background

The COVID–19 pandemic has created uncertainty for FICUs and their members. The Board continues to work with federal and state regulatory agencies, in addition to FICUs, to assist FICUs in managing their operations and to facilitate continued assistance to credit union members and communities impacted by the COVID–19 pandemic. In April 2020, as part of these ongoing efforts, the Board temporarily modified certain regulatory requirements to help ensure that FICUs remain operational and liquid during the COVID–19 pandemic.[1] The Board concluded that the amendments would provide FICUs necessary additional flexibility in a manner consistent with the NCUA's responsibility to maintain the safety and soundness of the credit union system. The temporary amendments were to remain in place through the end of calendar year 2020 unless the Board took action to extend the date. In December 2021, the Board concluded that continuing economic uncertainty merited a further extension of the amendments until December 31, 2021.[2]

The economic environment is a key determinant of credit union performance. While the recovery in economic activity and labor markets is expected to continue, it also poses challenges. The NCUA, like credit unions, needs to plan and prepare for a range of economic outcomes that could affect credit union performance. This includes ensuring a regulatory environment that provides FICUs with the flexibility necessary to cope with and address the range of potential COVID–19 impacts.

Due to the continuing impact of the COVID–19 pandemic on FICUs and their members, the Board has determined that it is necessary to again extend the effectiveness of these temporary provisions. The temporary amendments will remain in place through December 31, 2022.

II. Legal Authority

The Board is issuing this temporary final rule pursuant to its authority under the Federal Credit Union Act (Act).[3] The Act grants the Board a broad mandate to issue regulations governing both FCUs and, more generally, all FICUs. For example, section 120 of the Act is a general grant of regulatory authority and authorizes the Board to prescribe rules and regulations for the administration of the Act.[4] Section 209 of the Act is a plenary grant of regulatory authority to issue rules and regulations necessary or appropriate for the Board to carry out its role as share insurer for all FICUs.[5] Other provisions of the Act confer specific rulemaking authority to address prescribed issues or circumstances.[6] Accordingly, the Act grants the Board broad rulemaking authority to ensure that the credit union industry and the NCUSIF remain safe and sound.

III. The Regulatory Amendments

A. Aggregate Limit on Loan Participation Purchases (Section 701.22(b)(5)(ii))

The Board's regulation at § 701.22 limits the aggregate amount of loan participations that a FICU may purchase from any one originating lender to the greater of $5,000,000 or 100 percent of the FICU's net worth.[7] Under the temporary regulatory amendments, the aggregate limit below which a waiver from the appropriate NCUA Regional Director is not required is temporarily raised to the greater of $5,000,000 or 200 percent of a FICU's net worth.

The Board continues to believe that, as currently formulated in § 701.22, the limitation may be overly prescriptive during this time. Additional regulatory flexibility continues to be especially warranted to deal with the economic impact of the COVID–19 pandemic, which may result in additional stress on credit union balance sheets, potentially requiring robust liquidity management.

B. Purchase, Sale, and Pledge of Eligible Obligations (Section 701.23(b))

The Board's regulations in § 701.23 generally require that purchased eligible obligations be obligations of a purchasing FCU's members and loans the FCU is empowered to grant or the loan is refinanced to be one the FCU is empowered to grant. Section 701.23(b)(2) provides certain limited exceptions to the general requirements for well-capitalized FCUs that have composite CAMEL ratings of ''1'' or ''2.''[8] The regulations authorize these FCUs to purchase the eligible obligations of any FICU or of any liquidating credit union without regard to whether they are obligations of the purchasing FCU's members, provided they are loans the FCU is empowered to grant or the loan is refinanced to be one it is empowered to grant.

In the April 2020 temporary final rule, the Board temporarily amended its regulations to authorize FCUs with CAMEL composite ratings of 1, 2, or 3 to purchase eligible obligations of FICUs and liquidating credit unions irrespective of whether the obligation belongs to the purchasing FCU's members and without regard to whether they are loans the credit union is empowered to grant or are refinanced to ensure the obligations are ones the purchasing credit union is empowered to grant. This change did not alter the requirement for a purchasing FCU to be well-capitalized under § 701.23(b)(2).[9]

[1] 85 FR 22010 (Apr. 21, 2020).

[2] 85 FR 83405 (Dec. 22, 2020).

[3] 12 U.S.C. 1751 *et seq.*

[4] 12 U.S.C. 1766(a).

[5] 12 U.S.C. 1789.

[6] An example of a provision of the Act that provides the Board with specific rulemaking authority is section 207 (12 U.S.C. 1787), which is a specific grant of authority over share insurance coverage, conservatorships, and liquidations.

[7] 12 CFR 701.22(b)(5)(ii).

[8] Section 701.23 also contains exceptions to the membership requirement for certain purchases of student loans and real estate loans that an FCU purchases to complete a pool for sale. The Board established this exception in a 1979 final rule. 44 FR 27068 (May 9, 1979).

[9] Generally, credit unions with a CAMEL composite rating lower than 3 are considered to be in ''troubled condition'' under the NCUA's regulations. 12 CFR 700.2.

Due to the ongoing and unforeseeable impact of the COVID–19 pandemic, the Board believes it appropriate to extend these temporary provisions until the close of December 31, 2022. The Board recognizes that the need to support the extension of credit and facilitate the downstream loan purchases as a tool to manage liquidity remains, and likely will remain for the foreseeable future.

The Board reiterates that this change allows FCUs to continue to hold obligations purchased pursuant to this temporary final rule subsequent to the rule's expiration. The standard requirements applicable to the purchase of obligations under § 701.23 will resume after the expiration of the temporary provisions at the close of December 31, 2022, unless extended, and will apply to all future purchases, including to purchases of obligations previously acquired under the provisions of this temporary final rule. The Board also reiterates that the restrictions temporarily relieved in § 701.23 do not apply to state-chartered, federally insured credit unions. Any such restrictions applicable to state-chartered credit unions would be based on state laws or regulations. This temporary final rule does not modify the current authority of FCUs under § 701.23 to purchase the obligations of a liquidating credit union without regard to whether the obligations belong to the purchasing FCU's members.

In addition to the regulatory amendments discussed above, this final rule makes a technical change to § 703.23(i)(2) to conform the terminology used in the provision with that of the Board's final rule on the CAMELS rating system, which will become effective on April 1, 2022.[10]

C. FCU Occupancy and Disposal of Acquired Premises (Section 701.36(c))

The Board's regulation in § 701.36 provides that if an FCU acquires premises, including unimproved land or unimproved real property, it must partially occupy them ''no later than six years after the date of acquisition,'' subject to the NCUA granting a waiver.[11] Further, an FCU must make diligent efforts to dispose of abandoned premises and any other real property it does not intend to use in transacting business. Additionally, the FCU must advertise for sale premises that have been abandoned for four years.[12] Given the impact of physical distancing measures adopted by many states and localities, the April 2020 temporary final rule tolls the regulatory mandated timeframes in the rule.

Due to the ongoing nature of the COVID–19 pandemic and its continued impact on FICUs, the Board has decided it is necessary to extend the effectiveness of this temporary amendment until the close of December 31, 2022. Physical distancing practices continue to be a key component of preventing the spread of COVID–19[13] and make compliance with § 701.36 difficult. This temporary deferral will continue to provide FCUs additional flexibility to comply with the prescribed time periods, while still complying with the statutory and regulatory goals of ensuring that properties acquired or held by FCUs are used for credit union business.

IV. Regulatory Procedures

A. Administrative Procedure Act

The Board is issuing the extension of the temporary final rule without prior notice and the opportunity for public comment and the delayed effective date ordinarily prescribed by the Administrative Procedure Act (APA).[14] Pursuant to the APA, general notice and the opportunity for public comment are not required with respect to a rulemaking when an ''agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' [15]

The Board believes that the public interest is best served by implementing the extension of the previously issued temporary final rule immediately upon publication in the **Federal Register**. The Board notes that the COVID–19 pandemic is unprecedented. It is a continually changing situation and difficult to anticipate how the disruptions caused by the crisis will manifest themselves within the financial system and how individual credit unions may be impacted. Because of the widespread impact of a pandemic and the temporary nature of both the relief contemplated by the temporary final rule and this extension of such relief, the Board believes it is has good cause to determine that ordinary notice and public procedure are impracticable and that moving expeditiously to extend the temporary final rule is in the best of interests of the public and the FICUs that serve that public. The extension of these temporary regulatory changes are proactive steps that are designed help FICUs cope with the economic impact of the COVID–19 pandemic, which may result in additional stress on credit union balance sheets, potentially requiring robust liquidity management over the course of 2022. The changes are undertaken with expedience to ensure the maximum intended effects remain in place.

The Board values public input in its rulemakings and believes that providing the opportunity for comment enhances its regulations. Accordingly, the Board often solicits comments on its rules even when not required under the APA, such as for the rules it issues on an interim-final basis. The Board, however, notes that the provisions extended in this rule are temporary in nature, and designed specifically to help credit unions affected by the COVID–19 pandemic. The extension of the amendments made by this temporary final rule will automatically expire at the close of December 31, 2022, and are limited in number and scope. For these reasons, the Board finds that there is good cause consistent with the public interest to issue the rule without advance notice and comment.

The APA also requires a 30-day delayed effective date, except for: (1) Substantive rules which grant or recognize an exemption or relieve a restriction; (2) interpretative rules and statements of policy; or (3) as otherwise provided by the agency for good cause.[16] Because the rules relieve currently codified limitations and restrictions, the extension of the temporary final rule is exempt from the APA's delayed effective date requirement. As an alternative basis to make the rule effective without the 30-day delayed effective date, the Board finds there is good cause to do so for the same reasons set forth above regarding advance notice and opportunity for comment.

B. Congressional Review Act

For purposes of the Congressional Review Act,[17] the Office of Management and Budget (OMB) makes a determination as to whether a final rule

[10] 86 FR 59282 (Oct. 27, 2021).

[11] 12 CFR 701.36(c)(1).

[12] 12 CFR 701.36(c)(2).

[13] *See* Fabio Motta, *Face masks and distancing are most effective measures in reducing COVID–19 spread, study finds, as experts clamor for U.S. to expand booster program,* (November 18, 2021), (''Wearing a face mask and physically distancing from others are the most effective public safety measures against the coronavirus-borne illness COVID–19 and have a statistically significant impact on reducing the spread, according to a new global study.''), *https://www.marketwatch.com/story/face-masks-and-distancing-are-most-effective-measures-in-reducing-covid-19-spread-study-finds-as-experts-clamor-for-u-s-to-expand-booster-program-11637251008.*

[14] 5 U.S.C. 551 *et seq.*

[15] 5 U.S.C. 553(b)(3).

[16] 5 U.S.C. 553(d).

[17] 5 U.S.C. 801–808.

constitutes a ''major'' rule. If the OMB deems a rule to be a ''major rule,'' the Congressional Review Act generally provides that the rule may not take effect until at least 60 days following its publication. The Congressional Review Act defines a ''major rule'' as any rule that the Administrator of the Office of Information and Regulatory Affairs of the OMB finds has resulted in or is likely to result in (A) an annual effect on the economy of $100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies or geographic regions, or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.[18]

For the same reasons set forth above, the Board is adopting the extension of the temporary final rule without the delayed effective date generally prescribed under the Congressional Review Act. The delayed effective date required by the Congressional Review Act does not apply to any rule for which an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.[19] In light of current market uncertainty, the Board believes that delaying the effective date of the extension of the temporary final rule would be contrary to the public interest for the same reasons discussed above.

As required by the Congressional Review Act, the Board will submit the final rule and other appropriate reports to Congress and the Government Accountability Office for review.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) requires that the Office of Management and Budget (OMB) approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a valid OMB control number.

In accordance with the PRA, the information collection requirements included in this temporary final rule extension have been submitted to OMB for approval under control numbers 3133–0141, 3133–0127 and 3133–0040.

[18] 5 U.S.C. 804(2).

[19] 5 U.S.C. 808.

D. Executive Order 13132, on Federalism

Executive Order 13132 [20] encourages independent regulatory agencies to consider the impact of their actions on state and local interests. The NCUA, an independent regulatory agency, as defined in 44 U.S.C. 3502(5), voluntarily complies with the Executive order to adhere to fundamental federalism principles. The extension of the temporary final rule will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government. The Board has therefore determined that this rule does not constitute a policy that has federalism implications for purposes of the Executive order.

E. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that the extension of the temporary final rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act, 1999.[21]

F. Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (RFA) generally requires that when an agency issues a proposed rule or a final rule pursuant to the APA or another law, the agency must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such analysis in the **Federal Register**. Specifically, the RFA normally requires agencies to describe the impact of a rulemaking on small entities by providing a regulatory impact analysis. For purposes of the RFA, the Board considers credit unions with assets less than $100 million to be small entities.

As discussed previously, consistent with the APA, the Board has determined for good cause that general notice and opportunity for public comment is unnecessary, and therefore the Board is not issuing a notice of proposed rulemaking. Rules that are exempt from notice and comment procedures are also exempt from the RFA requirements, including conducting a regulatory flexibility analysis, when among other things the agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest. Accordingly, the Board has concluded that the RFA's requirements relating to initial and final regulatory flexibility analysis do not apply.

[20] Executive Order 13132 on Federalism, was signed by former President Clinton on August 4, 1999, and subsequently published in the **Federal Register** on August 10, 1999 (64 FR 43255).

[21] Public Law 105–277, 112 Stat. 2681 (1998).

List of Subjects in 12 CFR Part 701

Aged, Civil rights, Credit, Credit unions, Fair housing, Individuals with disabilities, Insurance, Mortgages, Reporting and recordkeeping requirements.

By the NCUA Board, this 17th day of December 2021.

Melane Conyers-Ausbrooks,

Secretary of the Board.

For the reasons discussed in the preamble, the Board amends 12 CFR part 701 as follows:

PART 701—ORGANIZATION AND OPERATION OF CREDIT UNIONS

■ 1. The authority citation for part 701 continues to read as follows:

Authority: 12 U.S.C. 1752(5), 1755, 1756, 1757, 1758, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1785, 1786, 1787, 1788, 1789. Section 701.6 is also authorized by 15 U.S.C. 3717. Section 701.31 is also authorized by 15 U.S.C. 1601 *et seq.*; 42 U.S.C. 1981 and 3601–3610. Section 701.35 is also authorized by 42 U.S.C. 4311–4312.

§ 701.22 [Amended]

■ 2. In § 701.22(e), remove the date ''December 31, 2021'' and add in its place the date ''December 31, 2022''.

§ 701.23 [Amended]

■ 3. Amend § 701.23 as follows:

■ a. In paragraph (i) introductory text, remove the date ''December 31, 2021'' and add in its place the date ''December 31, 2022''; and

■ b. Effective April 1, 2022, in paragraph (i)(2) remove the term ''CAMEL'', and add in its place the term ''CAMELS.''

§ 701.36 [Amended]

■ 4. In § 701.36(c)(3), remove the date ''December 31, 2021'' and add in its place the date ''December 31, 2022''.

[FR Doc. 2021–27771 Filed 12–20–21; 4:15 pm]

BILLING CODE 7535–01–P

DEPARTMENT OF STATE

22 CFR Part 51

[Public Notice: 11609]

RIN 1400–AE68

Passports: Option for Passport Applicants Eligible To Apply by Mail for Renewal of Passports To Apply On-Line

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: Pursuant to Department regulations, the renewal of a U.S. passport must meet certain requirements to qualify for submission of an application by mail. The Department will now provide qualified applicants the option of submitting renewal applications by mail or on-line via the Department's official website. This amendment will provide more flexibility for the renewal applicant, will improve the customer experience, and eliminate the added burden, time, and cost to the customer by providing the on-line option as an alternative to the mail in process.

DATES: This final rule is effective on December 23, 2021.

FOR FURTHER INFORMATION CONTACT: Kelly Cullum, Office of Adjudication, Passport Services, (202) 485–8800, or email *PassportOfficeofAdjudicationGeneral@state.gov.*

SUPPLEMENTARY INFORMATION: The Department published a proposed rule, Public Notice 11457 at 86 FR 43458, August 9, 2021 (the NPRM), with a request for comments to amend 22 CFR 51.21(b), (b)(2), (b)(3); and 51.8(a), (b), (c), and (d) to allow eligible applicants the option to apply on-line via the Online Passport Renewal (OPR) system. Applicants must meet all of the eligibility requirements for using OPR or will be referred to the paper application process. Applicants using OPR will enter their application information and upload their photos directly into the OPR system and submit their payment through pay.gov. This process will improve efficiency and accessibility by offering online verification of renewal eligibility, electronic photo upload, and electronic payment. Applications received through OPR will automatically enter review queues at the passport agency, thus eliminating the physical application and processing at the Lockbox. The new OPR system will improve the customer experience, reduce operational and maintenance costs, and focus on data quality, protection, and traceability. The first release of the OPR system will be limited in its release and apply to persons in the United States who are submitting an application in the same name, gender marker, date of birth, and place of birth as the most recently issued passport of the same type with the intent that future releases will permit changes and be used by persons applying abroad.

The rule was discussed in detail in Public Notice 11457, as were the Department's reasons for the other changes to the regulations. The Department is now promulgating a final rule with minor changes from the proposed rule and no substantive change.

Analysis of Comments: The Department provided 60 days for comment on the NPRM. The comment period closed October 8, 2021.

The Department received twelve responsive comments, none of which were opposed to this amendment. Several commenters noted their concerns about possible identity theft and insisted on the use of the latest technology to protect applicants. Online passport applications are subject to the same rigorous protection of personally identifiable information (PII) as physical applications. The Department processes passport applications, whether mailed or submitted online, on controlled workstations accessed by authorized employees only. The rollout of the OPR system is compliant with the Department's policy (5 FAM 772.1) in that ''encryption and digital certificates must be integrated into the applications to the greatest extent possible.''

Two commenters also requested that online payment be acceptable and specifically, that it include use of credit cards. As noted in the proposed rule, applicants using the OPR will submit payment through *pay.gov* which already accepts credit cards.

Two commenters discussed the need for online submission of supporting documents or using existing information in U.S. government databases to verify citizenship. They noted the difficulty of sending original vital records and naturalization certificates. As discussed in the proposed rule, eligible OPR users will upload applications and photos directly to the system eliminating the need for paper-based applications. Adults renewing passports who are eligible to use OPR generally do not need to submit supporting documentation because the issuance of a prior passport serves as citizenship evidence. In most cases prior passport issuance information is already available in adjudication systems. The Department coordinates with federal agencies such as USCIS as well as vital records offices to protect the integrity of the passport application process, verify citizenship documentation, and confirm entitlement to a U.S. passport. Passport Services' modernization efforts include online document verification.

One commenter requested that the Department make OPR available for first-time applicants and another requested it be available for applicants located outside the United States. As defined in 22 CFR 51.21(a), first-time applicants (who by statute, 22 U.S.C. 213, are required to verify their application by an in person oath), applicants who have never been issued a passport in his or her own name, applicants who have not been issued a passport for the full validity period of 10 years within 15 years of the date of a new application, and minors under the age of 16 must apply for a passport by appearing in person before a passport agent or passport acceptance agent. The applicant must verify the application by oath or affirmation before the passport agent or passport acceptance agent, sign the completed application, provide photographs and any other information or documents as prescribed or requested by the Department. These requirements cannot be addressed through OPR. As noted in the draft rule, the first release of the OPR system will apply to persons in the United States, with the intent for future releases applying to persons abroad.

One commenter stated that applicants requesting a change in gender marker and those identifying as any gender besides male or female should be ineligible for OPR due to fraud concerns. The Department takes fraud very seriously and reviews all passport applications for possible fraud. Adjudicators receive extensive fraud training and utilize facial recognition technology and social security and birth information data verification to detect fraud, regardless of the method of application. Thus, while the Department appreciates the commenter's concern, it does not believe that the possibility of someone successfully committing fraud would be any greater after OPR is operational.

Regarding gender markers and other changes that an applicant might wish to make to their information, the proposed regulatory text (proposed section 51.21(b)(iii)) provided that the ''first release of the OPR system will require that the application be submitted in the same name, sex [*i.e.,* gender] marker, date of birth, and place of birth as the most recently issued passport of the same type with the intent that future releases will permit changes''. This text was removed from the text of the final rule because the Department determined that it is more appropriate for a statement of policy in the preamble and is not regulatory text. It does, however, reflect the limitation on the first release of the OPR system, but not Department policy for future releases.

While supportive of OPR, several commenters noted the continued need for the Department to reduce service times and paperwork and the

assumption that OPR would provide faster processing times. As noted in the draft rule, OPR will provide more flexibility for the renewal applicant, will improve the customer experience, and eliminate the added burden, time, and cost to the customer by providing the on-line option as an alternative to the mail in process. Processing times listed on *www.travel.state.gov* are still Department standard for all passport applications, physical and electronic. Future expansion of OPR may allow for changes to expected service commitment times for online applications. The Department continuously strives to reduce passport processing service times through modernization initiatives.

One person suggested maintaining a walk-in passport agency in every U.S. city with a population greater than 250,000. This is outside the scope of the proposed rule. However, the Department coordinates with a network of approximately 7,500 passport application acceptance facilities across the United States, all of which offer in-person service (though they may be by appointment only, rather than offering walk-in service). The network of passport application acceptance facilities provides convenient, nationwide access.

Another commenter requested that the Department coordinate with USCIS to automatically link the passport application to the naturalization process. This is outside the scope of the proposed rule. However, the Department regularly coordinates with USCIS to provide passport application acceptance services at naturalization ceremonies.

Regulatory Findings

Administrative Procedure Act

The Department published this rulemaking as a proposed rule and provided 60 days for public comment. The Department finds good cause for the effective date to be less than 30 days from date of publication. As stated in *American Bankers Ass'n* v. *NCUA,* 38 F. Supp. 2d 114, 139–40 (D.D.C. 1999), according to the legislative history of the APA, the purpose for deferring the effectiveness of a final rule under § 553(d) was to ''afford persons affected a reasonable time to prepare for the effective date of a rule or rules or to take other action which the issuance may prompt.'' S. REP. NO. 79–752, at 15 (1946). In the same vein, the D.C. Circuit has explained that ''the purpose of the thirty-day waiting period is to give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' *Omnipoint Corp.* v. *FCC,* 316 U.S. App. D.C. 259, 78 F.3d 620, 630 (D.C. Cir. 1996).

There is no requirement for anyone to ''adjust their behavior'' or prepare for anything prior to this rule going into effect. Those who do not wish to renew their passports using the online procedure still have the current DS–82 available to them. The 30-day notice requirement of § 553(d) is ''subject to the rule of prejudicial error.'' *See* 5 U.S.C. 706; *Petaluma FX Partners, LLC* v. *Commissioner,* 416 U.S. App. D.C. 411, 420, 792 F.3d 72, 81 (2015).

In addition, the Department is providing a benefit to the public by this rulemaking. The Department estimates that the online application will take approximately five minutes to complete, as opposed to 40 minutes for the DS–82. OPR saves up to three weeks for initial application processing that includes mailing and receipt at the lockbox facility as well as the candling (fee processing, scanning, and batching) of the applications for physical transmission to passport agencies. Additionally, customers save time and money for transit to and from a post office for mailing, the price of an envelope, and either the cost of first-class stamp or express mail fees—of between $0.58 to $26.60 per application. Use of OPR allows the customer to create and submit a digital application, upload their photograph, and make a payment via pay.gov from a computer or mobile device with no physical/paper application involved.

Therefore, the Department finds good cause to publish this rule without a delayed effective date under 5 U.S.C. 553(d)(1) and (3).

Regulatory Flexibility Act

The Department of State certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule gives greater flexibility to applicants applying to renew their U.S. passport.

Unfunded Mandates Act of 1995

This final rule does not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it does not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act. This rule does not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and import markets.

Executive Order 12866

The Office of Information and Regulatory Affairs has designated this rule ''not significant'' under Executive Order 12866. As explained in the preamble and the APA section above, the benefits of the rule outweigh any costs to the public (which the Department assesses will be minimal).

Executive Order 13132—Federalism

This rule does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on federal programs and activities do not apply to this regulation.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department has determined that this rulemaking does not have tribal implications, does not impose substantial direct compliance costs on Indian tribal governments, and does not pre-empt tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rulemaking.

Paperwork Reduction Act

This rulemaking is related to the information collection described in OMB Control No. 1405–0020 (Form DS–82). The web-based version of this form was approved in July 2021.

List of Subjects in 22 CFR Part 51

Passports.

Accordingly, for the reasons set forth in the preamble, 22 CFR part 51 is amended as follows:

PART 51—PASSPORTS

■ 1. The authority citation for part 51 continues to read as follows:

Authority: *8 U.S.C. 1504; 18 U.S.C. 1621; 22 U.S.C. 211a, 212, 212b, 213, 213n (Pub. L. 106–113* Div. B, Sec. 1000(a)(7) [Div. A, Title II, Sec. 236], 113 Stat. 1536, 1501A–430); 214, 214a, 217a, 218, 2651a, 2671(d)(3), 2705, 2714, 2714a, 2721, & 3926; *26 U.S.C. 6039E; 31 U.S.C. 9701; 42 U.S.C. 652(k)* [Div. B, Title V of Pub. L. 103–317, 108 Stat. 1760]; E.O. 11295, Aug. 6, 1966, FR 10603, *3 CFR, 1966*–1970 Comp., p. 570; *Pub. L. 114–119,* 130 Stat. 15; Sec. 1 of *Pub. L. 109–210,* 120

Stat. 319; Sec. 2 of *Pub. L. 109–167,* 119 Stat. 3578; Sec. 5 of *Pub. L. 109–472,* 120 Stat. 3554; *Pub. L. 108–447,* Div. B, Title IV, Dec. 8, 2004, 118 Stat. 2809; *Pub. L. 108–458,* 118 Stat. 3638, 3823 (Dec. 17, 2004).

■ 2. Revise § 51.8 to read as follows:

§ 51.8 Submission of currently valid passport.

(a) When applying for a new passport in person or by mail, an applicant must submit for cancellation any currently valid passport of the same type.

(b) When applying for a new passport on-line, an applicant must have the currently valid passport of the same type available for cancellation via the on-line process.

(c) If an applicant is unable to produce a passport under paragraph (a) or (b) of this section, they must submit a signed statement in the form prescribed by the Department setting forth the circumstances regarding the disposition of the passport.

(d) The Department may deny or limit a passport if the applicant has failed to provide a sufficient and credible explanation for lost, stolen, altered or mutilated passport(s) previously issued to the applicant, after being given a reasonable opportunity to do so.

■ 3. Amend § 51.21 by revising the paragraph (b) heading, paragraph (b)(2) and adding paragraph (b)(3) to read as follows:

§ 51.21 Execution of passport application.

* * * * *

(b) *Application by mail or on-line—persons in the United States.* * * *

(2) A person in the United States who previously has been issued a passport valid for 10 years in their own name may apply for a new passport by filling out, signing, and submitting an on-line application via the Department's official website if:

(i) The applicant's most recently issued passport was issued when the applicant was 16 years of age or older, and has one year or less of validity remaining;

(ii) The application is made not more than 15 years following the issue date of the most recently issued passport of the same type;

(iii) The most recently-issued passport of the same type is available for verification via the on-line process.

(3) The applicant must also provide photographs as prescribed by the Department and pay the applicable fees prescribed in the Schedule of Fees for Consular Services (22 CFR 22.1).

* * * * *

Kevin E. Bryant,

Deputy Director, Office of Directives Management, U.S. Department of State.

[FR Doc. 2021–27404 Filed 12–21–21; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 310

[Docket ID: DoD–2020–OS–0095]

RIN 0790–AK96

Privacy Act of 1974; Implementation

AGENCY: Office of the Secretary of Defense (OSD), Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: The DoD is issuing a final rule to amend its regulations to exempt portions of the DoD–0004, ''Defense Repository for Common Enterprise Data (DRCED),'' system of records from certain provisions of the Privacy Act of 1974.

DATES: This rule is effective on January 21, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Lyn Kirby, *OSD.DPCLTD@mail.mil,* (703) 571–0070.

SUPPLEMENTARY INFORMATION:

Discussion of Comments and Changes

The proposed rule published in the **Federal Register** (86 FR 498–499) on January 6, 2021. Comments were accepted for 60 days until March 8, 2021. A total of four comments were received. Please see the summarized comments and the Department's response as follows:

Commentators generally agreed that exempting national security and classified data is appropriate under this exemption rule and that exempting national security and classified information is in the best interests of the Department and the Nation. Notwithstanding that, a majority of the comments voiced a desire for more transparency about the classification process itself within the DoD. Although these comments do not directly pertain to the Privacy Act and the exemption claimed for this system of records notice (SORN), to promote public understanding in this area a description of the classification process at DoD is provided below.

Executive Order 13526 prescribes the framework for the Federal Government (to include DoD) to classify national security information. Only DoD personnel who hold positions of trust and are delegated original classification authority in writing are authorized to review the Department's information and determine whether damage would result to national security if that information were disclosed to the public. Several oversight and compliance mechanisms exist to ensure the classification of information process is appropriate.

These safeguards include the following: Personnel authorized to make classification determinations are required to receive training in proper classification, including the avoidance of over-classification, and declassification at least once a calendar year; information may only be classified if it pertains to specific categories or subjects, including military plans, weapons systems, or operations and intelligence activities; and agency heads must (on a periodic basis) complete a comprehensive review of the agency's classification guidance, to include reviewing information that is classified within the agency, provide the results of such review to appropriate officials outside the agency at the National Archives, and release an unclassified version of the review to the public. Authorized holders of classified information are also encouraged and expected to ''challenge'' classification determinations if they believe the classification status is improper, and any individual or entity can request any Federal agency to review classified information for declassification, regardless of its age or origin, in accordance with the Mandatory Declassification Review (MDR) process. Additional information about the MDR process can be found on the National Archives and Records Administration's MDR program page at *https://www.archives.gov/isoo/training/mdr.* In the interests of protecting information critical to the Nation's defense, it is appropriate for the DoD to properly classify and exempt such information from public release under the Privacy Act so as to protect U.S. national security. Having considered the public comments, the Department will implement the rulemaking as proposed.

Additionally, DoD received one supportive, but non-substantive, comment on the system of records notice (SORN) that published in the **Federal Register** on January 6, 2021 (86 FR 526–529). The public comment period for the SORN ended on February 5, 2021.

Background

In finalizing this rule, DoD exempts portions of the updated and reissued DoD–0004 DRCED system of records from certain provisions of the Privacy Act. DoD uses this system of records to automate financial and business transactions, perform cost-management analysis, produce oversight and audit reports, and provide critical data linking to improve performance of mission objectives. This system of records supports DoD in creating predictive analytic models based upon specific data streams to equip decision makers with critical data necessary for execution of fiscal and operational requirements. Some of the records that are part of the DoD–0004 DRCED system of records may contain classified national security information and disclosure of those records to an individual may cause damage to national security. The Privacy Act, pursuant to 5 U.S.C. 552a(k)(1), authorizes agencies to claim an exemption for systems of records that contain information properly classified pursuant to executive order. For this reason, DoD has exempted portions of the DoD–0004 DRCED system of records from the access and amendment requirements of the Privacy Act, pursuant to 5 U.S.C. 552a(k)(1), to prevent disclosure of any information properly classified pursuant to executive order, including Executive Order 13526, as implemented by DoD Instruction 5200.01, ''DoD Information Security Program and Protection of Sensitive Compartmented Information (SCI)'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/520001p.PDF?ver=cF1II-jcFGP6jfNrnTr8lQ%3d%3d*); DoD Manual (DoDM) 5200.01, Volume 1, ''DoD Information Security Program: Overview, Classification, and Declassification'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/520001m_vol1.pdf?ver=2020-08-04-092500-203*); and DoDM 5200.01, Volume 3, ''DoD Information Security Program: Protection of Classified Information'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/520001m_vol3.pdf?ver=MJfVD-nRd2HTyLSzDse9VQ%3d%3d*).

This rule will deny an individual access under the Privacy Act to only those portions of records for which the claimed exemption applies. In addition, records in the DoD–0004 DRCED system of records are only exempt from the Privacy Act to the extent the purposes underlying the exemption pertain to the record.

Regulatory Analysis

Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. It has been determined that this rule is not a significant regulatory action.

Congressional Review Act

This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. Chapter 6)

The Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency has certified that this Privacy Act rule does not have significant economic impact on a substantial number of small entities because they are concerned only with the administration of Privacy Act systems of records within the DoD.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

It has been determined that this rule does not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Section 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

It has been determined that this rule does not involve a Federal mandate that may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more and that it will not significantly or uniquely affect small governments.

Executive Order 13132, ''Federalism''

It has been determined that this rule does not have federalism implications. This rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, ''Consultation and Coordination With Indian Tribal Governments''

Executive Order 13175 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on one or more Indian tribes, preempts tribal law, or effects the distribution of power and responsibilities between the federal government and Indian tribes. This rule will not have a substantial effect on Indian tribal governments.

List of Subjects in 32 CFR Part 310

Privacy.

Accordingly, 32 CFR part 310 is amended as follows:

PART 310—[AMENDED]

■ 1. The authority citation for 32 CFR part 310 continues to read as follows:

Authority: 5 U.S.C. 552a.

■ 2. Section 310.13 is amended by adding paragraph (e)(3) to read as follows:

§ 310.13 Exemptions for DoD-wide systems.

* * * * *

(e) * * *

(3) *System identifier and name.* DoD–0004, ''Defense Repository for Common Enterprise Data (DRCED).''

(i) *Exemptions.* This system of records is exempt from subsections 5 U.S.C. 552a(c)(3), (d)(1), (d)(2), (d)(3), and (d)(4) of the Privacy Act.

(ii) *Authority.* 5 U.S.C. 552a(k)(1).

(iii) *Exemption from the particular subsections.* Exemption from the particular subsections is justified for the following reasons:

(A) *Subsection (c)(3) (accounting of disclosures).* Because common enterprise records may contain information properly classified pursuant to executive order, the disclosure accountings of such records may also contain information properly classified pursuant to executive order, the disclosure of which may cause damage to national security.

(B) *Subsections (d)(1), (2), (3), and (4) (record subject's right to access and amend records).* Access to and amendment of records by the record subject could disclose information properly classified pursuant to executive order. Disclosure of classified records to an individual may cause damage to national security.

(iv) *Exempt records from other systems.* In addition, in the course of carrying out the overall purpose for this system, exempt records from other system of records may in turn become part of the records maintained in this system. To the extent that copies of exempt records from those other systems of records are maintained in this system, the DoD claims the same exemptions for the records from those other systems that are entered into this system, as claimed for the prior system(s) of which they are a part, provided the reason for the exemption remains valid and necessary.

* * * * *

Dated: December 16, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27706 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0294; FRL–9226–01–OCSPP]

Various Fragrance Components; Exemptions From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of various fragrance components listed in unit II of this document when they are used as inert ingredients in antimicrobial pesticide formulations for use on food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils with end-use concentration not to exceed 100 parts per million (ppm). Verto Solutions on behalf of The Clorox Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the establishment of such exemptions from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of various fragrance components.

DATES: This regulation is effective December 22, 2021. Objections and requests for hearings must be received on or before February 22, 2022, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2020–0294, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2020–0294 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before February 22, 2022. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2020–0294, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of June 24, 2020 (85 FR 37807) (FRL–10010–82), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11016) by Verto Solutions on behalf of The Clorox Company, 4900 Johnson Dr., Pleasanton, CA 94588. The petition requested that 40 CFR 180.940(a) be amended by

establishing an exemption from the requirement of a tolerance for residues of δ-decalactone (CAS Reg. No. 705–86–2), γ-decalactone (CAS Reg. No. 706–14–9), dimethyl-1-octanol (CAS Reg. No. 106–21–8), 3,7, ethyl acetate (CAS Reg. No. 141–78–6), ethyl butyrate (CAS Reg. No. 105–54–4), ethyl decanoate (CAS Reg. No. 110–38–3); ethyl heptanoate (CAS Reg. No. 106–30–9), ethyl hexanoate (CAS Reg. No. 123–66–0), ethyl isobutyrate (CAS Reg. No. 97–62–1), ethyl laurate (CAS Reg. No. 106–33–2), ethyl octanoate (CAS Reg. No. 106–32–1), ethyl nonanoate (CAS Reg. No. 123–29–5), γ-heptalactone (CAS Reg. No. 105–21–5), γ-hexalactone (CAS Reg. No. 695–06–7), cis-3-hexenyl butyrate (CAS Reg. No. 16491–36–4), cis-3-hexenyl hexanoate (CAS Reg. No. 31501–11–8), 3-hexenyl 2-methylbutanoate (CAS Reg. No. 10094–41–4), hexyl butyrate (CAS Reg. No. 2639–63–6), hexyl hexanoate (CAS Reg. No. 6378–65–0), hexyl isobutyrate (CAS Reg. No. 2349–07–7), hexyl propionate (CAS Reg. No. 2445–76–3), hydroxynonanoic acid, δ-lactone (CAS Reg. No. 3301–94–8), 5-hydroxyundecanoic acid lactone (CAS Reg. No. 710–04–3), isoamyl acetate (CAS Reg. No. 123–92–2), isoamyl alcohol (CAS Reg. No. 123–51–3), isoamyl butyrate (CAS Reg. No. 106–27–4), isobutyl acetate (CAS Reg. No. 110–19–0), isobutyl isobutyrate (CAS Reg. No. 97–85–8), isopropyl 2-methylbutyrate (CAS Reg. No. 66576–71–4), Lavandin oil (Lavandula hybrida) (CAS Reg. No. 8022–15–9), linalool (CAS Reg. No. 78–70–6), linalyl acetate (CAS Reg. No.115–95–7), γ-nonalactone (CAS Reg. No. 104–61–0), γ-octalactone (CAS Reg. No. 104–50–7), ω-pentadecalactone (CAS Reg. No. 106–02–5), Petitgrain bigarade oil (CAS Reg. No. 8014–17–3), α-terpineol (CAS Reg. No. 98–55–5), terpinyl acetate (isomer mixture) (CAS Reg. No. 8007–35–0), Tetrahydrolinalool (CAS Reg. No. 78–69–3), γ-undecalactone (CAS Reg. No. 104–67–6), 10-undecen-1-yl acetate (CAS Reg. No. 112–19–6) when used as an inert ingredient fragrance component in pesticide formulations applied to food contact surfaces in public eating places, dairy processing equipment, and food processing equipment with end-use concentrations not to exceed 100 ppm. That document referenced a summary of the petition prepared by Verto Solutions on behalf of The Clorox Company, the petitioner, which is available in the docket, *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for various fragrance components including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with various fragrance components follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by various fragrance components as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The Agency assessed these fragrance components via the Threshold of toxicological concern (TTC) approach as outlined by the European Food Safety Authority (EFSA) in their 2018 proposed guidance document on the use of TTC in food safety assessment. This approach relies on the most recent evaluation of the literature on TTC as reviewed by EFSA and the World Health Organization (WHO) in 2016. Information regarding the database of studies and chemicals used to derive TTCs are reviewed therein. The TTC approach has been used by the Joint Expert Committee on Food Additives of the United Nation's Food and Agriculture Organization and the World Health Organization, the former Scientific Committee on Food of the European Commission, the European Medicines Agency, and EFSA.

Thresholds of toxicological concern (TTC) are derived from a conservative and rigorous approach developed by

Munro and Kroes (Munro et al. 1996) to establish generic threshold values for human exposure at which a very low probability of adverse effects is likely. By comparing a range of compounds by their structure using the Cramer classification scheme, *i.e.,* Cramer Class (Cramer et al. 1978), and NOEL (no-observed-effect-level), fifth percentile NOELs were established for each Cramer Class as ''Human Exposure Thresholds'' assuming a 60 kg human. These determined values were 30, 9, and 1.5 µg/kg/day for Cramer Class I, II, and III, respectively.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/ safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www.epa.gov/pesticides/factsheets/riskassess.htm.*

The human exposure threshold value for threshold (*i.e.,* non-cancer) risks is based upon Cramer structural class. In the case of the fragrance components listed above, all the substances included are in the Cramer Class I category, which is defined as chemicals of simple structure and efficient modes of metabolism, suggesting low oral toxicity. The corresponding TTC value for substances in the Cramer Class I category is 30 µg/kg/day, which is based on a 5th percentile NOEL of 3 mg/kg/day.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to each of the fragrance components listed in Unit II, EPA considered exposure under the proposed tolerance exemptions at a concentration not to exceed 100 ppm for each of the fragrance components listed in Unit II. as well as any other sources of dietary exposure. EPA assessed dietary exposures from various fragrance components in food as follows:

The dietary assessment for food contact sanitizer solutions calculated the Daily Dietary Dose (DDD) and the Estimated Daily Intake (EDI). The assessment considered: Application rates, residual solution or quantity of solution remaining on the treated surface without rinsing with potable water, surface area of the treated surface which comes into contact with food, pesticide migration fraction, and body weight. These assumptions are based on Food and Drug Administration (FDA) guidelines.

The dietary assessment for food contact sanitizer solutions showed that children 1 to 2 years old would be the highest exposed subgroup (48% of the chronic PAD (cPAD)). The general U.S. population resulted in 19% of the cPAD. Any percent cPAD exceeding 100% would be of concern.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for various fragrance components a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Various fragrance components may be used as inert ingredients in products that are registered for specific uses that may result in residential exposure, such as pesticides used in and around the home. The Agency conducted a conservative assessment of potential residential exposure by assessing various fragrance components in pesticide in disinfectant-type uses (indoor scenarios). The Agency's assessment of adult residential exposure combines high-end dermal and inhalation handler exposure from indoor hard surface, wiping and aerosol spray. The Agency's assessment of children's residential exposure includes total post-application exposures associated with total exposures associated with contact with treated indoor surfaces (dermal and hand-to-mouth exposures.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' EPA has not made a common mechanism of toxicity finding as to these fragrance chemicals listed in unit II and any other substances, and these fragrance chemicals do not appear to produce toxic metabolites produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that these fragrance chemicals listed in unit II have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

FFDCA Section 408(b)(2)(C) provides that EPA shall retain an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor. The FQPA SF has been reduced to 1X in this risk assessment because clear NOELs and LOELs were established in the studies analyzed by Munro et al. 1996 (which included developmental and reproductive toxicity studies), maternal and

developmental-specific 5th percentile NOAELs calculated by van Ravenzwaay et al. 2011 indicate low potential for offspring susceptibility, and the conservative assumptions made in the exposure assessment are unlikely underestimate risk.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effects resulting from a single oral exposure were identified and no acute dietary endpoint were selected for any of the fragrance components. Therefore, the fragrance components listed in Unit II are not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to the fragrance components listed in Unit II from food and water will utilize 48% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

The fragrance components listed in Unit II are currently used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to the fragrance components listed in Unit II.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 109 for both adult males and females. EPA has concluded the combined short-term aggregated food, water, and residential pesticide exposures result in an aggregate MOE of 135 for children. Because EPA's level of concern for the fragrance components listed in Unit II of this document is an MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, the fragrance components listed in Unit II are not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for various fragrance components.

5. *Aggregate cancer risk for U.S. population.* No structural alerts for cancer that are relevant to humans were identified for the fragrance components listed in Unit II Therefore, there is low concern for genotoxicity/carcinogenicity in humans and the assessment under the TTC value for non-cancer risks is protective for all risks, including carcinogenicity.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to residues of the fragrance components listed in Unit II.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of the fragrances listed in unit II in or on any food commodities. EPA is establishing a limitation on the amount of the fragrances listed in unit II that may be used in pesticide formulations. This limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (''FIFRA''), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for food use that exceeds 100 ppm of any one of the fragrances listed in unit II in the final pesticide formulation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for the fragrance components listed in Unit II.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for δ-decalactone (CAS Reg. No. 705–86–2), γ-decalactone (CAS Reg. No. 706–14–9), dimethyl-1-octanol (CAS Reg. No. 106–21–8), 3,7, ethyl acetate (CAS Reg. No. 141–78–6), ethyl butyrate (CAS Reg. No. 105–54–4), ethyl decanoate (CAS Reg. No. 110–38–3); ethyl heptanoate (CAS Reg. No. 106–30–9), ethyl hexanoate (CAS Reg. No. 123–66–0), ethyl isobutyrate (CAS Reg. No. 97–62–1), ethyl laurate (CAS Reg. No. 106–33–2), ethyl octanoate (CAS Reg. No. 106–32–1), ethyl nonanoate (CAS Reg. No. 123–29–5), γ-heptalactone (CAS Reg. No. 105–21–5), γ-hexalactone (CAS Reg. No. 695–06–7), cis-3-hexenyl butyrate (CAS Reg. No. 16491–36–4), cis-3-hexenyl hexanoate (CAS Reg. No. 31501–11–8), 3-hexenyl 2-methylbutanoate (CAS Reg. No. 10094–41–4), hexyl butyrate (CAS Reg. No. 2639–63–6), hexyl hexanoate (CAS Reg. No. 6378–65–0), hexyl isobutyrate (CAS Reg. No. 2349–07–7), hexyl propionate (CAS Reg. No. 2445–76–3), hydroxynonanoic acid, δ-lactone (CAS Reg. No. 3301–94–8), 5-hydroxyundecanoic acid lactone (CAS Reg. No. 710–04–3), isoamyl acetate (CAS Reg. No. 123–92–2), isoamyl alcohol (CAS Reg. No. 123–51–3), isoamyl butyrate (CAS Reg. No. 106–27–

4), isobutyl acetate (CAS Reg. No. 110–19–0), isobutyl isobutyrate (CAS Reg. No. 97–85–8), isopropyl 2-methylbutyrate (CAS Reg. No. 66576–71–4), Lavandin oil (Lavandula hybrida) (CAS Reg. No. 8022–15–9), linalool (CAS Reg. No. 78–70–6), linalyl acetate (CAS Reg. No.115–95–7), γ-nonalactone (CAS Reg. No. 104–61–0), γ-octalactone (CAS Reg. No. 104–50–7), ω-pentadecalactone (CAS Reg. No. 106–02–5), Petitgrain bigarade oil (CAS Reg. No. 8014–17–3), α-terpineol (CAS Reg. No. 98–55–5), terpinyl acetate (isomer mixture) (CAS Reg. No. 8007–35–0), Tetrahydrolinalool (CAS Reg. No. 78–69–3), γ-undecalactone (CAS Reg. No. 104–67–6), 10-undecen-1-yl acetate (CAS Reg. No. 112–19–6) when used as an inert ingredient (fragrance components) in pesticide formulations applied to food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils with end-use concentration not to exceed 100 ppm.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 10, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.940, amend the table in paragraph (a) by revising the heading and adding in alphabetical order the inert ingredients ''δ-decalactone'', ''γ-decalactone'', ''dimethyl-1-octanol'', ''3,7, ethyl acetate'', ''ethyl butyrate'', ''ethyl decanoate''; ''ethyl heptanoate'', ''ethyl hexanoate'', ''ethyl isobutyrate'', ''ethyl laurate'', ''ethyl octanoate'', ''ethyl nonanoate'', ''γ-heptalactone'', ''γ-hexalactone'', ''cis-3-hexenyl butyrate'', ''cis-3-hexenyl hexanoate'', ''3-hexenyl 2-methylbutanoate'', ''hexyl butyrate'', ''hexyl hexanoate'', ''hexyl isobutyrate'', ''hexyl propionate'', ''hydroxynonanoic acid, δ-lactone'', ''5-hydroxyundecanoic acid lactone'', ''isoamyl acetate'', ''isoamyl alcohol'', ''isoamyl butyrate'', ''isobutyl acetate'', ''isobutyl isobutyrate'', ''isopropyl 2-methylbutyrate'', ''Lavandin oil (Lavandula hybrida)'', ''linalool'', ''linalyl acetate'', ''γ-nonalactone'', ''γ-octalactone'', ''ω-pentadecalactone'', ''Petitgrain bigarade oil'', ''α-terpineol'', ''terpinyl acetate (isomer mixture)'', ''Tetrahydrolinalool'', ''γ-undecalactone'', and ''10-undecen-1-yl acetate'' to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Pesticide chemical	CAS Reg. No.	Limits
*	*	* * * * *
δ-decalactone	705–86–2	When ready for use, the end-use concentration is not to exceed 100 ppm.
γ-decalactone	706–14–9	When ready for use, the end-use concentration is not to exceed 100 ppm.

TABLE 1 TO PARAGRAPH (a)—Continued

Pesticide chemical	CAS Reg. No.	Limits
* * *	* * *	* * *
3,7-dimethyl-1-octanol	106–21–8	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
ethyl acetate	141–78–6	When ready for use, the end-use concentration is not to exceed 100 ppm.
ethyl butyrate	105–54–4	When ready for use, the end-use concentration is not to exceed 100 ppm.
ethyl decanoate	110–38–3	When ready for use, the end-use concentration is not to exceed 100 ppm.
ethyl heptanoate	106–30–9	When ready for use, the end-use concentration is not to exceed 100 ppm.
ethyl hexanoate	123–66–0	When ready for use, the end-use concentration is not to exceed 100 ppm.
ethyl isobutyrate	97–62–1	When ready for use, the end-use concentration is not to exceed 100 ppm.
ethyl laurate	106–33–2	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
ethyl nonanoate	123–29–5	When ready for use, the end-use concentration is not to exceed 100 ppm.
ethyl octanoate	106–32–1	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
γ-heptalactone	105–21–5	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
γ-hexalactone	695–06–7	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
cis-3-hexenyl butyrate	16491–36–4	When ready for use, the end-use concentration is not to exceed 100 ppm.
cis-3-hexenyl hexanoate	31501–11–8	When ready for use, the end-use concentration is not to exceed 100 ppm.
3-hexenyl 2-methylbutanoate	10094–41–4	When ready for use, the end-use concentration is not to exceed 100 ppm.
hexyl butyrate	2639–63–6	When ready for use, the end-use concentration is not to exceed 100 ppm.
hexyl hexanoate	6378–65–0	When ready for use, the end-use concentration is not to exceed 100 ppm.
hexyl isobutyrate	2349–07–7	When ready for use, the end-use concentration is not to exceed 100 ppm.
hexyl propionate	2445–76–3	When ready for use, the end-use concentration is not to exceed 100 ppm.
hydroxynonanoic acid, δ-lactone	3301–94–8	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
5-hydroxyundecanoic acid lactone	710–04–3	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
isoamyl acetate	123–92–2	When ready for use, the end-use concentration is not to exceed 100 ppm.
isoamyl alcohol	123–51–3	When ready for use, the end-use concentration is not to exceed 100 ppm.
isoamyl butyrate	106–27–4	When ready for use, the end-use concentration is not to exceed 100 ppm.
isobutyl acetate	110–19–0	When ready for use, the end-use concentration is not to exceed 100 ppm.
isobutyl isobutyrate	97–85–8	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
isopropyl 2-methylbutyrate	66576–71–4	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Lavandin oil (*Lavandula hybrida*)	8022–15–9	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
linalool	78–70–6	When ready for use, the end-use concentration is not to exceed 100 ppm.
linalyl acetate	115–95–7	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
γ-nonalactone	104–61–0	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
γ-octalactone	104–50–7	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
ω-pentadecalactone	106–02–5	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Petitgrain bigarade oil	8014–17–3	When ready for use, the end-use concentration is not to exceed 100 ppm.
α-terpineol	98–55–5	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
terpinyl acetate (isomer mixture)	8007–35–0	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
tetrahydrolinalool	78–69–3	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
γ-undecalactone	104–67–6	When ready for use, the end-use concentration is not to exceed 100 ppm.

TABLE 1 TO PARAGRAPH (a)—Continued

Pesticide chemical	CAS Reg. No.	Limits
* * *	* * *	* * *
10-undecen-1-yl acetate	112–19–6	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *

* * * * *

[FR Doc. 2021–27580 Filed 12–21–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 483, 484, 488, 489, and 498

[CMS–1747–CN and CMS–5531–CN]

RINs 0938–AU37 and 0938–AU32

Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID–19 Reporting Requirements for Long-Term Care Facilities; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule; correction.

SUMMARY: This document corrects technical and typographical errors that appeared in the final rule published in the **Federal Register** on November 9, 2021 titled ''Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID–19 Reporting Requirements for Long-Term Care Facilities''.

DATES: This correcting document is effective January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Brian Slater, (410) 786–5229, for home health payment inquiries.

Frank Whelan (410) 786–1302, for provider enrollment inquiries.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2021–23993 of November 9, 2021 (86 FR 62431), there were a number of technical errors that are identified and corrected in this correcting document. The provisions in this correction document are effective as if they had been included in the document that appeared in the November 9, 2021 **Federal Register**.

II. Summary of Errors

A. Summary of Errors in the Preamble

On page 62240, we inadvertently included a website address that is not related to Home Health Value Based Purchasing Model.

On pages 62250 and 62251, in our discussion of the functional impairment levels under the Patient-Driven Groupings Model (PDGM), we made typographical errors in an Outcome and Assessment Information Set (OASIS) item number.

On page 62251, we inadvertently omitted a note following the table titled ''Table 2: OASIS Points Table for those Items Associated with Increases Resource Use Using a Reduced Set of OASIS Items, CY 2020''.

B. Summary of Errors in the Regulations Text

On page 62419, in our amendatory instructions for § 424.525, we made an inadvertent error in specifying the revisions to § 424.525(a)(3).

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rulemaking in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rulemaking in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA, and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the notice and comment and delay in effective date APA requirements; in cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process are impracticable, unnecessary, or contrary to the public interest. In addition, both section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) of the Act allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and an agency includes a statement of support.

We believe that this final rule correction does not constitute a rule that would be subject to the notice and comment or delayed effective date requirements. This document corrects typographical and technical errors in the CY 2022 HH PPS final rule, but does not make substantive changes to the policies or payment methodologies that were adopted in the final rule. As a result, this final rule correction is intended to ensure that the information in the CY 2022 HH PPS final rule accurately reflects the policies adopted in that document.

In addition, even if this were a rule to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the final rule or delaying the effective date would be contrary to the public interest because it is in the public's interest for providers to receive appropriate payments in as timely a manner as possible, and to ensure that

the CY 2022 HH PPS final rule accurately reflects our policies. Furthermore, such procedures would be unnecessary, as we are not altering our payment methodologies or policies, but rather, we are simply implementing correctly the methodologies and policies that we previously proposed, requested comment on, and subsequently finalized. This final rule correction is intended solely to ensure that the CY 2022 HH PPS final rule accurately reflects these payment methodologies and policies. Therefore, we believe we have good cause to waive the notice and comment and effective date requirements. Moreover, even if these corrections were considered to be retroactive rulemaking, they would be authorized under section 1871(e)(1)(A)(ii) of the Act, which permits the Secretary to issue a rule for the Medicare program with retroactive effect if the failure to do so would be contrary to the public interest. As we have explained previously, we believe it would be contrary to the public interest not to implement the corrections in this final rule correction because it is in the public's interest for providers to receive appropriate payments in as timely a manner as possible, and to ensure that the CY 2022 HH PPS final rule accurately reflects our policies.

IV. Correction of Errors

In FR Doc. 2021–23993 of November 9, 2021 (86 FR 62240), make the following corrections:

A. Correction of Errors in the Preamble

1. On page 62240, second column, fifth full paragraph, lines 3 through 5, the phrase ''*https://share.cms.gov/center/CCSQ/CSG/DIQS/LTC/LTCCOVIDReportingfinalrule/* please visit'' is corrected to read ''please visit''.

2. On page 62250, second column, second full paragraph, line 7, the figure ''M1032'' is corrected to read ''M1033''.

3. On page 62251:

a. In the Table titled ''Table 2: OASIS Points Table for those Items Associated with Increased Resource Use Using a Reduced Set of OASIS Items, CY 2020'', last row, first column, the ''M1032'' is corrected to read ''M1033''.

b. Following the table, after the table note that begins ''Source: CY 2020'' and ends ''July 12, 2021'', the table notes are corrected by adding the following:

''**Note:** For the OASIS items in this table, the association between OASIS points and responses is directly associated with the resource use for each item.''.

B. Correction of Errors in the Regulations Text

§ 424.525 [Corrected]

■ 1. On page 62419, second column, in § 424.525, amendatory instruction 7b. is corrected to read as follows:

''b. In—

■ i. Paragraphs (a)(2) and (b) by removing the phrase ''prospective provider'' and adding the word ''provider'' in its place; and

■ ii. Paragraph (a)(3) by removing the phrase ''prospective institutional provider'' and adding the phrase ''institutional provider'' in its place; and''.

Karuna Seshasai,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2021–27568 Filed 12–21–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180117042–8884–02; RTID 0648–XB675]

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; fishery reopening.

SUMMARY: NMFS reopens the General category fishery for four days within the December 2021 General category subquota period. This action is intended to provide a reasonable opportunity to harvest the annual U.S. bluefin tuna (BFT) quota without exceeding it, while maintaining an equitable distribution of fishing opportunities across time periods. This action affects Atlantic Tunas General category (commercial) permitted vessels and Highly Migratory Species (HMS) Charter/Headboat permitted vessels with a commercial sale endorsement when fishing commercially for BFT.

DATES: Effective 12:30 a.m., local time, December 20, 2021, through 11:30 p.m., local time, December 23, 2021.

FOR FURTHER INFORMATION CONTACT: Larry Redd, Jr., *larry.redd@noaa.gov,* 301–427–8503, Nicholas Velseboer, *nicholas.velsboer@noaa.gov,* 978–281–9260, or Thomas Warren, *thomas.warren@noaa.gov,* 978–281–9347.

SUPPLEMENTARY INFORMATION: Atlantic HMS fisheries, including BFT fisheries, are managed under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*). The 2006 Consolidated Atlantic HMS Fishery Management Plan (FMP) and its amendments are implemented by regulations at 50 CFR part 635. Section 635.27 divides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic fishing categories, per the allocations established in the 2006 Consolidated HMS FMP and its amendments. NMFS is required under the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest quotas under relevant international fishery agreements such as the ICCAT Convention, which is implemented domestically pursuant to ATCA.

The 2021 baseline quota for the General category is 555.7 mt. The General category baseline subquota for the December time period is 28.9 mt. Effective January 1, 2021, NMFS transferred 19.5 mt of BFT quota from the December 2021 subquota time-period to the January through March 2021 subquota time-period resulting in an adjusted subquota of 9.4 mt for the December 2021 time period (85 FR 83832, December 23, 2020). Effective December 1, 2021, NMFS transferred 9.5 mt of Reserve category quota and 20.2 mt of Harpoon category quota to the General category resulting in an adjusted December subquota of 39.1 mt (86 FR 66975, November 24, 2021). NMFS recently adjusted the December General category subquota by adding 15.5 mt of underharvest from the adjusted September and October through November time periods resulting in an adjusted December subquota of 54.6 mt (86 FR 71393, December 16, 2021). In that same action, NMFS projected that the adjusted December 2021 subquota of 54.6 mt would be reached shortly, and accordingly, closed the General category on December 14, 2021.

General Category Reopening

As of December 16, 2021, preliminary landings data indicate that the General category December fishery landed 48.8 mt of the adjusted 54.6 mt subquota before closing, leaving resulting in 5.8

mt (54.6 mt − 48.8 mt = 5.8 mt) of quota unused. Under § 635.28(a)(2), NMFS may reopen the fishery if NMFS determines that reasonable fishing opportunities are available. Based on these landings data, as well as average catch rates and anticipated fishing conditions, NMFS has determined that reopening the General category fishery for four days is appropriate given the amount of unused December subquota. Depending on weather conditions and fish availability, a longer reopening could risk exceeding the unused quota available for the December subquota period. NMFS will need to account for 2021 landings and dead discards within the adjusted U.S. quota, consistent with ICCAT recommendations, and anticipates having sufficient quota to do that. Thus, this action would allow fishermen to take advantage of the availability of fish on the fishing grounds to the extent consistent with the available amount of quota and other management objectives, while avoiding quota exceedance.

Therefore, the General category fishery will reopen at 12:30 a.m., Monday, December 20, 2021, and close at 11:30 p.m., Thursday, December 23, 2021. The General category daily retention limit during this reopening remains the same as prior to closing: One large medium or giant (*i.e.,* measuring 73 inches (185 cm) curved fork length or greater) BFT per vessel per day/trip. This action applies to Atlantic tunas General category (commercial) permitted vessels and HMS Charter/Headboat category permitted vessels with a commercial sale endorsement when fishing commercially for BFT. Retaining, possessing, or landing large medium or giant BFT by persons aboard vessels permitted in the General and HMS Charter/Headboat categories must cease at 11:30 p.m. local time on December 23, 2021. The General category will automatically reopen January 1, 2022, for the January through March 2022 subquota time period.

Fishermen aboard General category permitted vessels and HMS Charter/Headboat permitted vessels may catch-and-release and tag and release BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs at § 635.26. All BFT that are released must be handled in a manner that will maximize their survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the ''Careful Catch and Release'' brochure available at *https://www.fisheries.noaa.gov/resource/outreach-and-education/careful-catch-and-release-brochure/.*

Monitoring and Reporting

NMFS will continue to monitor the BFT fisheries closely. Dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustment, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, General and HMS Charter/Headboat category vessel owners are required to report the catch of all BFT retained or discarded dead within 24 hours of the landing(s) or end of each trip, by accessing *hmspermits.noaa.gov,* using the HMS Catch Reporting app, or calling (888) 872–8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

Classification

This action is taken pursuant to regulations at 50 CFR part 635, which were issued pursuant to section 304(c) of the Magnuson-Stevens Act, and is exempt from review under Executive Order 12866.

The Assistant Administrator for NMFS finds that pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice of, and an opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason adjustments to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Affording prior notice and opportunity for public comment to reopen the fishery is impracticable and contrary to the public interest. The General category recently closed, but based on the available category subquota, fishery performance in recent weeks, and the availability of BFT on the fishing grounds, is reopened in this action to allow fishermen to take advantage of availability of fish and of quota. NMFS could not have proposed this action earlier, as it needed to consider and respond to updated data and information about fishery conditions and this year's landings. If NMFS were to offer a public comment period now, after having appropriately considered that data, it would preclude fishermen from harvesting BFT that are legally available. For all of the above reasons, there is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: December 17, 2021.

Ngagne Jafnar Gueye,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–27761 Filed 12–17–21; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 201209–0332; RTID 0648–XB659

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfers From VA to NC and FL to RI

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification; quota transfers.

SUMMARY: NMFS announces that the Commonwealth of Virginia and the State of Florida are transferring a portion of their 2021 commercial bluefish quota to the states of North Carolina and Rhode Island, respectively. These quota adjustments are necessary to comply with the Atlantic Bluefish Fishery Management Plan quota transfer provisions. This announcement informs the public of the revised commercial bluefish quotas for Virginia, North Carolina, Florida, and Rhode Island.

DATES: Effective December 17, 2021, through December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Laura Hansen, Fishery Management Specialist, (978) 281–9225.

SUPPLEMENTARY INFORMATION: Regulations governing the Atlantic bluefish fishery are found in 50 CFR 648.160 through 648.167. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through Florida. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.162, and the final 2021 allocations were published on December 16, 2020 (85 FR 81421).

The final rule implementing Amendment 1 to the Bluefish Fishery Management Plan (FMP) published in the **Federal Register** on July 26, 2000 (65 FR 45844), and provided a mechanism for transferring bluefish quota from one state to another. Two or more states, under mutual agreement

and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can request approval to transfer or combine bluefish commercial quota under § 648.162(e)(1)(i) through (iii). The Regional Administrator must approve any such transfer based on the criteria in § 648.162(e). In evaluating requests to transfer a quota or combine quotas, the Regional Administrator shall consider whether: The transfer or combinations would preclude the overall annual quota from being fully harvested; the transfer addresses an unforeseen variation or contingency in the fishery; and the transfer is consistent with the objectives of the FMP and the Magnuson-Stevens Act.

Virginia is transferring 70,000 lb (31,751 kg) to North Carolina, and Florida is transferring 40,000 lb (18,144 kg) to Rhode Island through mutual agreement of the states. These transfers were requested to ensure that North Carolina and Rhode Island would not exceed their 2021 state quota. The revised bluefish quotas for 2021 are: Virginia, 168,800 lb (76,566 kg); North Carolina, 1,057,377 lb (479,618 kg); Florida 238,432 lb (108,151 kg); and Rhode Island, 304,434 lb (138,089 kg).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 648.162(e)(1)(i) through (iii), which was issued pursuant to section 304(b), and is exempted from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 16, 2021.

Ngagne Jafnar Gueye,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–27650 Filed 12–17–21; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 201209–0332; RTID 0648–XB660]

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfers From DE to NC and MD to RI

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification; quota transfers.

SUMMARY: NMFS announces that the states of Delaware and Maryland are transferring a portion of their 2021 commercial bluefish quota to the states of North Carolina and Rhode Island, respectively. These quota adjustments are necessary to comply with the Atlantic Bluefish Fishery Management Plan quota transfer provisions. This announcement informs the public of the revised commercial bluefish quotas for Delaware, North Carolina, Maryland, and Rhode Island.

DATES: Effective December 17, 2021, through December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Laura Hansen, Fishery Management Specialist, (978) 281–9225.

SUPPLEMENTARY INFORMATION: Regulations governing the Atlantic bluefish fishery are found in 50 CFR 648.160 through 648.167. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through Florida. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.162, and the final 2021 allocations were published on December 16, 2020 (85 FR 81421).

The final rule implementing Amendment 1 to the Bluefish Fishery Management Plan (FMP) published in the **Federal Register** on July 26, 2000 (65 FR 45844), and provided a mechanism for transferring bluefish quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can request approval to transfer or combine bluefish commercial quota under § 648.162(e)(1)(i) through (iii). The Regional Administrator must approve any such transfer based on the criteria in § 648.162(e). In evaluating requests to transfer a quota or combine quotas, the Regional Administrator shall consider whether: The transfer or combinations would preclude the overall annual quota from being fully harvested; the transfer addresses an unforeseen variation or contingency in the fishery; and the transfer is consistent with the objectives of the FMP and the Magnuson-Stevens Act.

Delaware is transferring 15,000 lb (6,804 kg) to North Carolina, and Maryland is transferring 10,000 lb (4,536 kg) to Rhode Island through mutual agreement of the states. These transfers were requested to ensure that North Carolina and Rhode Island would not exceed their 2021 state quota. The revised bluefish quotas for 2021 are: Delaware, 6,958 lb (3,156 kg); North Carolina, 1,072,377 lb (486,422 kg); Maryland 43,084 lb (19,542 kg); and Rhode Island, 314,434 lb (142,625 kg).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 648.162(e)(1)(i) through (iii), which was issued pursuant to section 304(b), and is exempted from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 17, 2021.

Ngagne Jafnar Gueye,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–27762 Filed 12–17–21; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 210210–0018; RTID 0648–XB656]

Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pacific Cod in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; reallocation.

SUMMARY: NMFS is reallocating the projected unused amounts of Pacific cod total allowable catch (TAC) from catcher vessels using trawl gear to catcher/processors using trawl gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to allow the 2021 TAC of Pacific cod in the Central Regulatory Area of the GOA to be harvested.

DATES: Effective December 21, 2021, through 2400 hours, Alaska local time (A.l.t.), December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2021 Pacific cod TAC apportioned to catcher vessels using trawl gear in the Central Regulatory Area of the GOA is 3,826 mt, as established by the final 2021 and 2022 harvest specifications for groundfish of the GOA (86 FR 10184, February 19, 2021).

The 2021 Pacific cod TAC specified for catcher/processors using trawl gear in the Central Regulatory Area of the GOA is 426 mt as established by the final 2021 and 2022 harvest specifications for groundfish of the GOA (86 FR 10184, February 19, 2021).

The Administrator, Alaska Region, NMFS, (Regional Administrator) has determined that catcher vessels using trawl gear will not be able to use 426 mt of the 2020 Pacific cod TAC allocated to those vessels under § 679.20(a)(12)(i)(B)(*4*).

In accordance with § 679.20(a)(12)(ii)(B), the Regional Administrator has also determined that catcher/processors using trawl gear currently have the capacity to harvest this excess allocation. Therefore, NMFS apportions 435 mt of Pacific cod from the catcher vessels using trawl gear to catcher/processors using trawl gear in the Central Regulatory Area of the GOA.

The harvest specifications for Pacific cod in the Central Regulatory Area of the GOA included in the final 2021 and 2022 harvest specifications for groundfish of the GOA (86 FR 10184, February 19, 2021) are revised as follows: 3,391 to catcher vessels using trawl gear and 861 mt to catcher/processors using trawl gear.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the reallocation of Pacific cod in the Central Regulatory Area of the GOA. NMFS was unable to publish a document providing time for public comment because the most recent, relevant data only became available as of December 9, 2021.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 16, 2021.

Ngagne Jafnar Gueye,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–27648 Filed 12–21–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 210210–0018; RTID 0648–XB658]

Fisheries of the Exclusive Economic Zone Off Alaska; Chinook Salmon Prohibited Species Catch Limits in the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; inseason adjustment.

SUMMARY: NMFS is reapportioning the projected unused amount, 200 Chinook salmon prohibited species catch limit, from the vessels participating in directed fishing for pollock in the Central Regulatory Area of the Gulf of Alaska (GOA) to Rockfish Program catcher vessel sector in the Central Regulatory Area of the GOA. This action is consistent with the goals and objectives of the Fishery Management Plan for Groundfish of the GOA.

DATES: Effective December 21, 2021, through 2400 hours, Alaska local time (A.l.t.), December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: Regulations governing fishing by U.S. vessels in accordance with the fishery management plan appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2021 Chinook salmon prohibited species catch (PSC) limit for the Rockfish Program catcher vessel sector in the Central Regulatory Areas of the GOA is 1,200 Chinook salmon (§ 679.21(h)(4)(i)(B)).

The 2021 Chinook salmon PSC limit for vessels directed fishing for pollock using trawl gear in the Central Regulatory Area of the GOA is 16,966 Chinook salmon (§ 679.21(h)(2)(ii) and reallocation (86 FR 46792, August 20, 2021).

The Administrator, Alaska Region, NMFS, (Regional Administrator) has determined that the vessels participating in directed fishing for pollock in the Central Regulatory Area of the GOA will not require 200 Chinook salmon of the Chinook salmon PSC limit allocated to those vessels under § 679.21(h)(2)(ii). Therefore, in accordance with § 679.21(h)(5)(iii) and taking into account the need of the sectors for Chinook salmon PSC, and following the limits set forth in § 679.21(h)(5)(iv)(C), NMFS reapportions 200 Chinook salmon PSC limit to the Rockfish Program catcher vessel sector in the Central Regulatory Area of the GOA.

The 2021 Chinook salmon PSC limits are revised as follows: 16,766 Chinook salmon for vessels participating in directed fishing for pollock in the Central Regulatory Area of the GOA (19,966 minus 200 Chinook salmon) and 1,400 Chinook salmon to the Rockfish Program catcher vessel sector in the Central Regulatory Areas of the GOA (1,200 plus 200 Chinook salmon).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the reallocation of Chinook salmon to the Rockfish Program catcher vessel sector in the Central Regulatory Areas of the GOA. NMFS was unable to publish a document providing time for public comment because the most recent, relevant data only became available as of December 9, 2021.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 16, 2021.

Ngagne Jafnar Gueye,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–27649 Filed 12–21–21; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 86, No. 243
Wednesday, December 22, 2021

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 310

[Docket ID: DoD–2021–OS–0048]

RIN 0790–AL13

Privacy Act of 1974; Implementation

AGENCY: Office of the Secretary of Defense (OSD), Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: The Department of Defense (Department or DoD) is giving concurrent notice of a new Department-wide system of records pursuant to the Privacy Act of 1974 for the DoD–0008, ''Freedom of Information Act and Privacy Act Records'' system of records and this proposed rulemaking. In this proposed rulemaking, the Department proposes to exempt portions of this system of records from certain provisions of the Privacy Act because of national security requirements; to avoid interference during the conduct of criminal, civil, or administrative actions or investigations; to prevent the compromise of protective services processes; to protect the identity of confidential sources incident to Federal employment, military service, contract, and security clearance determinations; and to prevent the undermining of testing and evaluation materials.

DATES: Send comments on or before February 22, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods.

* *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* The DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *https://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Tracy Rogers, (703) 571–0070, *OSD.DPCLTD@mail.mil.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, the DoD is establishing a new DoD-wide system of records titled ''Freedom of Information Act and Privacy Act Records,'' DoD–0008. This system of records notice describes access requests and administrative appeals under the Freedom of Information Act (FOIA), and access and amendment requests and administrative appeals under the Privacy Act. The system consists of both electronic and paper records and will be used by DoD components and offices to maintain records about individuals who submit FOIA access requests, Privacy Act access and amendment requests, administrative appeals to the Department under either the FOIA or Privacy Act, and individual requests referred from other agencies. These records may include information regarding the requesters and their attorneys or representatives, the original request for access, amendment, and administrative appeal, and other supporting documentation to include related memoranda, correspondence, notes, statements of disagreement, and, in some instances, copies of requested records and records under administrative appeal.

II. Privacy Act Exemption

The Privacy Act allows Federal agencies to exempt eligible records in a system of records from certain provisions of the Act, including those that provide individuals with a right to request access to and amendment of their own records. If an agency intends to exempt a particular system of records, it must first go through the rulemaking process pursuant to 5 U.S.C. 553(b)(1)–(3), (c), and (e). This proposed rule explains why an exemption is being claimed for this system of records and invites public comment, which DoD will consider before the issuance of a final rule implementing the exemption.

The DoD proposes to modify 32 CFR part 310 to add a new Privacy Act exemption rule for the DoD–0008, Freedom of Information Act and Privacy Act Records system of records. In this proposed rulemaking, the Department proposes to exempt portions of this system of records from certain provisions of the Privacy Act because records and information in this system of records may fall within the scope of the Privacy Act exemptions. As stated in the DoD–0008 system of records notice, this system of records generally will not be deemed to cover underlying records that are responsive to an access or amendment request; rather, the system covers the access, amendment, or appeal requests themselves, correspondence created as a result of such requests, and certain other categories of records identified in the notice. In certain limited instances, however, entire records, portions thereof, or information from such underlying records may be recompiled to become part of this system. Certain records may also be recompiled from other exempt systems of records as a result of a request for access to such records under the Privacy Act or the Freedom of Information Act, or a request for amendment of a record under the Privacy Act. Recompiled records and information may fall within the scope of the Privacy Act exemptions claimed for those systems of records, specifically the exemptions set forth in 5 U.S.C. 552a(j)(2), (k)(1), (k)(2), (k)(3), (k)(5), (k)(6), and (k)(7).

The DoD proposes this exemption rule for several reasons. First, some of the records in this system of records may contain information recompiled from other systems of records maintained by a DoD component or other agency which performs as its principal function activities pertaining to the enforcement of criminal laws and the records contain investigatory material compiled for criminal law enforcement purposes. The Privacy Act, pursuant to 5 U.S.C. 552a(j)(2), authorizes agencies to claim an exemption for systems of records that contain this type of information. The DoD therefore is proposing to claim an exemption from several provisions of the Privacy Act, including various

access, amendment, disclosure of accounting, and certain record-keeping and notice requirements, to prevent, among other harms, the identification of actual or potential subjects of criminal investigation and/or sources of criminal investigative information and to avoid frustrating the underlying criminal law enforcement purpose for which the records were collected.

Additionally, some of the records in this system of records may contain classified national security information and providing notice, access, amendment, and disclosure of accounting of those records to an individual, as well as certain recordkeeping requirements, may cause damage to national security. The Privacy Act, pursuant to 5 U.S.C. 552a(k)(1), authorizes agencies to claim an exemption for systems of records that contain information properly classified pursuant to executive order. The DoD therefore is proposing to claim an exemption from several provisions of the Privacy Act, including various access, amendment, disclosure of accounting, and certain record-keeping and notice requirements, to prevent disclosure of any information properly classified pursuant to executive order, as implemented by DoD Instruction 5200.01 and DoD Manual 5200.01, Volumes 1 and 3.

The DoD is also proposing this Privacy Act exemption rule because this system of records may contain investigatory material compiled for law enforcement purposes recompiled from other systems of records within the scope of 5 U.S.C. 552a(k)(2). This exemption allows the Department to claim an exemption for systems of records that contain investigatory materials compiled for law enforcement purposes, other than material within the scope of 5 U.S.C. 552a(j)(2), which is described above. The DoD therefore is proposing to claim an exemption from several provisions of the Privacy Act, including various access, amendment, disclosure of accounting, and certain recordkeeping and notice requirements, to prevent, among other harms, the identification of actual or potential subjects of investigation and/or sources of investigative information and to avoid frustrating the underlying law enforcement purpose for which the records were collected.

The DoD also proposes an exemption for this system of records because the records may in certain instances contain information recompiled from other systems of records pertaining to providing protective services to the President of the United States or other individuals pursuant to 18 U.S.C. 3056. The Privacy Act, pursuant to 5 U.S.C. 552a(k)(3), authorizes agencies to claim an exemption for systems of records that contain information concerning protective services for which access to, amendment of, or release of the accounting of disclosures of such records could compromise the effectiveness of the protective services, the safety of the individuals protected pursuant to 18 U.S.C. 3056, and the safety of the personnel providing protective services. The DoD is proposing to claim an exemption from several provisions of the Privacy Act, including various access, amendment, disclosure of accounting, and certain recordkeeping and notice requirements, to avoid, among other harms, frustrating the purposes of the protective services for which the information was gathered.

In addition, the DoD proposes an exemption for this system of records because the records may contain information recompiled from other systems of records consisting of investigatory material compiled solely for determining suitability, eligibility, and qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information. The Privacy Act, pursuant to 5 U.S.C. 552a(k)(5), authorizes agencies to claim an exemption for systems of records that contain information identifying sources crucial to determining suitability for holding positions of trust and who furnished information to the Government under an express promise that the source's identity would be held in confidence. The DoD is proposing to claim an exemption from several provisions of the Privacy Act, including various access, amendment, disclosure of accounting, and certain record-keeping and notice requirements, to prevent the compromise of the identity of such confidential sources within such investigatory material.

The DoD also proposes an exemption for this system of records because the records may contain examination and testing material recompiled from other systems of records that is used solely to determine individual qualification for appointment or promotion in the Federal service within the scope of 5 U.S.C. 552a(k)(6). The DoD is therefore proposing to claim an exemption from several provisions of the Privacy Act, including various access, amendment, disclosure of accounting, and certain record-keeping and notice requirements, to prevent disclosure of any information that would compromise the objectivity or fairness of testing and examination material.

Finally, the DoD proposes an exemption for this system of records because the records may contain evaluation material recompiled from other systems of records that is used to determine potential for promotion in the armed services within the scope of 5 U.S.C. 552a(k)(7). In some cases, such records may contain information pertaining to the identity of a source who furnished information to the Government under an express promise that the source's identity would be held in confidence (or prior to the effective date of the Privacy Act, under an implied promise). The DoD therefore is proposing to claim an exemption from several provisions of the Privacy Act, including various access, amendment, disclosure of accounting, and certain record-keeping and notice requirements, to prevent disclosure of any information that would compromise the identity of confidential sources who might not have otherwise come forward to assist the Government.

Records in this system of records are only exempt from the Privacy Act to the extent the purposes underlying the exemption pertain to the record. A notice of a new system of records for DoD–0008, Freedom of Information Act and Privacy Act Records, is also published in this issue of the **Federal Register**.

Regulatory Analysis

Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. It has been determined that this rule is not a significant regulatory action under these executive orders.

Congressional Review Act

This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. Chapter 6)

The Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency has certified that this Privacy Act rule does not have

significant economic impact on a substantial number of small entities because they are concerned only with the administration of Privacy Act systems of records within the DoD.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

It has been determined that this rule does not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Section 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

It has been determined that this rule does not involve a Federal mandate that may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more and that it will not significantly or uniquely affect small governments.

Executive Order 13132, ''Federalism''

It has been determined that this rule does not have federalism implications. This rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, ''Consultation and Coordination With Indian Tribal Governments''

Executive Order 13175 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on one or more Indian tribes, preempts tribal law, or effects the distribution of power and responsibilities between the federal government and Indian tribes. This rule will not have a substantial effect on Indian tribal governments.

List of Subjects in 32 CFR Part 310

Privacy.

Accordingly, 32 CFR part 310 is proposed to be amended as follows:

PART 310 [Amended]

■ 1. The authority citation for 32 CFR part 310 continues to read as follows:

Authority: 5 U.S.C. 552a.

■ 2. Section 310.13 is amended by adding paragraph (e)(7) to read as follows:

§ 310.13 Exemptions for DoD-wide systems.

* * * * *

(e) * * *

(7) *System identifier and name.* DoD–0008, ''Freedom of Information Act and Privacy Act Records.''

(i) *Exemptions.* This system of records is exempt from 5 U.S.C. 552a(c)(3) and (4); (d)(1), (2), (3), and (4); (e)(1); (e)(2); (e)(3); (e)(4)(G), (H), and(I); (e)(5); (e)(8); (f) and (g).

(ii) *Authority.* 5 U.S.C. 552a(j)(2), (k)(1), (k)(2), (k)(3), (k)(5), (k)(6), and (k)(7).

(iii) *Exemption from the particular subsections.* Exemption from the particular subsections is justified for the following reasons:

(A) *Subsection (c)(3), (d)(1), and (d)(2)*—(*1*) *Exemption (j)(2).* Records in this system of records may contain information recompiled from other systems of records maintained by a DoD component or other agency which performs as its principal function activities pertaining to the enforcement of criminal laws and contain investigatory material compiled for criminal law enforcement purposes, including information identifying criminal offenders and alleged offenders, information compiled for the purpose of criminal investigation, or reports compiled during criminal law enforcement proceedings. Application of exemption (j)(2) may be necessary because access to, amendment of, or release of the accounting of disclosures of such records could inform the record subject of an investigation of the existence, nature, or scope of an actual or potential law enforcement or disciplinary investigation, and thereby seriously impede law enforcement or prosecutorial efforts by permitting the record subject and other persons to whom he might disclose the records to avoid criminal penalties or disciplinary measures; reveal confidential sources who might not have otherwise come forward to assist in an investigation and thereby hinder DoD or the other agency's ability to obtain information from future confidential sources and result in an unwarranted invasion of the privacy of others. Amendment of such records could also impose a highly impracticable administrative burden by requiring investigations to be continuously reinvestigated.

(*2*) *Exemption (k)(1).* Records in this system of records may contain information that is properly classified pursuant to Executive order. Application of exemption (k)(1) may be necessary because access to and amendment of the records, or release of the accounting of disclosures for such records, could reveal classified information. Disclosure of classified records to an individual may cause damage to national security.

(*3*) *Exemption (k)(2).* Records in this system of records may may contain information recompiled from other systems of records pertaining to investigatory material compiled for law enforcement purposes other than material within the scope of 5 U.S.C. 552a(j)(2). Application of exemption (k)(2) may be necessary because access to, amendment of, or release of the accounting of disclosures of such records could: Inform the record subject of an investigation of the existence, nature, or scope of an actual or potential law enforcement or disciplinary investigation, and thereby seriously impede law enforcement or prosecutorial efforts by permitting the record subject and other persons to whom he might disclose the records or the accounting of records to avoid criminal penalties, civil remedies, or disciplinary measures; interfere with a civil or administrative action or investigation by allowing the subject to tamper with witnesses or evidence, and to avoid detection or apprehension, which may undermine the entire investigatory process; reveal confidential sources who might not have otherwise come forward to assist in an investigation and thereby hinder DoD's ability to obtain information from future confidential sources; and result in an unwarranted invasion of the privacy of others. Amendment of such records could also impose a highly impracticable administrative burden by requiring investigations to be continuously reinvestigated.

(*4*) *Exemption (k)(3).* Records in this system of records may contain information recompiled from other systems of records pertaining to providing protective services to the President of the United States or other individuals pursuant to 18 U.S.C. 3056. Application of exemption (k)(3) for such records may be necessary because access to, amendment of, or release of the accounting of disclosures of such records could compromise the effectiveness of protective services, the safety of the individuals protected pursuant to 18 U.S.C. 3056, and the safety of the personnel providing protective services.

(*5*) *Exemption (k)(5).* Records in this system of records may contain information recompiled from other systems of records concerning investigatory material compiled solely for determining suitability, eligibility, and qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information. In some cases, such records

may contain information pertaining to the identity of a source who furnished information to the Government under an express promise that the source's identity would be held in confidence (or prior to the effective date of the Privacy Act, under an implied promise). Application of exemption (k)(5) may be necessary because access to, amendment of, or release of the accounting of disclosures of such records could identify these confidential sources who might not have otherwise come forward to assist the Government; hinder the Government's ability to obtain information from future confidential sources; and result in an unwarranted invasion of the privacy of others. Amendment of such records could also impose a highly impracticable administrative burden by requiring investigations to be continuously reinvestigated.

(*6*) *Exemption (k)(6).* Records in this system of records may contain information recompiled from other systems of records relating to testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service. Application of exemption (k)(6) may be necessary when access to and amendment of the records, or release of the accounting of disclosure for such records, may compromise the objectivity and fairness of the testing or examination process. Amendment of such records could also impose a highly impracticable administrative burden by requiring testing and examinations to be continuously re-administered.

(*7*) *Exemption (k)(7).* Records in this system of records may contain evaluation material recompiled from other systems of records used to determine potential for promotion in the Armed Forces of the United States. In some cases, such records may contain information pertaining to the identity of a source who furnished information to the Government under an express promise that the source's identity would be held in confidence (or prior to the effective date of the Privacy Act, under an implied promise). Application of exemption (k)(7) may be necessary because access to, amendment of, or release of the accounting of disclosures of such records could identify these confidential sources who might not have otherwise come forward to assist the Government; hinder the Government's ability to obtain information from future confidential sources; and result in an unwarranted invasion of the privacy of others.

(B) *Subsection (c)(4) and (d)(3) and (4).* Subsections (c)(4) and (d)(3) and (4) are inapplicable to the extent that an exemption is being claimed from subsections (d)(1) and (2).

(C) *Subsection (e)(1).* In the collection of information for investigatory or law enforcement purposes, it is not always possible to conclusively determine the relevance and necessity of particular information in the early stages of the investigation or adjudication. In some instances, it will be only after the collected information is evaluated in light of other information that its relevance and necessity for effective investigation and adjudication can be assessed. Collection of such information permits more informed decision-making by the Department when making required disciplinary and prosecutorial determinations. Additionally, records within this system may be properly classified pursuant to executive order. Further, it is not always possible to determine relevancy or necessity of specific information in the earlier stages of responding to a FOIA or Privacy Act request or in litigation case development, including with respect to records pertaining to suitability determinations or armed services promotion evaluations that contain information about sources who were granted an express promise of confidentiality, or pertaining to testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service, the disclosure of which would compromise the objectivity or fairness of the testing or examination process. Such information may later be deemed unnecessary upon further assessment. Accordingly, application of exemptions (j)(2), (k)(1), (k)(2), (k)(3), (k)(5), (k)(6), or (k)(7) may be necessary.

(D) *Subsection (e)(2).* To collect information from the subject individual could serve notice that he or she is the subject of a criminal investigation and thereby present a serious impediment to such investigations. Collection of information only from the individual accused of criminal activity or misconduct could also subvert discovery of relevant evidence and subvert the course of justice. Accordingly, application of exemption (j)(2) may be necessary.

(E) *Subsection (e)(3).* To inform individuals as required by subsection (e)(3) could reveal the existence of a criminal investigation and compromise investigative efforts. Accordingly, application of exemption (j)(2) may be necessary.

(F) *Subsection (e)(4)(G) and (H).* Subsections (e)(4)(G) and (H) are inapplicable to the extent exemption is claimed from subsections (d)(1) and (2).

(G) *Subsection (e)(4)(I).* To the extent that subsection (e)(4)(I) is construed to require more detailed disclosure than the broad information currently published in the system notice concerning categories of sources of records in the system, an exemption from this provision is necessary to protect the confidentiality of sources of information, the privacy and physical safety of witnesses and informants, and testing or examination material used solely to determine individual qualifications for appointment of promotion in the Federal service. Accordingly, application of exemptions (j)(2), (k)(1), (k)(2), (k)(5), (k)(6), and (k)(7) may be necessary.

(H) *Subsection (e)(5).* It is often impossible to determine in advance if investigatory records contained in this system are accurate, relevant, timely and complete, but, in the interests of effective law enforcement, it is necessary to retain this information to maintain an accurate record of the investigatory activity to preserve the integrity of the investigation and satisfy various constitutional and evidentiary requirements, such as mandatory disclosure of potentially exculpatory information in the investigative file to a defendant. It is also necessary to retain this information to aid in establishing patterns of activity and provide investigative leads. With the passage of time, seemingly irrelevant or untimely information may acquire new significance as further investigation brings new details to light and the accuracy of such information can only be determined through judicial processes. Accordingly, application of exemption (j)(2) may be necessary.

(I) *Subsection (e)(8).* To serve notice could give persons sufficient warning to evade investigative efforts. Accordingly, application of exemption (j)(2) may be necessary.

(J) *Subsection (f).* To the extent that portions of the system are exempt from the provisions of the Privacy Act concerning individual access and amendment of records, DoD is not required to establish rules concerning procedures and requirements relating to such provisions. Accordingly, application of exemptions (j)(2), (k)(1), (k)(2), (k)(5), (k)(6), and (k)(7) may be necessary.

(K) *Subsection (g).* Subsection (g) is inapplicable to the extent that the system is exempt from other specific subsections of the Privacy Act to which the civil remedies provisions pertain.

(iv) *Exempt records from other systems.* In the course of carrying out the overall purpose for this system, exempt records from other systems of

records may in turn become part of the records maintained in this system. To the extent that copies of exempt records from those other systems of records are maintained in this system, the DoD claims the same exemptions for the records from those other systems that are entered into this system, as claimed for the prior system(s) of which they are a part, provided the reason for the exemption remains valid and necessary.

Dated: December 16, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 251

RIN 0596–AD44

Land Uses; Special Uses; Annual Programmatic Administrative Fee for Communications Use Authorizations

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Proposed rule.

SUMMARY: The Forest Service (Agency), U.S. Department of Agriculture, is proposing to amend its existing regulations to charge a statutorily required annual programmatic administrative fee for new and existing communications use authorizations to cover the costs of administering the Agency's communications use program. Existing communications use authorizations would be amended to provide for payment of the required annual programmatic administrative fee.

DATES: Comments must be received in writing by February 22, 2022.

ADDRESSES: Comments, identified by RIN 0596–AD44, may be submitted via one of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for sending comments.

2. *Mail:* Director, Lands & Realty Management Staff, 201 14th Street SW, Washington, DC 20250–1124.

3. *Hand Delivery:* Director, Lands & Realty Management Staff, 1st Floor South East, 201 14th Street SW, Washington, DC 20250–1124.

All timely comments, including names and addresses when provided, will be placed in the record and will be available for public inspection and copying. The public may review comments at Office of the Director, Lands & Realty Management, 1st Floor Southeast, Sidney R. Yates Federal Building, 201 14th Street SW, Washington, DC, during normal business hours. Visitors are encouraged to call ahead at 202–205–3563 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Joey Perry, Lands & Realty Management Staff, 530–251–3286, *joey.perry@usda.gov.* Individuals who use telecommunication devices for the deaf/hard-of-hearing (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 between 8:00 a.m. and 5:00 p.m., 24 hours per day, every day of the week, including holidays.

SUPPLEMENTARY INFORMATION:

Background

The Agency is responsible for managing Federal lands that are adjacent to rural and urban areas. These rural and urban communities depend on Federal lands for critical communications services, including emergency services, internet service, cellular communications, and television and radio broadcasting services. The Agency authorizes the use and occupancy of National Forest System (NFS) lands for communications facilities (buildings, towers, and ancillary improvements and fiber optic cable) that provide these critical communications services. The Agency administers over 3,700 special use authorizations for infrastructure that supports over 10,000 wireless communications uses at 1,367 communications sites and administers over 400 special use authorizations for fiber optic cable communications uses on NFS lands.

The U.S. Department of Agriculture's Rural Prosperity Task Force Report of 2017 identified connecting rural communities across the United States as a strategic priority for USDA because ''[i]n today's information-driven global economy, e-connectivity is not simply an amenity—it has become essential.''

Executive Order 13821, *Streamlining and Expediting Requests to Locate Broadband Facilities in Rural America,* issued January 8, 2018, states that ''Americans need access to reliable, affordable broadband internet service to succeed in today's information-driven, global economy'' (83 FR 1507). Executive Order 13821 directs Federal agencies ''to use all viable tools to accelerate the deployment and adoption of affordable, reliable, modern high-speed broadband connectivity to rural America. . . .'' *Id.* Agencies are encouraged to reduce barriers to capital investments, remove obstacles to broadband services, and more efficiently employ Government resources. *Id.*

On June 12, 2020, a Secretarial Memorandum was issued to the Chief of the Forest Service, which directs the Agency to focus resources on activities that support the productive use of NFS lands to deliver goods and services efficiently and effectively to meet the needs of the public. The Agency was specifically directed to expedite broadband development on NFS lands to increase connectivity in rural America.

Need for the Proposed Rule

Regardless of where they live, consumers require reliable communications services. The need for wireless connectivity for teleworking, tele-education, telehealth, and telemedicine is even more vital considering events like the COVID–19 pandemic. To meet the demand for these critical services, the Agency must be prepared to do its part by ensuring it has the necessary staff and expertise to administer its communications use program.

In addition to being statutorily mandated as outlined below, the annual programmatic administrative fee would provide the funds necessary to support a more modernized, efficient, and enhanced communications use program. Programmatic administrative fee revenues would be used to reduce the backlog of expired communications use authorizations; streamline implementation by fully staffing the program; enhance automated applications; improve internal and external outreach, including training for employees; fund the national billing team; conduct national oversight; and obtain or improve access to communications sites.

The Agriculture Improvement Act of 2018 (the 2018 Farm Bill) was signed into law on December 20, 2018. Title VIII, Subtitle G, section 8705, of the 2018 Farm Bill, as amended by Division D, Title IV, section 416, of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), codified as 43 U.S.C. 1761a, requires the Agency to charge an annual programmatic administrative fee for communications use authorizations to cover the costs of the Agency's communications use program. Specifically, section 8705(c)(3)(B) directs the Agency to issue regulations that require a structure of fees for issuing communications use authorizations based on the cost to the Agency for any maintenance or other activities required to be performed by the Agency as a result of the location or modification of a communications

facility. Section 8705 of the 2018 Farm Bill, as amended, also authorizes the Agency to retain and spend annual programmatic administrative fee revenues to cover the costs of the Agency's communications use program. The proposed rule would implement the statutory requirement to charge an annual programmatic administrative fee for communications use authorizations to cover the costs of administering the Agency's communications use program.

Current Forest Service regulations at 36 CFR part 251, subpart B, govern the processing of special use applications and issuance of special use authorizations for uses of NFS lands, including communications uses. Forest Service Handbook (FSH) 2709.11, Chapter 90, provides direction for communications use management, including processing of communications use applications and administration of communications use authorizations. The following is a description of the proposed regulatory and directive revisions needed to comply with section 8705 of the 2018 Farm Bill.

Proposed Revisions to Existing Regulations

Section 251.54(g)(5) of the Agency's current regulations sets forth the Agency's procedures for authorization of a special use. The Agency proposes to implement section 8705(c)(3)(B) of the 2018 Farm Bill by adding a new subparagraph to § 251.54(g)(5), which governs the issuance of special use authorizations. Consistent with section 8705(c)(3)(B), new paragraph (g)(5)(iii) would require that an annual programmatic administrative fee be charged for communications use authorizations to cover the costs of administering the Agency's communications use program.

Section 8705(f)(4) of the 2018 Farm Bill provides that programmatic administrative fee revenues are to be used to cover any costs incurred by the Agency in administering its communications use program, including but not limited to the costs of on-site reviews of communications sites, developing communications site management plans, hiring and training personnel for the communications use program, conducting internal and external outreach for and national oversight of the communications use program, and obtaining or improving access to communications sites on NFS lands. This annual programmatic administrative fee would be in addition to land use fees assessed based on the fair market value of the rights and privileges granted by each communications use authorization, as provided for in existing regulations at 36 CFR 251.57. The Agency does not have authority to retain and spend the land use fees it collects for communications uses, which must be deposited into the United States Treasury. In addition, the Agency charges fees to recover the Agency's costs for processing communications use applications and monitoring compliance with communications use authorizations, as provided for in existing regulations at 36 CFR 251.58. Cost recovery fees are charged to specific applicants for and holders of a communications use authorization to cover costs associated with processing their application and monitoring compliance with their communications use authorization. Neither of these existing fees covers the programmatic costs of administering the communications use program.

To meet the requirements of section 8705 of the 2018 Farm Bill, the Agency proposes to charge an annual programmatic administrative fee of $1,400 per communications use authorization for wireless uses such as television and radio broadcasting, cellular telephone, and microwave and $400 per communications use authorization for fiber optic cable. The annual programmatic administrative fee for authorizations for fiber optic cable would be lower because authorizations for this type of use have lower programmatic administrative costs, as explained below. These two programmatic administrative fees reflect the Agency's total estimated annual costs of administering its communications use program, allocated as deemed applicable by the Agency between communications use authorizations for wireless uses and communications use authorizations for fiber optic cable, and prorated to split the cost evenly among the authorizations of each type. This allocation and proration would provide for programmatic administrative fees for communications use authorizations that are equitable to the extent possible within the constraints of the 2018 Farm Bill, which requires the Forest Service to recover the programmatic administrative costs for its communications use program. The Agency will include in the rulemaking record documentation of the estimated costs upon which the $1,400 and $400 annual programmatic administrative fees are based. The two annual programmatic administrative fees would be updated annually based on the difference in the U.S. Department of Labor Consumer Price Index for All Urban Consumers, U.S. City Average (CPI–U), from July of one year to July of the following year, rounded up or down to the nearest dollar. The Agency would review the two annual programmatic administrative fees no later than 5 years after the effective date of the final rule and at least every 5 years thereafter and would revise the fees as needed to ensure they continue to reflect the Agency's total estimated annual costs of administering its communications use program.

In the last decade there has been a significant increase in the volume, complexity, and types of communications uses in the United States, including on NFS lands. Additional Agency personnel, improved efficiencies, and current technology are critical for meeting this increased demand for communications uses on NFS lands, as well as the Administration's goal of enhancing access to high-speed broadband on Federal lands. Per direction in the 2018 Farm Bill, the Agency would use the annual programmatic administrative fee revenues to cover the costs of administering its communications use program, including but not limited to the costs of on-site reviews of communications sites, preparation of communications site management plans, and program oversight and management. This includes reducing the backlog of expired communications use authorizations, streamlining program implementation, enhancing automated applications, hiring and training personnel for the communications use program, conducting internal and external outreach and enhanced training for employees, and obtaining or improving access to communications sites on NFS lands.

Estimated costs for administering the Agency's communications use program are $5.4 million per year, equivalent to the total programmatic administrative fee revenues that would be collected using the proposed fee structure from existing communications use authorization holders as of 2019. The revenues would cover the personnel and other resource costs needed to administer a more modernized, efficient, and enhanced communications use program, thereby enhancing deployment of wireless and wired communications services.

TABLE 1—ESTIMATED COST BREAKDOWN

Task	Wireless (3,715)	Fiber (444)	Totals	Rates	Remarks
On-site Reviews	$2,799,215.35	$0.00	$2,799,215.35	$753.49	3,715 (wireless).
Communications Site Management Plans	435,984.69	0.00	435,984.69	117.36	3,715 (wireless).
Program Oversight and Management					
• Salary, benefits, and overhead costs	1,542,616.60	184,366.56	1,726,983.16	415.24	4,159 (wireless & fiber optic cable).
• Staff training	108,960.95	13,022.52	121,983.47	29.33	4,159 (wireless & fiber optic cable).
• Access	300,000000	0.00	300,000.00	80.75	3,715 (wireless).
Total	5,186,777.59	197,389.08	5,384,166.67		
Total Share for Wireless Authorizations ($5,186,777.59/3715)	1,396.17	1,400 rounded			
Total Share for Fiber Optic Cable Authorizations ($197,389.08/444).	444.57	400 rounded			

To determine the two annual programmatic administrative fees, the Agency first estimated the total annual programmatic administrative costs for its communications use program, including the costs of on-site reviews of authorized communications sites, preparation of communications site management plans, hiring and training personnel for the communications use program, land use fee billing and collection, and obtaining or improving access to communications sites. Those costs were then allocated between communications use authorizations for wireless uses and communications use authorizations for fiber optic cable. The total costs for each authorization type was then prorated to divide the total equally among all communications use authorizations of each type: 3,715 wireless authorizations and 444 fiber optic authorizations. As shown in Table 1 above and explained in further detail below, fiber optic cable authorizations are not allocated the costs of on-site reviews of communications sites, preparation of communications site management plans, or obtaining or improving access to communications sites because those costs are not incurred in connection with those authorizations. All other annual programmatic administrative costs were allocated to communications use authorizations for wireless uses and fiber optic cable.

On-Site Reviews

Annual costs of on-site reviews of communications sites were allocated only to communications use authorizations for wireless uses. This is because wireless use authorizations involve installation, operation, and maintenance of above-ground communications facilities such as towers, which require annual on-site reviews. However, fiber optic cable authorizations typically do not require on-site reviews because fiber optic cable is buried or co-located on other infrastructure, such as a utility line.

The total annual estimated cost of on-site reviews of communications sites on NFS lands is approximately $2,800,000. The estimate of $2,800,000 is based on the cost to conduct an annual on-site review of each of the 1,367 communications sites on NFS lands, including:

- Reviewing any pertinent information related to communications sites and authorized uses;
- Notifying and coordinating with communications use authorization holders regarding on-site reviews;
- Traveling to and from communications sites;
- Conducting on-site reviews, including gathering data for development and implementation of the communications site management plans governing all communications uses at each site and ensuring that technical and administrative requirements for management of each site are being met to provide for compatibility of communications uses;
- Documenting and approving maintenance activities;
- Preparing a report and any follow-up correspondence; and
- Entering data into the Special Uses Data System and conducting any needed follow-up.

On average, this work is conducted by a General Schedule (GS)-11, step 1, employee at a daily rate of $326. The daily rate was based on the yearly salary in 2019 for a GS–11, step 1, employee of $62,236, plus estimated employee benefits (*e.g.,* health insurance and retirement benefits) of $22,764, or $85,000 per year. The daily rate was calculated by dividing the yearly salary and benefits of $85,000 by 2,087 hours per year (the divisor used by the Office of Personnel Management to compute federal employees' cost-to-government hourly rate) and multiplying the quotient of $40.73 per hour by 8 hours, a typical workday, which equals $325.84, or $326 rounded to the nearest dollar. On-site reviews of authorized communications uses take approximately 2.125 days to complete, or $692.75 for employee salary, plus $60.74 for vehicle expenses (2 days of vehicle use at $11.87 per day and an estimated 100 miles driven at $0.37 per mile), for a total estimated cost of $753.49 annually per authorization. The total annual estimated cost of $2,800,000 for on-site reviews of communications sites was determined by multiplying the annual estimated cost of $753.49 per authorization by 3,715, the total number of communications use authorizations for wireless uses, rounded.

Communications Site Management Plans

Similar to the cost of on-site reviews, annual costs of development, approval, and maintenance of communications site management plans were also allocated only to communications use authorizations for wireless uses. Wireless use authorizations are subject to a communications site management plan to facilitate orderly development of communications sites, ensure authorized uses are compatible, and provide for a safe and high-quality communications environment. Fiber optic cable authorizations do not need a communications site management plan because fiber optic cable is buried or co-located on other infrastructure and cannot cause interference concerns.

For development, approval, and maintenance of communications site management plans, the Agency estimated a total annual programmatic administrative cost of $436,000. This estimate was based on the cost of completing or updating 137 communications site management plans per year, given that there are 1,367 communications sites on NFS lands and standard Agency practice requires communications site management plans to be updated every 10 years to keep

pace with changes in technology and industry protocols. The preparation work, coordination of the site visit, and approval of the communications site management plan takes approximately 2 days for a local employee to complete, at an estimated cost of $652 for employee salary and benefits (a GS–11, step 1, employee at a daily rate of $326, see calculations above), travel costs of $2,500 (using standard per diem rates and typical travel costs) for a national or regional communications site specialist to visit the site and complete the work, and $30.37 for vehicle expenses (1 day of vehicle use at $11.87 per day and an estimated 50 miles driven at $0.37 per mile). The salary costs for the national or regional communications site specialist that visits the site were included under the program oversight and management costs described below, so they are not included in the estimate of total costs for communications site management plans. The total annual estimated cost of $436,000 for development, approval, and maintenance of communications site management plans was determined by multiplying the annual estimated cost of $3,182.37 per site by 137, the total number of communications site management plans that would be completed or updated each year, rounded.

Program Oversight and Management

The Agency estimated a total annual programmatic administrative cost of approximately $2,149,000 for program oversight and management of the Agency's communications use program, including a trained and dedicated staff of 14 employees; overhead for travel, staff training, office space, supplies, and information technology development and support; biannual employee training; and the cost of obtaining or improving access to communications sites on NFS lands. Specifically, the total estimated annual cost of program oversight and management was based on the following:

- *Salary, benefits, and overhead costs:* Costs for general program administration, salary, and overhead costs of approximately $1,727,000 for the 14 employees needed to manage the program, ranging from a GS–9 to a GS–14 employee.
- *Staff training:* Costs of approximately $122,000 for 2 yearly employee trainings for communications use management. Each 1-week training session includes the cost of training materials, the venue, and incidental costs for 23 employees (20 students, who are employees who administer the communications use program at the field level, and 3 instructors).
- *Access:* Costs of approximately $300,000 for obtaining or improving access to communications sites (fiber optic cable authorizations are exempt from this cost because they do not require additional access).

Of the above listed costs, the total estimated allocations for the 3,715 communications use authorizations for wireless uses are as follows: $2,799,215 for annual on-site reviews of communications sites, $435,985 for development, approval, and maintenance of communications site management plans, $1,542,617 for general program administration (prorated to 3,715 of the total 4,159 authorizations this cost applies to), $108,961 for training (prorated to 3,715 of the total 4,159 authorizations this cost applies to), and $300,000 for obtaining or improving access to communications sites. This results in a wireless use authorization cost total of approximately $5,186,777. Divided by 3,715 authorizations for wireless uses, the annual programmatic administrative fee for wireless use authorization is set at $1,400 ($1,396.17 rounded to the nearest hundred dollars).

For the 444 communications use authorizations for fiber optic cable, the total estimated annual programmatic administrative costs include $184,367 for general program administration (prorated to 444 of the total 4,159 authorizations), and $13,023 for training (prorated to 444 of the total 4,159 authorizations), resulting in a total of $197,390. The annual programmatic administrative fee for those authorizations is calculated by dividing $197,390 by 444 authorizations for fiber optic cable, which equals $444.57, or $400 rounded to the nearest hundred dollars.

Section 8705(f) of the 2018 Farm Bill authorizes the Agency to retain and spend the annual programmatic administrative fee revenues that would be collected under the proposed rule to cover the costs of administering the Agency's communications use program. The total fees proposed here would collect $5,186,777 for wireless use authorizations and $197,390 for fiber optic cable use authorizations, a total of $5,384,167 to be collected and retained by the Forest Service for administering the communications use program.

Proposed Revisions to Agency Directives

FSH 2709.11, Chapter 90

The Agency is proposing to revise its directives in FSH 2709.11, Chapter 90, concurrently with this rulemaking. Consistent with section 8705(c)(3) of the 2018 Farm Bill and the proposed revisions to the Agency's regulations, the proposed directive would amend Chapter 90 to implement an annual $1,400 programmatic administrative fee for communications use authorizations for wireless uses and an annual $400 programmatic administrative for communications use authorizations for fiber optic cable and provide for updating the two annual programmatic administrative fees every 5 years. The proposed directive would also amend Chapter 90 to establish direction on expenditure of annual programmatic administrative fee revenues.

Upon adoption of a final rule, a separate notice will be published in the **Federal Register** announcing the availability of the proposed directive, including information on how to comment on the directive and a link to the proposed directive, which will be posted on the Agency's website.

Regulatory Certifications

Executive Order 12866

For rules designated as significant by the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget, Executive Order (E.O.) 12866, as supplemented by E.O. 13563, directs agencies to conduct a regulatory impact analysis, including an assessment of costs and benefits of available regulatory alternatives and regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and distributive impacts). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The regulatory impact analysis must assess both the costs and benefits of the regulation, recognizing quantifiable analysis is not always possible, but that a reasoned determination be made that the benefits justify the regulatory costs.

The Agency conducted a regulatory impact analysis for the proposed amendments to 36 CFR part 251, subpart B, and FSH 2709.11, Chapter 90, to charge an annual programmatic administrative fee for new and existing communications use authorizations to cover the costs of administering a more modernized, efficient, and enhanced Agency communications use program. The regulatory impact analysis compares the costs to administer the communications use program under the existing regulations with the costs to administer the more modernized, efficient, and enhanced

communications use program under the proposed rule. Administrative costs of the program under the existing regulations are covered by federal budget allocations; under the proposed rule, administrative costs of the program would be covered by revenues from the annual programmatic administrative fee for communications use authorizations (*i.e.,* payment for the annual cost of administering the program would be transferred from the Federal government to communications use authorization holders). Benefits, including programmatic modernization, efficiencies, and enhancements, are addressed qualitatively.

As of 2019, a total of 4,159 (wireless and fiber optic cable) communications use authorizations were held by 1,448 unique entities, including 765 businesses, 384 governments or agencies, 266 organizations, and 33 individuals or households. Of the 4,159 communications use authorizations, 3,715 were for wireless communication uses, and 444 were for fiber optic cable. Based on an annual programmatic administrative fee of $1,400 per communications use authorization for wireless uses and $400 per communications use authorization for fiber optic cable, the Agency would collect a total of approximately $5.4 million annually from communications use authorization holders. The revenue generated from the annual programmatic administrative fee would cover the annual costs of administering the Agency's communications use program. Based on the costs of a more modernized, efficient, and enhanced program, annual programmatic administrative costs under the proposed rule are estimated to be $1.8 million greater than annual programmatic administrative costs under the current regulations. Assuming annual incremental costs of $1.8 million are constant over a period of 15 years, the present value of these costs is estimated at $18 million using a 7% discount rate and $22 million using a 3% discount rate. Providing present value costs using these assumptions is consistent with Office of Management and Budget Circular A–4 implementing E.O. 12866 when there is uncertainty about discount periods.

The annual programmatic administrative fee would provide the funds necessary to support a more modernized, efficient, and enhanced communications use program. Programmatic administrative fee revenues would be used to reduce the backlog of expired communications use authorizations; streamline implementation by fully staffing the program; enhance automated applications; improve internal and external outreach, including training for employees; fund the national billing team; conduct national oversight; and obtain or improve access to communications sites. The benefits from a more modernized, efficient, and enhanced communications use program funded by the annual programmatic administrative fee for communications use authorizations are expected to exceed the incremental annual programmatic administrative costs of $1.8 million per year.

The benefits that would be achieved under the proposed rule are consistent with the objectives E.O. 13821, *Streamlining and Expediting Requests to Locate Broadband Facilities in Rural America* (2018), which encourages Federal agencies to reduce barriers to capital investments, remove obstacles to broadband services, and more efficiently employ Federal resources. The benefits from implementation of the proposed rule would also be consistent with the goals of the 2020 Secretarial Memorandum to the Chief of the Forest Service, which directs the Agency to expedite broadband development on NFS lands to increase connectivity in rural America. The proposed rule is also required by section 8705 of the 2018 Farm Bill, which directs the Agency to charge an annual programmatic administrative fee for communications use authorizations to cover the Agency's costs to administer its communications use program. Section 8705 of the 2018 Farm Bill, as amended, authorizes the Agency to retain and spend programmatic administrative fee revenues.

Costs associated with potential loss of other resources or environmental goods and services foregone by the presence of communications uses on NFS lands (opportunity costs) are assumed to be no different and could be lower under the proposed rule compared to baseline administrative conditions. Requirements to identify and mitigate environmental impacts from communications uses through National Environmental Policy Act compliance and Agency land management planning would remain unchanged under the proposed rule. More modernized, efficient, and enhanced program administration supported by the annual programmatic administrative fee charged under the proposed rule would provide greater opportunities to ensure environmental and resource protection.

Average annual programmatic administrative fees incurred by communications use authorization holders are projected to range from $3,400 to $4,800 per entity, given that a single entity often has more than one authorization. There is potential for existing or future customers to alter their decisions about obtaining a communications use authorization in response to the cost of the annual programmatic administrative fee or anticipated benefits (*e.g.,* time-valued revenue gains). However, the effect of these disincentives and incentives on decision making is likely to be small or hard to measure in comparison to the magnitude of other operating costs or expenditures, annual revenues, or other market factors affecting management and investment decisions. In many cases, a decision to pursue a communications use authorization is also driven by the comparative operating advantages of locating communications uses or facilities on NFS lands versus locating them on non-NFS lands. The proposed rule is therefore not expected to trigger significant changes in the number of communications use authorizations or the output of communications services under those authorizations. Economic or distributional impacts (*i.e.,* changes in jobs and labor income) of communications use authorizations are likewise not expected to be significant.

Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act) (5 U.S.C. 801 *et seq.*), OIRA has designated this proposed rule as not a major rule as defined by 5 U.S.C. 804(2).

National Environmental Policy Act

The proposed rule would establish procedures for charging an annual programmatic administrative fee for communications use authorizations to cover the costs of administering the Agency's communications use program. Agency regulations at 36 CFR 220.6(d)(2) (73 FR 43093) exclude from documentation in an environmental assessment (EA) or environmental impact statement (EIS) ''rules, regulations, or policies to establish Service-wide administrative procedures, program processes, or instructions.'' The Agency has concluded that the proposed rule falls within this category of actions and that no extraordinary circumstances exist which would require preparation of an EA or EIS.

Regulatory Flexibility Act Analysis

Consistent with the Regulatory Flexibility Act (RFA), 5 U.S.C. 602 *et seq.,* as amended by the Small Business Regulatory Flexibility Enforcement

Fairness Act of 1996, and E.O. 13272, the Agency conducted a threshold regulatory flexibility analysis to determine whether the proposed rule would have a significant economic impact on a substantial number of small entities. If the threshold regulatory flexibility analysis supports a determination that the proposed rule would not have a significant economic impact on a substantial number of small entities, a regulatory flexibility analysis is not needed.

Pursuant to the threshold regulatory flexibility analysis, the Agency has determined that the proposed rule would impact 1,448 unique entities that hold a communications use authorization. Of those 1,448 unique entities, 1,080 qualify as small entities, including 645 small businesses, 187 small governmental entities, and 248 small organizations.

The threshold RFA analysis results suggest that the economic impact from the proposed rule would be less than 1% of annual salaries and wages for most (180 of 187) small governments that currently hold a communications use authorization. Of the seven small governments with an estimated economic impact greater than 1%, only 3 small governments are projected to experience an economic impact of approximately 9% to 14% of annual salaries and wages, but they account for less than 1% of the estimated population of small local governmental units (cities and towns) within the economic impact areas of National Forests.

The threshold RFA analysis results show that the economic impact from the proposed rule would be less than 0.5% of annual expenses for 74 or 30% of the 248 small organizations known to have communications use authorizations. The economic impact would range from approximately 1% to 2% of annual expenses for 138 or 56% of small organizations and approximately 2% to 5% of annual expenses for 33 or 13% of small organizations. The remaining 3 or 1% of small organizations are projected to experience an economic impact of approximately 5% to 11% of annual expenses from the proposed rule. There may be unknown small organizations that would be subject to the proposed rule, but the relatively low number of known small organizations projected to experience an economic impact of approximately 2% to 5% of annual expenses and the few organizations (estimated at 3) projected to experience an economic impact of approximately 5% to 11% of annual expenses suggest that the proposed rule would not have a significant economic impact on a substantial number of small organizations.

The threshold RFA analysis results suggest that the average annual programmatic administrative fees under the proposed rule (*i.e.,* its economic impact) would be 1% or less of annual receipts for 536 (83%) of the 645 small businesses that have existing communications use authorizations. The 536 include all small businesses with annual receipts of $100,000 to $500,000 (except for 7 small businesses in the Wireless Telecommunications industry), as well as small businesses with annual receipts greater than $500,000.

Economic impacts are estimated to be 4% to 5% of annual receipts for the remaining 109 small businesses distributed across 65 industries and earning annual receipts of less than $100,000 (representing the smallest receipt category). For most industries, only 1 to 5 small businesses per industry are projected to experience economic impacts of 4% to 5% of annual receipts. The 1 to 5 small businesses account for 8% to 17% of small businesses with communications use authorizations within each industry and less than 0.1% to 8% of the U.S. population of small businesses with annual receipts of less than $100,000 within each industry. For two industries, Telecommunications Resellers (NAICS 517911) and Other Telecommunications (NAICS 517919), 20 and 19 small businesses, respectively, are estimated to experience impacts of 5%, accounting for 13% and 24%, respectively, of small businesses with communications use authorizations in these two industries and 4% and 8% of the U.S. small business population with annual receipts of less than $100,000 in these two industries.

The programmatic efficiencies from a more modernized, efficient, and enhanced communications use program funded by the annual programmatic administrative fee would benefit small entity communications use authorization holders.

For the foregoing reasons, the proposed rule would not have a significant economic impact on a substantial number of small entities, and small entities are expected to benefit indirectly from programmatic changes made possible by the programmatic administrative fees under the proposed rule. Therefore, an RFA analysis is not required for the proposed rule.

Federalism

The Agency has considered the proposed rule under the requirements of E.O. 13132, *Federalism.* The Agency has determined that the proposed rule conforms with the federalism principles set out in this E.O.; would not impose any compliance costs on the states; and would not have substantial direct effects on the states, on the relationship between the Federal government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, the Agency has concluded that the proposed rule does not have federalism implications.

Consultation and Coordination With Indian Tribal Governments

The Agency has reviewed this proposed rule in accordance with the requirements of E.O. 13175, *Consultation and Coordination with Indian Tribal Governments.* The Agency has determined that national tribal consultation is not necessary for the proposed rule. The proposed rule, which would implement the statutory requirement to charge an annual programmatic administrative fee for communications use authorizations to cover the Agency's costs of administering its communications use program, is programmatic and would not have any direct effects on tribes. Tribal consultation will occur as appropriate in connection with specific applications for communications facilities on NFS lands.

Environmental Justice

The Agency has considered the proposed rule under the requirements of E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations. The Agency has determined that the proposed rule is consistent with E.O. 12898.

No Takings Implications

The Agency has analyzed the proposed rule in accordance with the principles and criteria in E.O. 12630, *Governmental Actions and Interference with Constitutionally Protect Property Rights.* The Agency has determined that the proposed rule would not pose the risk of a taking of private property.

Energy Effects

The Agency has reviewed the proposed rule under E.O. 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.* The Agency has determined that the proposed rule would not constitute a significant

energy action as defined in E.O. 13211, and OIRA has not otherwise designated the proposed rule as a significant energy action.

Civil Justice Reform

The Agency has analyzed the proposed rule in accordance with the principles and criteria in E.O. 12988, *Civil Justice Reform.* After adoption of the proposed rule, (1) all state and local laws and regulations that conflict with the proposed rule or that impede its full implementation would be preempted; (2) no retroactive effect would be given to the proposed rule; and (3) it would not require administrative proceedings before parties may file suit in court challenging its provisions.

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), signed into law on March 22, 1995, the Agency has assessed the effects of the proposed rule on state, local, and tribal governments and the private sector. The proposed rule would not compel the expenditure of $100 million or more by any state, local, or tribal government or anyone in the private sector. Therefore, a statement under section 202 of the Act is not required.

Controlling Paperwork Burdens on the Public

The proposed rule does not contain information collection requirements as defined in 5 CFR part 1320 that are not already required by law or not already approved for use. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320 do not apply.

List of Subjects in 36 CFR Part 251

Electric power, Mineral resources, National forests, Rights-of-way, and Water resources.

Therefore, for the reasons set forth in the preamble, the Agency proposes to amend part 251, subpart B, of title 36 of the Code of Federal Regulations as follows:

PART 251—LAND USES

Subpart B—Special Uses

■ 1. The authority citation for part 251 continues to read:

Authority: 16 U.S.C. 460*l*–6a, 460*l*–6d, 472, 497b, 497c, 551, 580d, 1134, 3210; 30 U.S.C. 185; 43 U.S.C. 1740, 1761–1772.

■ 2. Amend § 251.54 by adding paragraph (g)(5)(iii) to read as follows:

§ 251.54 Proposal and application requirements and procedures.

* * * * *

(g) * * *

(5) * * *

(iii) *Annual programmatic administrative fee for communications use authorizations.* An annual programmatic administrative fee shall be assessed for each new and existing communications use authorization as of [Effective date of final rule] based on the total annual estimated costs to the Forest Service of administering its communications use program, allocated as deemed applicable by the Forest Service between communications use authorizations for wireless uses and communications use authorizations for fiber optic cable and prorated as deemed applicable by the Forest Service among all holders of those authorizations. The Forest Service shall maintain a schedule in its directive system (36 CFR 200.4) of the annual programmatic administrative fee for communications use authorizations for wireless uses and the annual programmatic administrative fee for communications use authorizations for fiber optic cable. These two annual programmatic administrative fees shall be updated annually based on the difference in the U.S. Department of Labor Consumer Price Index for All Urban Consumers, U.S. City Average (CPI–U), from July of one year to July of the following year, rounded up or down to the nearest dollar. The Forest Service shall also enumerate in its directive system the annual programmatic administrative costs for which the two fees are charged. Within 5 years of [Effective date of final rule], and at least every 5 years thereafter, the Forest Service shall review the amount of and bases for the two annual programmatic administrative fees and shall revise them as needed to ensure they continue to reflect the Forest Service's total annual estimated costs of administering its communications use program.

Dated: December 16, 2021.

Meryl Harrell,

Deputy Under Secretary, Natural Resources and Environment.

[FR Doc. 2021–27681 Filed 12–21–21; 8:45 am]

BILLING CODE 3411–15–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 9

[PS Docket Nos. 20–291 and 09–14; Report No. 3184; FR ID 63299]

Petitions for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for Reconsideration.

SUMMARY: Petitions for Reconsideration (Petitions) have been filed in the Commission's rulemaking proceeding by Joseph P. Benkert on behalf of the Boulder Emergency Telephone Service Authority (BRETSA), and by Scott Newman on behalf of the City of Aurora 911 Authority, et al.

DATES: Oppositions to the Petitions must be filed on or before January 6, 2022. Replies to an opposition must be filed on or before January 18, 2022.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Brenda Boykin, Policy and Licensing Division, Public Safety and Homeland Security Bureau, at (202) 418–2062 or *Brenda.Boykin@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, Report No. 3184, released December 15, 2021. The full text of the Petitions may be accessed online via the Commission's Electronic Comment Filing System at: *https://www.fcc.gov/ecfs/*. The Commission will not send a Congressional Review Act (CRA) submission to Congress or the Government Accountability Office pursuant to the CRA, 5 U.S.C. 801(a)(1)(A), because no rules are being adopted by the Commission.

Subject: 911 Fee Diversion; New and Emerging Technologies 911 Improvement Act of 2008, Report and Order, FCC 21–80, published at 86 FR 45892, August 17, 2021, in PS Docket Nos. 20–291 and 09–14. This document is being published pursuant to 47 CFR 1.429(e). *See also* 47 CFR 1.4(b)(1) and 1.429(f), (g).

Number of Petitions Filed: 2.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

[FR Doc. 2021–27721 Filed 12–21–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 20

[GN Docket No. 13–111; Report No. 3183; FR ID 62697]

Petition for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for Reconsideration.

SUMMARY: Petition for Reconsideration (Petition) has been filed in the Commission's rulemaking proceeding by Thomas C. Power, on behalf of CTIA.

DATES: Oppositions to the Petition must be filed on or before January 6, 2022. Replies to oppositions must be filed on or before January 18, 2022.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Halie Peacher, Attorney-Advisor, Mobility Division, Wireless Telecommunications Bureau, (202) 418–0514 or via email at *halie.peacher@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, Report No. 3183, released December 13, 2021. The full text of the Petition can be accessed online via the Commission's Electronic Comment Filing System at: *http://apps.fcc.gov/ecfs/.* The Commission will not send a Congressional Review Act (CRA) submission to Congress or the Government Accountability Office pursuant to the CRA, 5 U.S.C. 801(a)(1)(A), because no rules are being adopted by the Commission.

Subject: In the Matter of Promoting Technological Solutions to Combat Contraband Wireless Device Use in Correctional Facilities, Second Report and Order, published at 86 FR 44635, August 13, 2021, in GN Docket No. 13–111. This document is being published pursuant to 47 CFR 1.429(e). *See also* 47 CFR 1.4(b)(1) and 1.429(f), (g).

Number of Petitions Filed: 1.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

[FR Doc. 2021–27727 Filed 12–21–21; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2021–0098; FF09E21000 FXES1111090FEDR 223]

RIN 1018–BF25

Endangered and Threatened Wildlife and Plants; Threatened Species Status With Section 4(d) Rule for Cactus Ferruginous Pygmy-Owl

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the cactus ferruginous pygmy-owl *(Glaucidium brasilianum cactorum),* a subspecies found in Mexico, southern Arizona, and southern Texas, as a threatened species under the Endangered Species Act of 1973, as amended (Act). This determination also serves as our 12-month finding on a petition to list the cactus ferruginous pygmy-owl. After a review of the best available scientific and commercial information, we find that listing the subspecies is warranted. Accordingly, we propose to list the cactus ferruginous pygmy-owl as a threatened species with a rule issued under section 4(d) of the Act (''4(d) rule''). If we finalize this rule as proposed, it would add this subspecies to the List of Endangered and Threatened Wildlife and extend the Act's protections to the subspecies. The finalization of this rule as proposed would include the issuance of a 4(d) rule. Designation of critical habitat was found to be prudent, but not determinable at this time. We also are notifying the public that we have scheduled an informational meeting followed by a public hearing on the proposed rule.

DATES: We will accept comments received or postmarked on or before February 22, 2022. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date.

Public informational meeting and public hearing: We will hold a public informational session from 4:00 p.m. to 5:30 p.m., Mountain Standard Time, followed by a public hearing from 6:00 p.m. to 7:30 p.m., Mountain Standard Time, on January 25, 2022.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter the docket number or RIN for this rulemaking (presented above in the document headings). For best results, do not copy and paste either number; instead, type the docket number or RIN into the Search box using hyphens. Then, click on the Search button. On the resulting page, in the panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment.''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R2–ES–2021–0098, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Public informational meetings and public hearings: The public informational meetings and the public hearings will be held virtually using the Zoom platform. See Public Hearing, below, for more information.

FOR FURTHER INFORMATION CONTACT: Jeff Humphrey, Field Supervisor, U.S. Fish and Wildlife Service, Arizona Ecological Services Field Office, 9828 N 31st Ave., Phoenix, AZ, 85051; telephone 602–242–0210. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, a species warrants listing if it meets the definition of an endangered species (in danger of extinction throughout all or a significant portion of its range) or a threatened species (likely to become endangered in the foreseeable future throughout all or a significant portion of its range). We have determined that the cactus ferruginous pygmy-owl meets the definition of a threatened species; therefore, we are proposing to list it as such. To the maximum extent prudent and determinable, we must designate critical habitat for any species that we determine to be an endangered or threatened species under the Act. Listing a species as an endangered or threatened species and designation of critical habitat can be completed only by issuing a rule.

What this document does. We propose to list the cactus ferruginous pygmy-owl as a threatened species under the Act with a rule issued under section 4(d) of the Act. As explained in this document, we find that the designation of critical habitat for the cactus ferruginous pygmy-owl is not determinable at this time.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

We have determined that threats to the cactus ferruginous pygmy-owl include: (1) Habitat loss and fragmentation from urbanization, invasive species, and agricultural or forest production; and (2) climate change (effects from future changes in climate) and climate conditions (effects from current and past climate), resulting in hotter, more arid conditions throughout much of the subspecies' geographic range. The proposed 4(d) rule would generally prohibit the same activities as prohibited for an endangered species but would allow exemptions for specific types of education and outreach activities already permitted under a Migratory Bird Treaty Act permit and habitat restoration and enhancement activities that improve habitat conditions for the cactus ferruginous pygmy-owl.

Section 4(a)(3) of the Act requires the Secretary of the Interior (Secretary) to designate critical habitat concurrent with listing to the maximum extent prudent and determinable. As explained later in this proposed rule, we find that the designation of critical habitat for the cactus ferruginous pygmy-owl is not determinable at this time.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties concerning this proposed rule.

We particularly seek comments concerning:

(1) The subspecies' biology, range, and population trends, including:

(a) Biological or ecological requirements of the subspecies, including habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the subspecies, its habitat, or both, and the effectiveness of such measures.

(2) Factors that may affect the continued existence of the subspecies, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors. We are also seeking information indicating where threats are disproportionately affecting the cactus ferruginous pygmy-owl within specific portions of its geographical range.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this subspecies and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, range, distribution, and population size of this subspecies, including the locations of any additional populations of this subspecies.

(5) Information on regulations that are necessary and advisable to provide for the conservation of the cactus ferruginous pygmy-owl and that the Service can consider in developing a 4(d) rule for the subspecies. In particular, we are seeking information concerning the extent to which we should include any of the section 9 prohibitions in the 4(d) rule or whether we should consider any additional exceptions from the prohibitions in the 4(d) rule. We encourage public and agency comments related to our consideration of using the State permitting process, if required, in the 4(d) rule as the basis of an exception to the prohibitions on take related to certain pygmy-owl survey and monitoring activities. We are also specifically seeking documentation of the effects and benefits of properly managed grazing on cactus ferruginous pygmy-owl habitat, as well as the threat of current and historical improper grazing in both the United States and Mexico.

(6) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including information to inform the following factors that the regulations identify as reasons why designation of critical habitat may be not prudent:

(a) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(b) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(c) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States; or

(d) No areas meet the definition of critical habitat.

(7) Specific information on:

(a) Demographic information for the cactus ferruginous pygmy-owl, including dispersal patterns, prey relationships, survival, reproduction, sources of mortality, updated occurrence records, and population trends;

(b) The amount and distribution of cactus ferruginous pygmy-owl habitat, including habitat connectivity, patch size, geographic range, and future climate change effects on the subspecies' habitat;

(c) Which areas, that were occupied at the time of listing and that contain the physical or biological features essential to the conservation of the subspecies, should be included in the designation and why;

(d) Any additional areas occurring within the range of the species, [*i.e.,* Yuma, Maricopa, Pinal, Pima, Santa Cruz, Cochise, Graham, Gila counties in Arizona and Kleberg, Kenedy, Willacy, Cameron, Hidalgo, Brooks, Jim Wells, Duval, Jim Hogg, Starr, Zapata, and Webb counties in Texas], that should be included in the designation because they (1) are occupied at the time of listing and contain the physical or biological features that are essential to the conservation of the species and may require special management considerations, or (2) are unoccupied at the time of listing and are essential for the conservation of the species;

(e) Special management considerations or protection that may be needed in critical habitat areas, including managing for the potential effects of climate change; and

(f) Which areas, not occupied at the time of listing, are essential for the

conservation of the subspecies. We particularly seek comments:

(i) Regarding whether occupied areas are adequate for the conservation of the subspecies; and

(ii) Providing specific information regarding whether or not unoccupied areas would, with reasonable certainty, contribute to the conservation of the subspecies and contain at least one physical or biological feature essential to the conservation of the species; and

(iii) Explaining whether or not unoccupied areas fall within the definition of ''habitat'' at 50 CFR 424.02 and why.

Please include sufficient information with your submission (such as scientific journal articles, research reports, survey results, maps, or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov.*

Because we will consider all comments and information we receive during the comment period, our final determinations may differ from this proposal. Based on any new information we receive (and any comments on that new information), we may conclude that the subspecies is endangered instead of threatened, or we may conclude that the subspecies does not warrant listing as either an endangered species or a threatened species. We may also conclude that the subspecies is not warranted for listing rangewide, but is warranted in one of the petitioned Distinct Population Segments (DPSs) (see Previous Federal Actions, below). In addition, we may change the parameters of the prohibitions or the exceptions to those prohibitions in the 4(d) rule if we conclude it is appropriate in light of comments and new information received. For example, we may expand the prohibitions to include prohibiting additional activities if we conclude that those additional activities are not compatible with conservation of the species. Conversely, we may establish additional exceptions to the prohibitions in the final rule if we conclude that the activities would facilitate or are compatible with the conservation and recovery of the species.

Public Hearing

We have scheduled a public informational meeting and public hearing on this proposed rule to list the cactus ferruginous pygmy-owl as a threatened species. We will hold the public informational meeting and public hearing on the date and at the times listed above under Public informational meeting and public hearing in **DATES**. We are holding the public informational meeting and public hearing via the Zoom online video platform and via teleconference so that participants can attend remotely. For security purposes, registration is required. To listen and view the meeting and hearing via Zoom, listen to the meeting and hearing by telephone, or provide oral public comments at the public hearing by Zoom or telephone, you must register. For information on how to register, or if you encounter problems joining Zoom the day of the meeting, visit *https://www.fws.gov/southwest/*. Registrants will receive the Zoom link and the telephone number for the public informational meeting and public hearing. If applicable, interested members of the public not familiar with the Zoom platform should view the Zoom video tutorials (*https://support.zoom.us/hc/en-us/articles/206618765-Zoom-video-tutorials*) prior to the public informational meeting and public hearing. The public hearing will provide interested parties an opportunity to present verbal testimony (formal, oral comments) regarding this proposed rule. The public informational meeting will be an opportunity for dialogue with the Service. The public hearing is a forum for accepting formal verbal testimony. In the event there is a large attendance, the time allotted for oral statements may be limited. Therefore, anyone wishing to make an oral statement at the public hearing for the record is encouraged to provide a prepared written copy of their statement to us through the Federal eRulemaking Portal, or U.S. mail (see **ADDRESSES**, above). There are no limits on the length of written comments submitted to us. Anyone wishing to make an oral statement at the public hearings must register before the hearing (*https://www.fws.gov/southwest/*). The use of a virtual public hearing is consistent with our regulations at 50 CFR 424.16(c)(3).

Reasonable Accommodation

The Service is committed to providing access to the public informational meeting and public hearing for all participants. Closed captioning will be available during the public informational meeting and public hearing. Further, a full audio and video recording and transcript of the public hearing will be posted online at *https://www.fws.gov/southwest/* after the hearing. Participants will also have access to live audio during the public informational meeting and public hearing via their telephone or computer speakers. Persons with disabilities requiring reasonable accommodations to participate in the meeting and/or hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** at least 5 business days prior to the date of the meeting and hearing to help ensure availability. An accessible version of the Service's public informational meeting presentation will also be posted online at *https://www.fws.gov/southwest/* prior to the meeting and hearing (see **DATES**, above). See *https://www.fws.gov/southwest/* for more information about reasonable accommodation.

Previous Federal Actions

A thorough summary of previous Federal actions related to the pygmy-owl can be found in the March 10, 1997, final rule (62 FR 10730) to list the cactus ferruginous pygmy-owl in Arizona as endangered; the April 14, 2006, final rule (71 FR 19452) removing the listing promulgated in the March 10, 1997, final rule; the June 2, 2008, 90-day finding (73 FR 31418); and the October 5, 2011, 12-month finding on a petition to list (76 FR 61856).

On March 20, 2007, we received a petition dated March 15, 2007, from the Center for Biological Diversity and Defenders of Wildlife (CBD, DOW; petitioners) requesting that we list the cactus ferruginous pygmy-owl (*Glaucidium brasilianum cactorum*) (pygmy-owl) as an endangered or

threatened species under the Act (CBD and DOW 2007, entire). The petitioners described three potentially listable entities of the pygmy-owl: (1) An Arizona DPS of the pygmy-owl; (2) a Sonoran Desert DPS of the pygmy-owl; and (3) the western subspecies of the pygmy-owl, which they identified as *Glaucidium ridgwayi cactorum.* On October 5, 2011, we published in the **Federal Register** (76 FR 61856) a 12-month finding on the petition to list the pygmy-owl as endangered or threatened. We found that *Glaucidium ridgwayi cactorum* was not a valid taxon and, therefore, not a listable entity under the Act. Additionally, using the currently accepted taxonomic classification of the pygmy-owl (*Glaucidium brasilianum cactorum*), we found that listing the pygmy-owl was not warranted throughout all or a significant portion of its range, including the petitioned and other potential DPS configurations.

In 2014, the Center for Biological Diversity and Defenders of Wildlife challenged our determination that listing the pygmy-owl was not warranted under the Act (*Ctr. For Biological Diversity* v. *Jewell,* 248 F. Supp. 3d 946). The challenge centered on whether we had correctly defined language in the Act authorizing listing of a species that is endangered or threatened in either ''all or a significant portion of its range'' (SPR). The plaintiffs challenged our final policy interpreting this SPR language (SPR Policy) and how it was applied in listing determinations. In its decision on March 28, 2017, the court reasoned that ''if a portion of a species' range is 'significant' only 'if its contribution to the viability of the species is so important that, without that portion, the species would be in danger of extinction,' and the species is endangered or threatened in that portion (as would be required for listing), then the species is necessarily endangered or threatened overall'' (248 F.Supp.3d at 959). The court thus found the SPR Policy invalid because it defined ''significant'' in such a way as to limit the SPR language to situations in which it is unnecessary. The court vacated and remanded the definition of ''significant'' in the SPR Policy. The not-warranted finding for the cactus ferruginous pygmy-owl relied on a draft of this SPR Policy, which was slightly different than the final policy. The draft SPR Policy interpretation defined a range portion as ''significant'' ''if its contribution to the viability of the species is so important that, without that portion, the species would be in danger of extinction [*i.e.,* endangered]'' (76 FR 76987, December 9, 2011; p. 77002). The court also found this interpretation of SPR impermissible by limiting the SPR language to situations in which it is unnecessary, and the court vacated our not-warranted finding for the pygmy-owl. On November 14, 2019, the parties to the lawsuit agreed that the Service would submit a 12-month finding to the **Federal Register** no later than August 5, 2021. On July 6, 2021, the court granted an extension to allow additional time to review new data provided by the Arizona Game and Fish Department. The new deadline requires that the Service submit the 12-month finding to the **Federal Register** no later than December 16, 2021. This document complies with the court's deadline.

Distinct Population Segment Analysis

Regarding the petitioned DPSs in Arizona and the Sonoran Desert included in the 2007 petition, we reaffirm our October 5, 2011, 12-month finding (76 FR 61856). Specifically, we considered a DPS for the Sonoran Desert population of the pygmy-owl and concluded that this population does not meet the discreteness conditions of the Service's policy regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act (61 FR 4722, February 7, 1996). We also considered a DPS for the Arizona population of the pygmy-owl and concluded that, while the discreteness criteria for the DPS were met, we could not show that this DPS was significant to the taxon as a whole. For information regarding our rationale, please see *Analysis of Potential Distinct Population Segments* in our previous 12-month finding (76 FR 61856, October 5, 2011, pp. 61885–61889). We will accept comments related to these DPS decisions during the public comment period on this proposed rule (see **DATES**, above).

Supporting Documents

A species status assessment (SSA) team prepared an SSA report for the cactus ferruginous pygmy-owl. The SSA team was composed of Service biologists, in consultation with other species experts. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the subspecies, including the impacts of past, present, and future factors (both negative and beneficial) affecting the subspecies. In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we sought the expert opinions of five appropriate specialists regarding the SSA report. We received three responses. We also sent the SSA report to 13 partners, including Tribes and scientists with expertise in land management, pygmy-owl and raptor ecology, and climate science, for review. We received review from 11 partners, including State and Federal agencies, universities, and nonprofit organizations.

I. Proposed Listing Determination

Background

A thorough review of the taxonomy, life history, and ecology of the cactus ferruginous pygmy-owl is presented in the SSA report. We summarize this information here.

The cactus ferruginous pygmy-owl is a diurnal, nonmigratory subspecies of ferruginous pygmy-owl (*Glaucidium brasilianum*) and is found from central Arizona south to Michoacán, Mexico, in the west and from south Texas to Tamaulipas and Nuevo Leon, Mexico, in the east. Pygmy-owls eat a variety of prey including birds, insects, lizards, and small mammals, with the relative importance of prey type varying throughout the year.

The pygmy-owl is a small bird, approximately 17 centimeters (cm) (6.7 inches (in)) long. Generally, male pygmy-owls average 58 grams (g) to 66 g (2.0 to 2.3 ounces (oz)) and females average 70 g to 75 g (2.4 to 2.6 oz). The pygmy-owl is reddish brown overall, with a cream-colored belly streaked with reddish brown. The crown is lightly streaked, and a pair of dark brown or black spots outlined in white occurs on the nape, suggesting eyes (Oberholser 1974, p. 451). The species lacks obvious ear tufts (Santillan et al. 2008, p. 154), and the eyes are yellow. The tail is relatively long for an owl and is reddish brown in color, with darker brown bars. Males have pale bands between the dark bars on the tail, while females have darker reddish bands between the dark bars.

Cactus ferruginous pygmy-owls are secondary cavity nesters, nesting in cavities of trees and columnar cacti, with nesting substrate varying throughout its range. Pygmy-owls can breed in their first year and typically mate for life, with both sexes breeding annually. Clutch size can vary from two to seven eggs with the female incubating the eggs for 28 days (Johnsgard 1988, p. 162; Proudfoot and Johnson 2000, p. 11). Fledglings disperse from their natal sites about 8 weeks after they fledge (Flesch and Steidl 2007, p. 36). Pygmy-owls live on average 3 to 5 years, but

have been documented to live 7 to 9 years in the wild (Proudfoot 2009, pers. comm.) and 10 years in captivity (AGFD 2009, pers. comm.).

Pygmy-owls are found in a variety of vegetation communities, including Sonoran desertscrub and semidesert grasslands in Arizona and northern Sonora, thornscrub and dry deciduous forests in southern Sonora south to Michoacán, Tamaulipan brushland in northeastern Mexico, and live oak forest in Texas. At a finer scale, the pygmy-owl is a creature of edges found in semi-open areas of thorny scrub and woodlands in association with giant cacti and in scattered patches of woodlands in open landscapes, such as dry deciduous forests and riparian communities along ephemeral, intermittent, and perennial drainages (König et al. 1999, p. 373). It is often found at the edges of riparian and xeroriparian drainages and even habitat edges created by villages, towns, and cities (Abbate et al. 1999, pp. 14–23; Proudfoot and Johnson 2000, p. 5).

The taxonomy of *Glaucidium* is complicated and has been the subject of much discussion and investigation. Following delisting of the pygmy-owl in 2006 (71 FR 19452; April 14, 2006), the Service was petitioned to relist the pygmy-owl (CBD and DOW 2007, entire). The petitioners requested a revised taxonomic consideration for the pygmy-owl based on Proudfoot et al. (2006a, p. 9; 2006b, p. 946) and König et al. (1999, pp. 160, 370–373), classifying the northern portion of *Glaucidium brasilianum*'s range as an entirely separate species, *G. ridgwayi* and recognizing two subspecies of *G. ridgwayi: G. r. cactorum* in western Mexico and Arizona and *G. r. ridgwayi* in eastern Mexico and Texas. Other recent studies proposing or supporting the change to *G. ridgwayi* for the northern portion of *G. brasilianum's* range have been published in the past 20 years (Navarro-Sigüenza and Peterson 2004, p. 5; Wink et al. 2008, pp. 42–63; Enríquez et al. 2017, p. 15).

As we evaluated the cactus ferruginous pygmy-owl's current status, we found that, although there is genetic differentiation at the far ends of the pygmy-owl's distribution represented by Arizona and Texas, there continues to be uncertainty in the southern portion of the range. This area represents the boundary between the two proposed subspecies, which raises the question of whether there is adequate data to support a change in species classification and define the eastern and western distributions as separate subspecies. While future work and studies may clarify and resolve these issues, we will continue to use the currently accepted distribution of *G. brasilianum cactorum* as described in the 1957 American Ornithologists' Union (now the American Ornithological Society) checklist and various other publications (Friedmann et al. 1950, p. 145; Oberholser 1974, p. 452; Johnsgard 1988, p. 159; Millsap and Johnson 1988, p. 137).

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an endangered species or a threatened species. The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an endangered species or a threatened species because of any of the following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term ''foreseeable future'' extends only so far into the future as the Service can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial

data regarding the status of the cactus ferruginous pygmy-owl, including an assessment of the potential threats to the subspecies. The SSA report does not represent a decision by the Service on whether the subspecies should be proposed for listing as an endangered or threatened species under the Act. However, it does provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies. The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found under Docket No. FWS–R2–ES–2021–0098 at *http://www.regulations.gov* and at *https://www.fws.gov/southwest/es/arizona/*.

To assess the cactus ferruginous pygmy-owl's viability, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency supports the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years), redundancy supports the ability of the species to withstand catastrophic events (for example, droughts, large pollution events), and representation supports the ability of the species to adapt over time to long-term changes in the environment (for example, climate changes). In general, the more resilient and redundant a species is and the more representation it has, the more likely it is to sustain populations over time, even under changing environmental conditions. Using these principles, we identified the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluate the individual species' life-history needs. The next stage involves an assessment of the historical and current condition of the species' demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. The final stage of the SSA involves making predictions about the species' responses to positive and negative environmental and anthropogenic influences. Throughout all of these stages, we use the best available information to characterize viability as the ability of a species to sustain populations in the wild over time. We use this information to inform our regulatory decision.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the cactus ferruginous pygmy-owl and its resources, and the threats that influence the subspecies' current and future condition, in order to assess the subspecies' overall viability and the risks to that viability. The overall geographic range of the pygmy-owl is very large (approximately 140,625 square miles [364,217 square kilometers]) and covers two countries, the United States and Mexico. To assist in our analysis, we divided the overall geographic range of the pygmy-owl into five analysis units based upon biological, vegetative, political, climatic, geographical, and conservation differences. The five analysis units are: Arizona, northern Sonora, western Mexico, Texas, and northeastern Mexico. We analyzed each of these analysis units individually and looked at a combined outcome across the entire range of the subspecies.

Threats

We reviewed the potential risk factors that could be affecting the pygmy-owl now and in the future including: Climate change and climate condition (Factor E), habitat loss and fragmentation (Factor A), human activities and disturbance (Factors B and E), human-caused mortality (Factors B and E), disease and predation (Factor C), and small population size (Factor E). In this proposed rule, we will discuss only those factors in detail that could meaningfully impact the status of the subspecies. Those risks that are not known to have effects on pygmy-owl populations, such as disease, are not discussed here but are evaluated in the SSA report. The primary risk factors affecting the current and future status of the pygmy-owl are: (1) Habitat loss and fragmentation (Factor A), and (2) climate change and climate conditions (Factor E). For a detailed description of the threats analysis, please refer to the Species Status Assessment report (USFWS 2021, entire).

Habitat Loss and Fragmentation

Pygmy-owls require habitat elements, such as mature woodlands, that include appropriate cavities for nest sites, adequate structural diversity and cover, and a diverse prey base. Urbanization, invasive species, and agricultural or forest production are all leading to a reduction in the extent of habitat and an increase in habitat fragmentation throughout the geographic range of the subspecies.

Urbanization

Urbanization causes permanent impacts on the landscape that potentially result in the loss and alteration of pygmy-owl habitat. Residential, commercial, and infrastructure development replace and fragment areas of native vegetation resulting in the loss of available pygmy-owl habitat and habitat connectivity needed to support pygmy-owl dispersal and demographic support (exchange of individuals and rescue effect) of population groups.

Urbanization can also have detrimental effects on wildlife habitat by increasing the channelization or disruption of riverine corridors, the proliferation of exotic species, and the fragmentation of remaining patches of natural vegetation into smaller and smaller pieces that are unable to support viable populations of native plants or animals (Ewing et al. 2005, pp. 1–2; Nabhan and Holdsworth 1998, p. 2). Human-related mortality (*e.g.,* shooting, collisions, and predation by pets) also increases as urbanization increases (Banks 1979, pp. 1–2; Churcher and Lawton 1987, p. 439). Development of roadways and their contribution to habitat loss and fragmentation is a particularly widespread impact of urbanization (Nickens 1991, p. 1). Data from Arizona and Mexico indicate that roadways and other open areas lacking cover affect pygmy-owl dispersal (Flesch and Steidl 2007, pp. 6–7; Abbate et al. 1999, p. 54). Nest success and juvenile survival were also lower at pygmy-owl nest sites closer to large roadways, suggesting that habitat quality may be reduced in those areas (Flesch and Steidl 2007, pp. 6–7).

From 2010 to 2020, population growth rates increased in all Arizona counties where the pygmy-owl occurs: Pima (9.3 percent); Pinal (25.7 percent); and Santa Cruz (13 percent) (OEO 2021, unpaginated). Many cities and towns within the historical distribution of the pygmy-owl in Arizona experienced substantial growth between April 2010 and July 2019: Casa Grande (20.7 percent); City of Eloy (17.8 percent); City of Florence (7.7 percent); Town of Marana (41.9 percent); Town of Oro Valley (12.2 percent); and the Town of Sahuarita (20.9 percent) (U.S. Census Bureau 2021, unpaginated).Urban expansion and human population growth trends in Arizona are expected to continue into the future. The Maricopa-Pima-Pinal County areas of Arizona are expected to grow by as much as 132 percent between 2005 and 2050, creating rural-urban edge effects across thousands of acres of pygmy-owl

habitat (AECOM 2011, p. 13). Additionally, a wide area from the international border in Nogales, through Tucson, Phoenix, and north into Yavapai County (called the Sun Corridor ''Megapolitan'' Area) is projected to have 11,297,000 people by 2050, a 132 percent increase from 2005 (AECOM 2011, p. 13). If build-out occurs as expected, it will encompass a substantial portion of the current and historical distribution of the pygmy-owl in Arizona.

In Texas, the pygmy-owl occurred in good numbers until approximately 90 percent of the mesquite-ebony woodlands of the Rio Grande delta were cleared in 1910–1950 (Oberholser 1974, p. 452). Currently, most of the pygmy-owl habitat occurs on private ranch lands and therefore the threat of habitat loss and fragmentation of the remaining pygmy-owl habitat due to urbanization is reduced. However, urbanization and agriculture along the United State-Mexico border are likely to continue to isolate the Texas population of pygmy-owls by restricting movements between Texas and northeastern Mexico.

The United States-Mexico border region has a distinct demographic pattern of permanent and temporary development related to warehouses, exports, and other border-related activities, and patterns of population growth in this area of northern Mexico has accelerated relative to other Mexican States (Pineiro 2001, pp. 1–2). The Sonoran border population has been increasing faster than that State's average and faster than Arizona's border population; between 1990 and 2000, the population in the Sonoran border municipios increased by 33.4 percent, compared to Sonora's average (21.6 percent) and the average increase of Arizona's border counties (27.8 percent). Urbanization has increased habitat conversion and fragmentation, which, along with immigration, population growth, and resource consumption, were ranked as the highest threats to the Sonoran Desert Ecoregion (Nabhan and Holdsworth 1998, p. 1). This pattern focuses development, and potential barriers or impediments to pygmy-owl movements, in a region that is important for demographic support (immigration events and gene flow) of pygmy-owl population groups, including movements such as dispersal. When looking specifically at the United States-Mexico border region extending from Texas to California, the human population is approximately 15 million inhabitants and this population is expected to double by 2025 (HHS 2017, p. 1).

Significant human population expansion and urbanization in the Sierra Madre foothill corridor may represent a long-term risk to pygmy-owls in northeastern Mexico. From 2010 to 2015 the population in Tamaulipas increased by 8 percent to 3,527,735 and the population in Nuevo León increased by 24 percent to 5,784,442 (DataMexico 2021, unpaginated). Such increasing urbanization results in the permanent removal of pygmy-owl habitat reducing habitat availability and, more significantly, increases habitat fragmentation affecting the opportunity for pygmy-owl movements within northeastern Mexico and between Mexico and Texas. Habitat removal in northeastern Mexico is widespread and nearly complete in northern Tamaulipas (Hunter 1988, p. 8). Demographic support (rescue effect) of pygmy-owl population groups is threatened by ongoing loss and fragmentation of habitat in this area. Urbanization has the potential to permanently alter the last major landscape linkage between the pygmy-owl population in Texas and those in northeastern Mexico (Tewes 1993, pp. 28–29).

Human population growth in Sinaloa, Nayarit, Colima, and Jalisco, Mexico are relatively slow compared to Sonora and northeastern Mexico. From 2010 to 2015, the population in Sinaloa grew at a rate of 9.3 percent, Nayarit grew at a rate of 13.9 percent, Jalisco grew at a rate of 13.6 percent, and Colima grew at a rate of 12.4 percent (DataMexico 2021, unpaginated). These areas of Mexico are not experiencing the very high growth rates of Sonora and other border regions of Mexico, but will likely have some concurrent spread of urbanization. In addition, most of the growth is taking place in the large cities, and rather than in the rural areas that likely support pygmy-owl habitat (Brinkhoff 2016, unpaginated). However, these Mexican states have other threats to pygmy-owl habitat occurring such as agricultural development and deforestation that, in combination with habitat lost to urbanization, represent threats to the continued viability of the pygmy-owl in this area.

Invasive Species

The invasion of nonnative vegetation, particularly nonnative grasses, has altered the natural fire regime over the Sonoran Desert ecoregion of the pygmy-owl range (Esque and Schwalbe 2002, p. 165). In areas comprised entirely of native species, ground vegetation density is mediated by barren spaces that do not allow fire to carry across the landscape. However, in areas where nonnative species have become established, the fine fuel load is continuous, and fire is capable of spreading quickly and efficiently (Esque and Schwalbe 2002, p. 175). As a result, fire has become a significant threat to the native vegetation of the Sonoran Desert.

Nonnative annual plants prevalent within the Sonoran range of the pygmy-owl include *Bromus rubens* and *B. tectorum* (brome grasses), *Schismus* spp. (Mediterranean grasses), and Sahara mustard (*Brassica tournefortii*) (Esque and Schwalbe 2002, p. 165; ASDM 2021, entire). However, the nonnative species that is currently the greatest threat to vegetation communities in Arizona and northern Sonora, Mexico is the perennial *Cenchrus ciliaris* (buffelgrass), which is prevalent and increasing throughout much of the Sonoran range of the pygmy-owl (Burquez and Quintana 1994, p. 23; Van Devender and Dimmit 2006, p. 5).

Buffelgrass is not only fire-tolerant (unlike native Sonoran Desert plant species), but is actually fire-promoting (Halverson and Guertin 2003, p. 13). Invasion sets in motion a grass-fire cycle where nonnative grass provides the fuel necessary to initiate and promote fire. Nonnative grasses recover more quickly than native grass, tree, and cacti species and cause a further susceptibility to fire (D'Antonio and Vitousek 1992, p. 73; Schmid and Rogers 1988, p. 442). While a single fire in an area may or may not produce long-term reductions in plant cover or biomass, repeated wildfires in a given area, due to the establishment of nonnative grasses, are capable of ecosystem type-conversion from native desertscrub to nonnative annual grassland. These repeated fires may render the area unsuitable for pygmy-owls and other native wildlife due to the loss of trees and columnar cacti, and reduced diversity of cover and prey species (Brooks and Esque 2002, p. 336).

The distribution of buffelgrass has been supported and promoted by governments on both sides of the United States-Mexico border as a resource to increase range productivity and forage production. A 2006 publication estimates that 1.8 million ha (4.5 million ac) have been converted to buffelgrass in Sonora, and that between 1990 and 2000, there was an 82 percent increase in buffelgrass coverage (Franklin et al. 2006, pp. 62, 66). Following establishment, buffelgrass fuels fires that destroy Sonoran desertscrub, thornscrub, and, to a lesser extent, tropical deciduous forest; the disturbed areas are quickly converted to open savannas composed entirely of buffelgrass which removes pygmy-owl nest substrates and generally renders

areas unsuitable for future occupancy by pygmy-owls. Buffelgrass is now fully naturalized in most of Sonora, southern Arizona, and some areas in central and southern Baja California (Burquez-Montijo et al. 2002, p. 131), and now commonly spreads without human cultivation (Arriaga et al. 2004, pp. 1509–1511; Perramond 2000, p. 131; Burquez et al. 1998, p. 26).

Similar issues occur in Texas. Buffelgrass is now one of the most abundant nonnative grasses in South Texas, and a prevalent invasive grass within the range of the pygmy-owl. During the 1950's, federal and state land management agencies promoted buffelgrass as a forage grass in South Texas (Smith 2010, p. 113). Buffelgrass is very well adapted to the hot, semi-arid climate of South Texas due to its drought resistance and ability to aggressively establish in heavily grazed landscapes (Smith 2010, p. 113). Despite increasing awareness of the ecological damage caused by nonnative grasses, buffelgrass is still planted in areas affected by drought and overgrazing to stabilize soils and to increase rangeland productivity. Prescribed burning used for brush control typically promotes buffelgrass forage production in South Texas (Hamilton and Scifres 1982, p. 11). Buffelgrass often creates homogeneous monocultures by out-competing native plants for essential resources (Lyons et al. 2013, p. 8). Furthermore, buffelgrass produces phytotoxins in the soil that inhibit the growth of neighboring native plants (Vo 2013, unpaginated). With regard to pygmy-owl habitat, the loss of trees and canopy cover and the creation of dense ground cover resulting from buffelgrass conversion reduces nest cavity availability, cover for predator avoidance and thermoregulation, and prey availability. Overall, buffelgrass is the dominant herbaceous cover on 10 million ha in southern Texas and northeastern Mexico (Wied et al. 2020, p. 47).

The impacts of buffelgrass establishment and invasion are substantial for the pygmy-owl in the United States and Mexico because conversion results in the loss of important habitat features, particularly columnar cacti and trees that provide nest sites. Buffelgrass invasion and the subsequent fires eliminate most columnar cacti, trees, and shrubs of the desert (Burquez-Montijo et al. 2002, p. 138). This elimination of trees, shrubs, and columnar cacti from these areas is a potential threat to the survival of the pygmy-owl in the northern part of its range, as these vegetation components are necessary for roosting, nesting, protection from predators, and thermal regulation. Invasion and conversion to buffelgrass also negatively affect the diversity and availability of prey species in these areas (Franklin et al. 2006, p. 69; Avila-Jimenez 2004, p. 18; Burquez-Montijo et al. 2002, pp. 130, 135).

Buffelgrass is adapted to dry, arid conditions and does not grow in areas with high rates of precipitation or high humidity, above elevations of 1,265 m (4,150 ft), or in areas with freezing temperatures. Areas that support pygmy-owls south of Sonora and northern Sinaloa typically are wetter and more humid, and the best available information does not indicate that buffelgrass is invading the southern portion of the pygmy-owl's range. Surveys completed in Sonora and Sinaloa in 2006 noted buffelgrass was present in Sonora and northern Sinaloa, but the more southerly locations were noted as sparse or moderate (Van Devender and Dimmitt 2006, p. 7). As such, this nonnative species only affects the northern parts of the pygmy-owl's range.

Agricultural Production and Wood Harvesting

Agricultural development and wood harvesting can result in substantial impacts to the availability and connectivity of pygmy-owl habitat. Conversion of native vegetation communities to agricultural fields or pastures for grazing has occurred within historical pygmy-owl habitat in both the United States and Mexico, and not only removes existing pygmy-owl habitat elements, but also can affect the long-term ability of these areas to return to native vegetation communities once agricultural activities cease. Wood harvesting has a direct effect on the amount of available cover and nest sites for pygmy-owls and is often associated with agricultural development. Wood harvesting also occurs to supply firewood and charcoal, and to provide material for cultural and decorative wood carvings.

In Arizona, although new agricultural development is limited, the effects to historical habitat are still evident. Many areas that historically supported meso- and xeri-riparian habitat have been converted to agricultural lands and associated groundwater pumping has affected the hydrology of these valleys (Jackson and Comus 1999, pp. 233, 249). These riparian areas are important pygmy-owl habitat, especially within drier upland vegetation communities like Sonoran desertscrub and semi-desert grasslands.

Habitat fragmentation as a result of agricultural development has also occurred within Texas. Brush clearing, pesticide use, and irrigation practices associated with agriculture have had detrimental effects on the Lower Rio Grande Valley (Jahrsdoerfer and Leslie 1988, p. 1). From the 1920's until the early 1970's, over 90 percent of pygmy-owl habitat in the Lower Rio Grande Valley of Texas was cleared for agricultural and urban expansion (Oberholser 1974, p. 452). The Norias Division of the King Ranch in southern Texas has been isolated by agricultural expansion, which has restricted pygmy-owl dispersal (Oberholser 1974). This has resulted in loss of pygmy-owl habitat connectivity between pygmy-owl population groups in Texas and in Mexico. Historically, agriculture in Sonora, Mexico, was restricted to small areas with shallow water tables, but it had, nonetheless, seriously affected riparian areas by the end of the nineteenth century. For example, in the Rio Mayo and Rio Yaqui coastal plains, nearly one million ha (2.5 million ac) of mesquite, cottonwood, and willow riparian forests and coastal thornscrub disappeared after dams upriver started to operate (Burquez and Martinez-Yrizar 2007, p. 543).

Other Mexican states within the range of the pygmy-owl show similar potential for habitat loss. For example, in Tamaulipas, area under irrigation increased from 174,400 to 494,472 ha (431,000 to 1.22 million ac) between 1998 and 2004, with an area of 668,872 ha (1.65 million ac) equipped for irrigation. However, agricultural development in the States of Colima, Jalisco, Nayarit, and Nuevo Leon had substantial decreases in the amount of irrigated lands over the same period (FAO 2007, unpaginated). Although land continues to be converted to agriculture within the geographic range of the pygmy-owl, we do not know if the areas being converted currently support pygmy-owl habitat. Continuing destruction of pygmy-owl habitat for agricultural production is not occurring with the same intensity throughout the range of the pygmy-owl, and the area in agricultural production may be declining in some parts of its southern range.

Wood harvesting is also a potential threat to pygmy-owl habitat. Ironwood (*Olneya tesota*) and mesquite (*Prosopis* spp.) are harvested throughout the Sonoran Desert for use as charcoal, fuelwood, and carving (Burquez and Martinez Yrizar 2007, p. 545). For instance, by 1994, 202,000 ha (500,000 ac) of mesquite had been cleared in northern Mexico to meet the growing demand for mesquite charcoal (Haller 1994, p. 1). Unfortunately, woodcutters

and charcoal makers utilize large, mature mesquite and ironwood trees growing in riparian areas (Taylor 2006, p. 12), which is the tree class that is of most value as pygmy-owl habitat. Loss of leguminous trees results in long-term effects to the soil as they add organic matter, fix nitrogen, and add sulfur and soluble salts, affecting overall habitat quality and quantity (Rodriguez Franco and Aguirre 1996, p. 6–47). Ironwood and mesquite trees are important nurse species for saguaros, the primary nesting substrate for pygmy-owls in the northern portion of their range (Burquez and Quintana 1994, p. 11). Declining tree populations in the Sonoran Desert as a result of commercial uses and land conversion threatens other plant species and may alter the structure and composition of the vertebrate and invertebrate communities as well (Bestelmeyer and Schooley 1999, p. 644). This has implications for pygmy-owl prey availability because pygmy-owls rely on a seasonal diversity of vertebrate and invertebrate prey species; loss of tree structure and diversity reduces prey diversity and availability.

Once common in areas of the Rio Grande delta, significant habitat loss and fragmentation due to woodcutting have now caused the pygmy-owl to be a rare occurrence in this area of Texas. Oberholser (1974, p. 452) concluded that agricultural expansion and subsequent loss of native woodland and thornscrub habitat, begun in the 1920's, preceded the rapid demise of pygmy-owl populations in the Lower Rio Grande Valley of southern Texas. Because much of the suitable pygmy-owl habitat in Texas occurs on private ranches, habitat areas are subject to potential impacts that are associated with ongoing ranch activities such as grazing, herd management, fencing, pasture improvements, construction of cattle pens and waters, road construction, and development of hunting facilities. Brush clearing, in particular, has been identified as a potential factor in present and future declines in the pygmy-owl population in Texas (Oberholser 1974, p. 452). However, relatively speaking, the current loss of habitat is much reduced in comparison to the historical loss of habitat in Texas. Conversely, ranch practices that enhance or increase pygmy-owl habitat to support ecotourism can contribute to conservation of the pygmy-owl in Texas (Wauer et al. 1993, p. 1076). The best available information does not indicate that current ranching practices are significantly affecting pygmy-owl habitat in Texas.

Habitat fragmentation in northeastern Mexico is extensive, with only about two percent of the ecoregion remaining intact, and no habitat blocks larger than 250 square km (96.5 square mi), and no significant protected areas (Cook et al. 2000, p. 4). Fire is often used to clear woodlands for agriculture in this area of Mexico, and many of these fires are not adequately controlled. There may be fire-extensive related effects to native plant communities (Cook et al. 2000, p. 4); however, there is no available information of how much area may be affected by this activity.

Areas of dry subtropical forests, important habitat for pygmy-owls in southwestern Mexico, have been used by humans through time for settlement and various other activities (Trejo and Dirzo 2000, p. 133). The long-term impact of this settlement has converted these dry subtropical forests into shrublands and savannas lacking large trees, columnar cacti, and cover and prey diversity that are important pygmy-owl habitat elements. In Mexico, dry tropical forest is the major type of tropical vegetation in the country, covering over 60 percent of the total area of tropical vegetation. About 8 percent (approximately 160,000 square km (61,776 square mi)) of this forest remained intact by the late 1970s, and an assessment made at the beginning of the present decade suggested that 30 percent of these tropical forests have been altered and converted to agricultural lands and cattle grasslands (Trejo and Drizo 2000, p. 134). However, the best available information indicates that there are still expanses of dry tropical forest along the Pacific coast in Mexico, including some areas below 1,200 m (4,000 ft) where pygmy-owls are found.

Summary of Habitat Loss and Fragmentation

In summary, pygmy-owls require habitat elements such as mature woodlands that include appropriate cavities for nest sites, adequate structural diversity and cover, and a diverse prey base. These habitat elements need to be available across the geographic range of the pygmy-owl and spatially arranged to allow connectivity between habitat patches. Pygmy-owl habitat loss and fragmentation are affecting pygmy-owl viability throughout its range. These threats vary in scope and intensity throughout the pygmy-owl's geographic range and specific threats are a more significant issue in certain parts of the range than in others. For example, in Arizona and Northern Sonoran, pygmy-owl habitat loss and fragmentation resulting from urbanization, changing fire regimes due to the invasion of buffelgrass, and agricultural development and woodcutting are significant threats that have negatively affected pygmy-owl habitat. In Texas, historical loss of habitat has reduced the pygmy-owl range, but current impacts are reduced from historical levels in their magnitude and severity. However, in Texas and other areas of the pygmy-owl's range, these past impacts continue to affect the current extent of available pygmy-owl habitat, because of the extended time it takes for these lands to recover. Therefore, even if habitat destruction ceases, the negative effects of past land use are expected to continue in many of these areas into the future.

For the remainder of the pygmy-owl's range and habitat in Mexico (northeastern Mexico and south of Sonora), data available for our analysis were limited. The rate of growth in these southern Mexican States appears to be lower than in Sonora and the Arizona border region. Historical loss of pygmy-owl habitat in northeastern Mexico has occurred, but the extent to which significant habitat destruction is currently taking place is not available. In addition, pygmy-owls are still considered common in the southern part of their range (Enriquez-Rocha et al. 1993, p. 154; Cartron et al. 2000, p. 5; GBIF 2020).

This information indicates that the impacts to pygmy-owl habitat discussed herein may be having different levels of effects on the populations of pygmy-owls throughout their range, and habitat effects may not have the impacts to pygmy-owl population groups in the southern portion of the pygmy-owl's range due to increased pygmy-owl numbers. Nonetheless, Enríquez and Vazquez-Perez (2017, p. 546) indicate that during the last 50 years, Mexico has seen drastic changes in land uses due to rapid urbanization and industrialization, which has been poorly planned. The result has been impacts to the natural environment, including the degradation and loss of biological diversity in Mexico. There has been limited work in Mexico, however, to understand what the direct impacts of these threats are on owl population losses and changes in distribution and abundance of subspecies in long term (Enríquez and Vazquez-Perez 2017, p. 546).

Climate Change and Climate Conditions

Climate change projections within the geographic range of the pygmy-owl show that increasing temperatures, decreasing precipitation, and increase intensity of weather events are likely

(Karmalkar et al. 2011, entire; Bagne and Finch 2012, entire; Coe et al. 2012, entire; and Jiang and Yang 2012, entire). Climate influences pygmy-owl habitat conditions and availability through the loss of vegetation cover, reduced prey availability, increased predation, reduced nest site availability, and vegetation community change. The majority of the current range of the pygmy-owl occurs in tropical or subtropical vegetation communities, which may be reduced in coverage if climate change results in hotter, more arid conditions. Additionally, models predict that the distribution of suitable habitat for saguaros, the primary pygmy-owl nesting substrate within the Sonoran Desert ecoregion, will substantially decrease over the next 50 years under a moderate climate change scenario (Weiss and Overpeck 2005, p. 2074; Thomas et al. 2012, p. 43). Climate change scenarios project that drought will occur more frequently and increase in severity, with a decrease in the frequency and increase in severity of precipitation events (Seager et al. 2007, p. 9; Cook et al. 2015, p. 6; Pascale et al. 2017, p. 806; Williams et al. 2020, p. 317). Drought and changes to the timing and intensity of precipitation events may reduce available cover and prey for pygmy-owls adjacent to riparian areas through scouring flood events and reduced moisture retention. Although the extent to which changing climatic patterns will affect the pygmy-owl is better understood following the past decade of observations in the field, there remains uncertainty with regard to the overall extent and timing of impacts.

Synergistic interactions are likely to occur between the effects of climate change and habitat fragmentation and loss. Climate change projections indicate that conditions will likely favor increased occurrence and distribution of nonnative, invasive species and alteration of historical fire regimes. Climate change may also affect the viability of the pygmy-owl through precipitation-driven changes in plant and insect biomass, which in turn influence abundance of lizards, small mammals, and birds (Jones 1981, p. 111; Flesch 2008, p. 5; Flesch et al. 2015, p. 26). Decreased precipitation generally reduces plant cover and insect productivity, which in turn reduce the abundance and availability of pygmy-owl prey species. Similarly, increased temperatures reduce pygmy-owl prey activity due to increased energetic demands of thermoregulation and a decreased availability of prey and cover (Flesch et al. 2015, p. 26). These indirect effects on prey availability and direct effects on prey activity affect nestling growth, development, and survival. When decreased precipitation affects food supply and increased temperature affects prey activity, reduced pygmy-owl productivity is likely to result in reduced pygmy-owl resiliency (Flesch et al. 2015, p. 26). Climate change can also influence natural events, such as hurricanes and tropical storms, which can modify and fragment habitats, primarily through loss of woody cover. Historical and ongoing threats to the pygmy-owl from habitat loss and fragmentation as well as from climate change and climate conditions, have shaped the current habitat and population conditions of the subspecies throughout its range.

Current Condition

To assess resiliency, we evaluated six components that broadly related to the subspecies' population demography or physical environment and for which we had data sufficient to conduct the analysis. We assessed each analysis unit's physical environment by examining three components determined to have the most influence on the subspecies: Habitat intactness, prey availability, and vegetation health and cover. We also assessed each analysis unit's demography through abundance, occupancy, and evidence of reproduction. We established parameters for each component by evaluating the range of existing data and separating those data into categories based on our understanding of the subspecies' demographics and habitat. Using the demographic and habitat parameters, we then categorized the overall condition of each analysis unit. We provide a summary of each of the six factors below and describe them in detail in the SSA report (Service 2021, entire).

Demographic Factors

Abundance: Larger populations have a lower risk of extinction than smaller populations (Pimm et al. 1988, pp. 773–775; Trombulak et al. 2004, p. 1183). In contrast, small populations are less resilient and more vulnerable to the effects of demographic, environmental, and genetic stochasticity, and have a higher risk of extinction than larger populations (Trombulak et al. 2004, p. 1183). Small populations may experience increased inbreeding, loss of genetic variation, and ultimately a decreased potential to adapt to environmental change (Trombulak et al. 2004, p. 1183; Harmon and Braude 2010, p. 125; Benson et al. 2016, pp. 1–2). The abundance of pygmy-owls within each analysis unit must be high enough to support persistence of pygmy-owl population groups (multiple breeding pairs of pygmy-owls within relatively discrete geographic areas) within the analysis unit. This is accomplished by having adequate patches of habitat to support multiple nesting pairs of pygmy-owls and their offspring, have adequate habitat connectivity to support establishment of additional territories by dispersing young, and supply floaters (unpaired individuals of breeding age) within each pygmy-owl population group to offset loss of breeding adults and to provide potential mates for dispersing juveniles.

Occupancy: Sufficiently resilient pygmy-owl populations must occupy large enough areas such that stochastic events and environmental fluctuations that affect individual pygmy-owls, or population group of pygmy-owls, do not eliminate the entire population. Pygmy-owls are patchily distributed across the landscape in population groups of nesting owls. Each of these population groups must be occupied by large enough numbers of pygmy-owls to enable the population group to persist on the landscape over time. Enough occupied population groups of pygmy-owls must also exist on the landscape, with interconnected habitat supporting movement among population groups, so that each population group can receive or exchange individuals with any given adjacent population group.

Pygmy-owl occupancy is an indicator of habitat conditions as well as demographic factors, such as reproduction and survival. Habitats that support large numbers of pygmy-owls are better able to provide floaters and available mates to dispersing pygmy-owls from adjacent populations. These floaters are able to serve as replacement breeders if either or both members of an existing breeding pair are lost. Observations indicate that if a site is occupied by a breeding pair, they will breed. Survival of adults also affects occupancy, as some occupied sites will be abandoned if one of the adult breeders perishes. These sites can be reoccupied in the future when floaters or dispersing birds move into the area.

Evidence of reproduction: Resilient pygmy-owl populations must also reproduce and produce a sufficient number of young such that recruitment equals or exceeds mortality. Current population size and abundance reflects previous influences on the population and habitat, while reproduction and recruitment reflect population trends that may be stable, increasing, or decreasing in the future. Adequately resilient populations of the pygmy-owl must have sufficient numbers of

individuals to replace members of breeding pairs that have been lost and to support persistent population groups of nesting pygmy-owls through dispersal. However, the necessary reproductive rate needed for a self-sustaining population is unknown. Additionally, key demographic parameters of pygmy-owl populations (*e.g.,* survival, life expectancy, lifespan, productivity, etc.) are unknown throughout most of the geographic range. Due to the lack of information on demographic parameters of reproduction, recruitment, and survival, we broadly considered evidence of reproduction to include any evidence of reproduction (*e.g.,* active nests, presence of eggs or nestlings, fledglings, etc.), as well as persistence of occupied territories and population groups in an area over a sufficient amount of time to indicate evidence of reproduction. Thus, evidence of reproduction on a consistent basis over time likely indicates a sufficiently resilient population.

Habitat intactness: Adequately resilient pygmy-owl populations need intact habitat that is large enough to support year-round occupancy, as well as connectivity between habitat patches to enable dispersal. Pygmy-owls are patchily distributed across much of their geographic range. These pygmy-owl population groups are dependent on interchange of individuals in order to maintain adequate numbers and genetic diversity on the landscape. Habitat connectivity is crucial to maintaining pathways for the interchange of individuals among pygmy-owl population groups.

Prey availability: Adequate prey availability is a key component for maintaining resiliency in pygmy-owl populations. Year-round prey availability is essential throughout the range of the pygmy-owl, with portions of the geographic range characterized by seasonal variability in available prey resources. The abundance of many of these prey species is influenced by annual and seasonal precipitation through increases and decreases in vegetation cover and diversity, which also influences insect abundance and availability. Sufficiently resilient pygmy-owl populations require adequate precipitation to support year-round prey availability. This includes appropriately timed precipitation to support seasonally available prey such as lizard, insects, and small mammals.

Vegetation cover: Sufficiently resilient pygmy-owl populations require adequate vegetation to provide cover for predator avoidance, thermoregulation, hunting, and nest cavities. Of primary importance for cover is the presence of woody vegetation canopy. Maintenance of the health and vigor of this woody cover is a key component to maintaining resiliency of pygmy-owl populations.

Summary of Current Condition of the Subspecies

Currently, the cactus ferruginous pygmy-owl occurs from southern Arizona, south to Michoacán in the western portion of its range, and from southern Texas to Tamaulipas and Nuevo Leon in the eastern portion of its range. For our analysis, we divided the pygmy-owl's overall range into five analysis units: Arizona, northern Sonora, western Mexico, Texas, and northeastern Mexico (see Figure 1, below). The primary factors currently affecting the condition of cactus ferruginous pygmy-owl populations include climate conditions, and habitat fragmentation and loss.

Resiliency

The Arizona analysis unit currently has the lowest pygmy-owl abundance of all analysis units, which is estimated to be in the low hundreds. Habitat fragmentation and loss from urbanization and increases in invasive species such as buffelgrass, have reduced the availability and connectivity of habitat in this analysis unit. Additionally, climate conditions have reduced prey availability and vegetative cover through increased temperatures and drought. These factors result in a reduced capacity for this analysis unit to withstand stochastic events and result in a low resiliency currently.

The northern Sonora analysis unit has an estimated pygmy-owl abundance in the high hundreds. However, this analysis unit is affected by habitat fragmentation from urbanization, agricultural development, and associated infrastructure. These stressors increase water use and, in conjunction with climate conditions, result in a reduction in the quality and availability of pygmy-owl habitat. Due to moderate owl abundance and some decrease in habitat availability and connectivity, the northern Sonora analysis unit has a moderate level of population resiliency.

The western Mexico analysis unit is estimated to have tens of thousands of pygmy-owls. This analysis unit has some habitat fragmentation from urbanization, agricultural development, and deforestation of the tropical deciduous forests. Overall, the western Mexico analysis unit has high population resiliency due to high abundance of pygmy-owls and healthy vegetation cover, likely as a result of high levels of precipitation in the region.

The Texas analysis unit has an estimated pygmy-owl abundance in the high hundreds. Land ownership within this analysis unit has resulted in habitat fragmentation and, due to agricultural development and wood harvesting within the Rio Grande Valley, this analysis unit is somewhat genetically isolated from the rest of the geographic range of the subspecies. Due to moderate pygmy-owl abundance, fragmentation of habitat, and some genetic isolation, the Texas analysis unit has a moderate level of population resiliency.

The northeast Mexico analysis unit is estimated to have tens of thousands of pygmy-owls. However, this unit has high levels of habitat fragmentation due to urbanization and agricultural development. Overall, the northeast Mexico analysis unit has a moderate level of population resiliency with some capacity to withstand stochastic events. Rangewide, current condition of the pygmy-owl populations indicate that three analysis units are maintaining a moderate level of population resiliency, one analysis has low resiliency, and one analysis unit has high resiliency.

Representation

Resiliency, and the factors that drive resiliency, also contribute to the pygmy-owl's representation on the landscape. Pygmy-owls occupy a diversity of habitat types throughout the geographic range of the subspecies and maintain substantial genetic diversity. The subspecies' adaptive potential (representation) is currently high due to genetic and ecological variability across the range. There is substantial genetic diversity across the range (Proudfoot et al. 2006a, entire; 2006b, entire) due to isolation-by-distance and geographic barriers. Additionally, across the range, the pygmy-owl occupies a diverse range of ecological settings as a result of geographic gradients of vegetation, climate, elevation, topography, and other landscape elements. Such ecological diversity could help the pygmy-owl adapt to and survive future environmental changes, such as warming temperatures or decreased precipitation from climate change.

Redundancy

We assessed the number and distribution of populations across the pygmy-owl's geographic range as a measure of its redundancy. While the numbers and densities of pygmy-owls are lower in some analysis units, these portions of the range still contribute in

a meaningful way to the overall pygmy-owl population. Each analysis unit within the geographic range of the subspecies maintains a network of population groups that are connected both within and between analysis units. These population groups have the potential to recolonize areas where other population groups are lost to catastrophic events. All analysis units contribute to the total rangewide population, and population groups within each analysis unit provide population support for that analysis unit and adjacent portions of the range. If an analysis unit is self-sustaining, it provides redundancy across the range, and may provide emigrants to support adjacent analysis units. Research and monitoring have documented exchange of individual cactus ferruginous pygmy-owls among population groups within the Arizona, northern Sonora, and Texas analysis units, and between the Arizona and northern Sonora analysis units (Abbate et al. 2000, p. 30; Flesch and Steidl 2007, p. 37; Proudfoot et al. 2020, unpaginated; AGFD unpublished data). Habitat fragmentation and reduced vegetation health as a result of ongoing drought have resulted in the extirpation of population groups in Arizona and Texas, but redundancy was exhibited in the northern Sonora analysis unit when drought conditions eased and historically occupied areas were reoccupied (Flesch et al. 2017, p. 12). Despite existing habitat fragmentation, research and monitoring have documented that exchange of individual pygmy-owls between population groups and between some analysis units is still occurring. Habitat types used by pygmy-owls vary across the range, with some vegetation types being restricted to certain portions of the geographic range. It is important to maintain pygmy-owl populations throughout the range to provide redundancy to adjacent populations in similar habitat conditions. Due to the broad geographic distribution and network of populations groups that are connected within and between some analysis units throughout most of its range, the pygmy-owl has some ability to recolonize following catastrophic events and is considered to have adequate redundancy.

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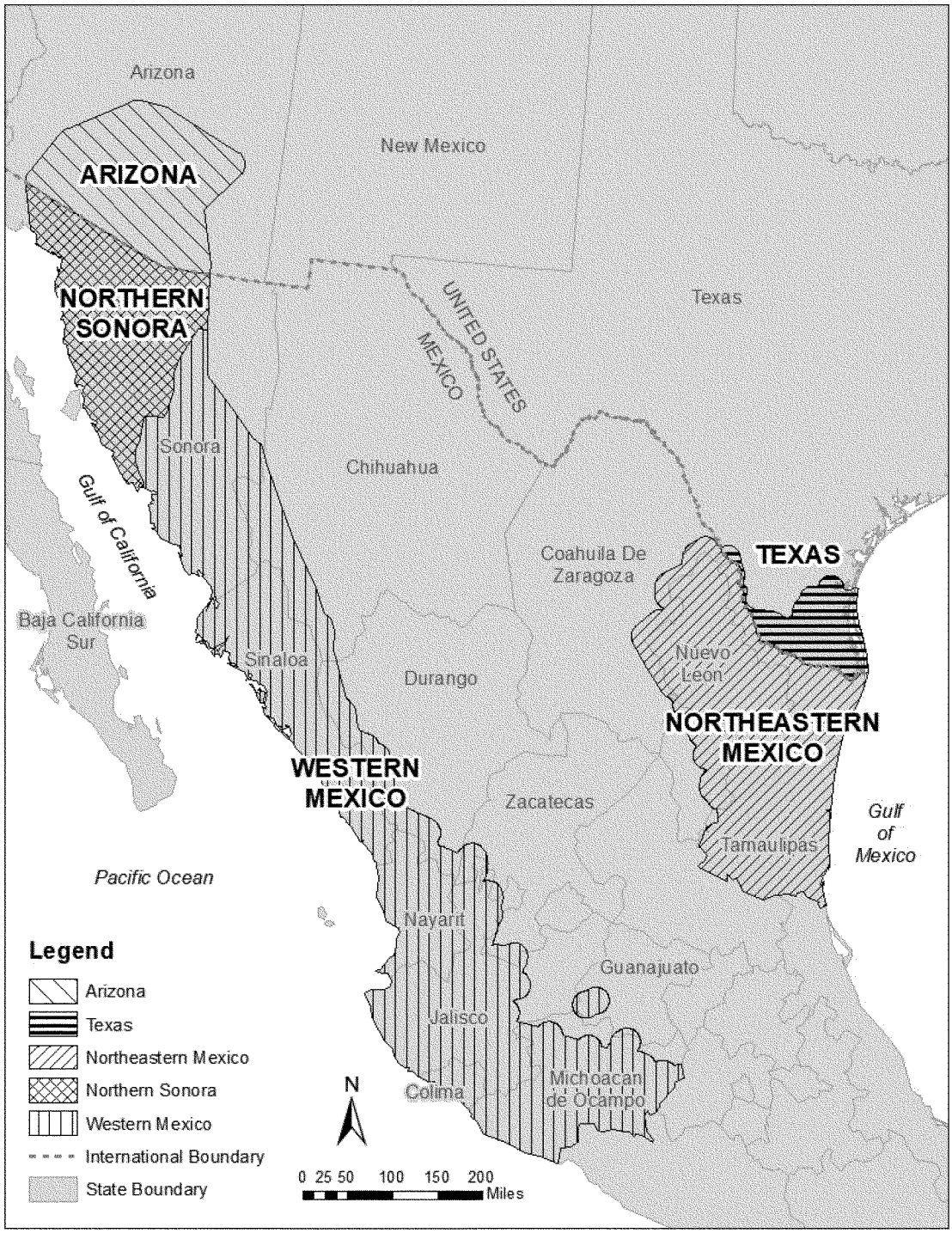

Figure 1. Cactus ferruginous pygmy-owl's range in the United States and Mexico, including the five analysis units used in the SSA.

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Future Scenarios

In our SSA report, we defined viability as the ability of a species to sustain populations in the wild over time. To help address uncertainty associated with the degree and extent of potential future stressors and their impacts on species' needs, the concepts of resiliency, redundancy, and representation were assessed using three plausible future scenarios. We developed these scenarios by identifying information on the following primary factors anticipated to affect the cactus ferruginous pygmy-owl in the future: Climate change, habitat loss and fragmentation, and conservation activity. The three scenarios capture the range of uncertainty in the changing landscape and how the pygmy-owl

would respond to the changing conditions. We used the best available data and models to project out 30 years into the future (*i.e.,* 2050).

We chose this timeframe based on the subspecies' life span and observed cycles in population abundance, as well as the time period where we could reasonably project certain land use changes and urbanization patterns relevant to the pygmy-owl and its habitat. The majority of the projections of urbanization and population growth within the geographic range of the pygmy-owl extend to 2050. Since urbanization and development are some of the primary drivers of habitat loss and fragmentation, we extended our analysis only as far as we could reasonably project these changes and the species response to those changes. Additionally, the average lifespan of a pygmy-owl is 3 to 5 years. Thus, over a 30-year timeframe, we would expect eight to ten generations of pygmy-owls to be produced which should be adequate to assess the effects of both threats and conservation actions. Because the primary avenue through which pygmy-owls move across the landscape is through the dispersal of juveniles, it can take multiple generations to provide adequate exchange of individuals to elicit detectable change at the population group and analysis unit scale. Including multiple generations of pygmy-owls also allows adequate time to account for lags in demographic factors resulting from changes in environmental conditions. Therefore, this number of generations is sufficient to assess the effective levels of resiliency, redundancy and representation. Monitoring of pygmy-owl occupancy and productivity also indicates that, at least in Arizona and northern Sonora, 30 years was an adequate time period to document abundance cycles driven by climate conditions. Monitoring in both Arizona and northern Sonora from the mid-1990s to present showed a period of decline in occupancy and productivity, primarily due to drought, followed by an increase in productivity and occupancy during years of better precipitation such that abundance and occupancy recovered to nearly the original levels (Flesch et al. 2017, p. 12; Service 2021, entire). For more information on the models and their projections, please see the SSA report (Service 2021, entire).

Under Scenario 1 (continuation of current trends), we projected there would be no significant changes to the rate of habitat loss and fragmentation within the subspecies' range. For this scenario, we considered that climate change would track Representative Concentration Pathway (RCP) 4.5, which is one of four alternative trajectories for carbon dioxide emissions set forth by the International Panel on Climate Change. Specifically, RCP4.5 is an intermediate scenario where carbon dioxide emissions continue to increase through the mid-21st century, but then decline. This scenario would result in atmospheric carbon dioxide levels between 580 and 720 parts per million (ppm) between 2050 and 2100 and would represent an approximately 2.5 °C increase in global mean temperature relative to the period 1861–1880 (IPCC 2014, p. 9). We also considered that conservation efforts that are currently underway, such as captive rearing, would continue to be limited in their efficacy, due to limited resources and the continued efforts to identify appropriate and effective methodologies and protocols. Additionally, climate change will continue to affect the suitability of conditions at release sites for captive-reared pygmy-owls, potentially limiting the effectiveness of pygmy-owl releases.

Under these conditions, we do not anticipate that any of the factors used to evaluate resiliency would improve and, in fact, vegetation intactness would be reduced due to continued development. Northeastern Mexico is projected to maintain its current level of high pygmy-owl abundance because significant changes to habitat conditions are not expected. Because of this, the northeastern Mexico analysis unit is expected to maintain a moderate level of population resiliency under this scenario. Conditions in the Arizona analysis unit would continue to decline due to continued habitat fragmentation and climate change, and resiliency would remain low. Resiliency in the remaining three analysis units, northern Sonora, western Mexico, and Texas, would decline due to continued loss of cactus ferruginous pygmy-owl habitat, reduced habitat intactness, and a reduction in cover and prey availability for cactus ferruginous pygmy-owls. Overall, current levels of population redundancy and representation would be maintained rangewide because all analysis units would remain occupied; however, representation within each analysis unit would likely decline at the population-group scale.

Under Scenario 2 (worsening or increased effects scenario), we projected increased rates of habitat loss and fragmentation leading to a decline in pygmy-owl habitat conditions. For this scenario, we considered that climate change would track RCP8.5, which is the highest greenhouse gas emission scenario. Under this scenario, atmospheric carbon dioxide concentrations are projected to exceed 1,000 ppm between 2050 and 2100 and would represent a 4.5 °C increase in global mean temperature (IPCC 2014, p. 9). We also considered that conservation efforts that are currently underway would not be effective or would not be implemented.

Increased habitat loss and fragmentation would result in the greatest effect to overall resiliency through a reduction in abundance and occupancy of pygmy-owls. Increased development and urbanization would result in a permanent loss of habitat. Indirect effects to vegetation and prey availability as a result of climate change would also be expected. Due to increased habitat fragmentation, such as agricultural development, as well as a reduction in vegetation health from drought, resiliency in the western Mexico analysis unit is projected to decline. Under this scenario, climate change and increased habitat fragmentation from urbanization and agricultural development lead to the loss of some population groups within the Texas, Arizona, and northern Sonora analysis units. The resultant decline would decrease representation and redundancy within these analysis units. In particular, the Texas and Arizona analysis units would become more vulnerable to extirpation because of low pygmy-owl abundance and occupancy driven by reduced habitat quality as a result of drought and high levels of habitat fragmentation from ongoing urbanization and agricultural development. Genetic representation would be reduced through the loss of population groups or analysis units and the subsequent reduction of gene flow. Overall, there would be a reduction in resiliency, representation, and redundancy within most analysis units and the likelihood of maintaining long-term viability would be considerably reduced.

Under Scenario 3 (improving or reduced effects scenario), we project that habitat loss and fragmentation would continue, but at a reduced rate. For this scenario, we considered that climate change would track RCP4.5, and conservation efforts that are currently underway would be effective. We did not include other planned conservation efforts in this scenario because we are not aware of any that would significantly influence the viability of the species.

Despite effective conservation actions in portions of the range, the viability of pygmy-owl populations would continue to decline within all five analysis units

due to the ongoing effects of habitat loss, fragmentation, and climate change. Resiliency would remain low in the Arizona analysis unit and would decline in both the northern Sonora and western Mexico analysis units due to a reduction in habitat quality as a result of climate change. Pygmy-owl habitat fragmentation from urbanization, deforestation, and agricultural development are expected to continue under this scenario, though at a slower rate. Resiliency would remain in moderate condition for the Texas and northeastern Mexico analysis units. Although habitat conditions are expected to continue to decline due to drought and climate change, we do not expect a large decline in pygmy-owl occupancy and abundance in Texas and northeastern Mexico. Under this scenario, each analysis unit remains occupied and contributes to the representation and redundancy across the range of the pygmy-owl. However, within each analysis unit, threats continue, albeit at a reduced rate, and the resiliency of population groups would decline in three of the five analysis units. Thus, within analysis units, representation and redundancy is likely to decrease at the population-group scale.

Cumulative Effects

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have not only analyzed individual effects on the subspecies, but we have also analyzed their potential cumulative effects. We incorporate the cumulative effects into our SSA analysis when we characterize the current and future condition of the subspecies. To assess the current and future condition of the subspecies, we undertake an iterative analysis that encompasses and incorporates the threats individually and then accumulates and evaluates the effects of all the factors that may be influencing the subspecies, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire subspecies, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative effects analysis.

Conservation Efforts and Regulatory Mechanisms

Because we are considering the best available information and because the discussion above primarily addresses the viability of the cactus ferruginous pygmy-owl in relation to the threats and factors affecting its viability, here we will discuss regulatory mechanisms and conservation actions that potentially have or will influence the current and future viability of the cactus ferruginous pygmy-owl.

Federal Protections

Although the pygmy-owl in Arizona is considered nonmigratory, it is included on the list of birds protected under the Migratory Bird Treaty Act (MBTA) (16 U.S.C. 703–712). The MBTA prohibits ''take'' of any migratory bird. However, unlike the Endangered Species Act, there are no provisions in the MBTA preventing habitat destruction unless direct mortality or destruction of an active nest occurs. Approximately 31 percent of the pygmy-owl's historical geographic range in the United States is federally owned, with Federally-owned lands making up approximately 40 percent of pygmy-owl habitat in Arizona. However, a substantial extent of the known currently occupied habitats occur on State Trust lands in Arizona and on private lands in Texas. Other Federal regulations and policies such as the Clean Water Act (33 U.S.C. 1251 *et seq.*), the military's integrated natural resources management plans (INRMPs, such as the one for the Barry M. Goldwater Range) (Uken 2008, pers. comm.), and National Park Service policy provide varying levels of protection, but they have not been effective in protecting the pygmy-owl from further decline in Arizona. As a result of the implementation of the 2005 Real ID Act (Division B of Pub. L. 109–13), the U.S. Department of Homeland Security (DHS) has waived application of the Act and other environmental laws in the construction of border infrastructure, including areas occupied by the pygmy-owl (73 FR 5272; January 29, 2008). As recently as 2020, DHS waived environmental compliance for the construction of border walls along the U.S.-Mexico border in Arizona and Texas (Fischer 2019, entire; USCBP 2020, entire). Consequently, pygmy-owl habitat has been lost and fragmented along most of the border area in Arizona and, to a lesser extent, Texas. Of particular concern is the potential for border infrastructure to reduce habitat connectivity into occupied pygmy-owl habitat in Mexico.

State Protections

The pygmy-owl is included on the State of Arizona's list of species of concern (AGFD 2021, p. 16). Arizona statute does not address the root causes leading to destruction or alteration of pygmy-owl habitat. The State of Texas lists the pygmy-owl as threatened (Texas Administrative Code, title 31, part 2, chapter 65, subchapter G, rule 65.175; TPWD 2009, p. 1). This designation allows permits to be issued for the taking, possession, propagation, transportation, sale, importation, or exportation of pygmy-owls if necessary to properly manage that species, but does not provide any habitat protections (Texas Park and Wildlife Code, chapter 67, section 67.0041).

Protections in Mexico

Within Mexico, the distribution of owls is large and includes multiple States. The administration of land use in Mexico depends on the national government, which implements Natural Protected Areas and other Federal programs, and also the policies of each State and even municipal governments (Enríquez 2021, pers. comm.). This system represents a wide range of management, conservation, and natural resource use approaches that affect pygmy-owl conservation, resulting in inconsistent policies and implementation of conservation activities. Similar to state laws in the United States, there are currently no laws or regulations in Mexico that specifically protect pygmy-owls and pygmy-owl habitat. As is the case throughout the geographic range of the pygmy-owl, with so many entities involved in how lands in Mexico are used and managed, it is complicated and, sometimes, unrealistic to implement widespread, consistent application of regulations that promote the conservation of pygmy-owls in Mexico.

Conservation Efforts

Cactus ferruginous pygmy-owl conservation activities have occurred sporadically over the past three decades in both the United States and in northern Sonora in Mexico. Initial conservation efforts developed effective and safe protocols for studying the cactus ferruginous pygmy-owl and on gathering basic life-history information. Efforts expanded in the late 1990s and early 2000s to include important pygmy-owl work in Arizona, Texas, and northern Sonora. For the past two decades, studies have been irregular and focused on monitoring of known territories.

Surveying and Monitoring

The Arizona Game and Fish Department (AGFD) initiated surveys to determine the extent of cactus ferruginous pygmy-owl occurrences in Arizona in 1992, when the cactus ferruginous pygmy-owl was first

petitioned to be listed under the Act. Survey and monitoring work by a variety of entities continued through 2006, when the species was delisted. Prior to delisting, survey and monitoring efforts were focused in Pima and Pinal Counties to document the occupancy pattern of cactus ferruginous pygmy-owls in areas of land use changes, primarily urban development. After the pygmy-owl was delisted in 2006, a small number of monitoring surveys continued to be conducted by Service and AGFD biologists. In 2020, AGFD coordinated a comprehensive survey effort, with the help of numerous partners, to gather data on the current numbers and distribution of the cactus ferruginous pygmy-owl in Arizona to inform this listing decision. Specifically, this effort included surveys to document distribution, territory occupancy monitoring, and some nest searches to document reproduction. This latest effort provided data on current distribution of the pygmy-owl in Arizona and the number of occupied territories, as well as some information on the number of active nesting territories (AGFD 2020, pers. comm.). These data are incorporated into the SSA report. However, these efforts did not provide any information on productivity or survival at these sites.

Nest Box Trials

Because cactus ferruginous pygmy-owls are secondary cavity nesters, the number of available cavities may influence the viability of cactus ferruginous pygmy-owls on the landscape (Proudfoot 1996, p. 68). Using nest boxes as a management tool may enhance the viability of cactus ferruginous pygmy-owls by increasing cavity availability and reducing predation. Nest boxes also enhance access to the owls during nesting and facilitate our ability to conduct research. Research in Texas demonstrated successful use of artificial nest structures by cactus ferruginous pygmy-owls (Proudfoot et al. 1999, pp. 5–6). In response to concerns about cavity availability, two nest box trials were conducted in Arizona in 1998 and 2006. No cactus ferruginous pygmy-owls used the nest boxes in these studies, but low cavity availability was confirmed based on high use of the nest boxes by other species, including screech owls. No additional nest box studies have been undertaken in Arizona, and the nest box study in Texas is no longer active.

Captive Breeding and Population Augmentation

A pygmy-owl captive-breeding feasibility study was initiated by the AGFD in partnership with the Wild at Heart raptor care facility in Cave Creek, Arizona, in 2006. Since then, Wild at Heart has been researching and testing protocols for a managed breeding program for cactus ferruginous pygmy-owls. In 2017, the Phoenix Zoo became the second captive breeding site for pygmy-owls in Arizona and part of the managed breeding program when it entered into partnership with the Service and the AGFD. Both the AGFD and the Service oversee this program.

The goal of the managed breeding program for the cactus ferruginous pygmy-owl is to develop appropriate protocols for the husbandry and breeding of captive pygmy-owls to provide individuals to augment existing population groups or establish new population groups in areas where suitable habitat exists in Arizona (AGFD 2015, entire). To date, these efforts have demonstrated: (a) Successful capture and transport of wild cactus ferruginous pygmy-owls; (b) safe, healthy, and stress-free captive facilities; (c) the development of appropriate care, feeding, and maintenance protocols; (d) successful breeding; and (e) appropriate care and development of young-of-the-year birds. Three pilot releases of captive-bred pygmy-owls have been implemented since the inception of this program. This effort establishes the first formal captive-breeding for the subspecies and provides the groundwork for evaluation of this strategy in wild cactus ferruginous pygmy-owl population augmentation. These pilot releases have not resulted in the establishment of new pygmy-owl territories or population groups, but have contributed valuable information to developing appropriate release strategies and protocols to improve the potential for conservation benefits to the pygmy-owl in the future.

Conservation Planning

When the pygmy-owl was listed previously, several municipalities located within current or historical pygmy-owl activity areas explored or implemented habitat conservation plans (HCPs) under the Act to address potential conflicts between development projects and requirements of the Act. These HCP plans included the Sonoran Desert Conservation Plan (Multi-Species Conservation Plan) developed by Pima County (Pima County 2016, entire), the Town of Marana HCP (Town of Marana 2009, entire), and the City of Tucson's Avra Valley (City of Tucson 2019, entire) and Southlands HCPs (City of Tucson 2013, entire). Each of these four HCP efforts identified the cactus ferruginous pygmy-owl as one of the covered species within their plans. However, most of these plans have yet to be completed: To date, only the Pima County HCP has been completed and is being implemented. Pima County is currently conducting ongoing surveys and monitoring of pygmy-owl territories on county-managed lands and has set aside pygmy-owl habitat as part of their conservation lands system in compliance with their HCP. The establishment of these conservation lands is an important contribution to pygmy-owl conservation in Pima County, but continuing efforts are needed to address other threats such as habitat impacts from climate change. Pima County's efforts are expected to continue for the 30-year life of their permit (through 2046) and longer if the County renews the permit.

Another ongoing conservation planning effort that has the potential to support pygmy-owl conservation in the Altar Valley of southern Arizona is the Altar Valley Watershed Management Plan. This plan being developed by the Altar Valley Conservation Alliance with numerous partners and participants builds upon existing efforts within the Altar Valley to restore and enhance the watershed. The plan will describe stewardship practices and identify a series of high-priority projects that maximize positive impacts on the land. While this planning effort has yet to be completed, projects related to watershed restoration have been implemented at three ranches in the Altar Valley. These projects have included one-rock dams and other structures to stabilize waterways, road grading to promote water harvesting, and enhancement of grasslands through invasive species control to promote infiltration and reduce runoff and sedimentation. These actions improve vegetation health through increased water infiltration and reduce loss of soil and vegetation due to erosion. Specific benefits occur to riparian vegetation along drainages enhancing pygmy-owl habitat conditions and connectivity.

In Mexico, there are Federal, State, or municipal protected areas which comprise approximately 11 percent of the historical pygmy-owl range in Mexico. These areas can work well as conservation strategies for the cactus ferruginous pygmy-owl. There is now a new option for protected areas called Voluntary Conservation Areas (Áreas Destinadas Voluntariamente a la Conservación; ADVA), which are areas identified for conservation. These ADVA could be a potential conservation strategy for the pygmy-owl in the future (Enríquez 2021, pers. comm.).

Determination of Cactus Ferruginous Pygmy-Owl's Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an ''endangered species'' or a ''threatened species.'' The Act defines an ''endangered species'' as a species in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of an ''endangered species'' or a ''threatened species'' because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

Status Throughout All of Its Range

We examined the following threats to the cactus ferruginous pygmy-owl: Climate change and climate condition (Factor E), habitat loss and fragmentation (Factor A), human activities and disturbance (Factors B and E), human-caused mortality (Factors B and E), disease and predation (Factor C), and small population size (Factor E), and we determined that the primary threats to the subspecies are climate change and climate condition, and habitat loss and fragmentation. Existing regulatory mechanisms (Factor D) and conservation efforts do not address the threats to the cactus ferruginous pygmy-owl to the extent that listing the subspecies is not warranted.

Population resiliency is highly variable across the range of the pygmy-owl. Overall, three analysis units maintain a moderate level of resiliency, with western Mexico maintaining a high level of resiliency and Arizona with a low level of resiliency. Therefore, the majority of the analysis units we examined maintain some ability to withstand stochastic events. Additionally, the western Mexico and northeast Mexico analysis units are estimated to support tens of thousands of pygmy-owls. Due to the broad geographic distribution and network of population groups that are connected within and between some analysis units throughout most of its range, the pygmy-owl has some ability to recolonize following catastrophic events and is considered to have adequate redundancy. Additionally, the cactus ferruginous pygmy-owl currently has high genetic and ecological variability across the range. This ecological diversity provides the subspecies with sufficient representation and may allow the pygmy-owl to adapt to, and survive, future environmental change.

After evaluating threats to the subspecies and assessing the cumulative effect of the threats under the Act's section 4(a)(1) factors, we conclude that the risk factors acting on the cactus ferruginous pygmy-owl and its habitat, either singly or in combination, are not of sufficient imminence, intensity, or magnitude to indicate that the subspecies is in danger of extinction now (an endangered species) throughout all of its range. Despite current stressors, the subspecies currently maintains adequate resiliency, redundancy, and representation across the range such that the subspecies is currently able to withstand stochastic and catastrophic events and maintain adequate genetic and ecological variation throughout its range.

However, our analysis of the cactus ferruginous pygmy-owl's future conditions shows that the threats to the subspecies are likely to continue into the future, resulting in continued loss and fragmentation of habitat putting the species at risk of extinction within the foreseeable future.

Under all future scenarios, we project a continued reduction in species viability throughout the range of the subspecies due to climate change, habitat loss, and habitat fragmentation. In 30 years, even under our most optimistic scenario, the reduced effects scenario, there will be no analysis units in high condition. This represents a decrease from current conditions with one analysis unit declining from high to moderate condition, and one analysis unit declining from moderate to low condition. Additionally, despite maintaining their current condition categories over the next 30 years, habitat and demographic conditions within the other three analysis units continue to decline. Over the next 30 years, many of the analysis units will become increasingly vulnerable to extirpation through the degradation of habitat conditions. We anticipate that urbanization and development will continue under all future scenarios and in all analysis units. Invasive species will continue to spread into pygmy-owl habitat in most analysis units and deforestation and wood harvesting will continue in all three analysis units in Mexico. Continued loss and degradation of pygmy-owl habitat will reduce overall species resiliency, impeding the ability of the subspecies to withstand stochastic events and increasing the risk of extirpation following such events. The loss of population groups will lead to a reduction in representation, reducing the subspecies' ability to adapt over time to changes in the environment, such as climate changes. This expected reduction in both the number and distribution of sufficiently resilient population groups will reduce redundancy and impede the ability of the subspecies to recolonize following catastrophic disturbance. Thus, after assessing the best available information, we conclude that the cactus ferruginous pygmy-owl is not currently in danger of extinction but is likely to become in danger of extinction within the foreseeable future throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. The court in *Center for Biological Diversity* v. *Everson,* 2020 WL 437289 (D.D.C. Jan. 28, 2020) *(Center for Biological Diversity),* vacated the aspect of the Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species'' (79 FR 37578; July 1, 2014) that provided that the Service does not undertake an analysis of significant portions of a species' range if the species warrants listing as threatened throughout all of its range. Therefore, we proceed to evaluating whether the species is endangered in a significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant; and (2) the species is in danger of extinction in that portion. Depending on the case, it might be more efficient for us to address the ''significance'' question or the ''status'' question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

Following the court's holding in *Center for Biological Diversity,* we now consider whether there are any significant portions of the species' range where the species is in danger of

extinction now (*i.e.,* endangered). In undertaking this analysis for cactus ferruginous pygmy-owl, we choose to address the status question first—we consider information pertaining to the geographic distribution of both the species and the threats that the species faces to identify any portions of the range where the species is endangered.

The statutory difference between an endangered species and a threatened species is the timeframe in which the species becomes in danger of extinction; an endangered species is in danger of extinction now while a threatened species is not in danger of extinction now but is likely to become so in the foreseeable future. Thus, we reviewed the best scientific and commercial data available regarding the time horizon for the threats that are driving the cactus ferruginous pygmy-owl to warrant listing as a threatened species throughout all of its range. We considered whether the threats are geographically concentrated in any portion of the species' range in a way that would accelerate the time horizon for the species' exposure or response to the threats. We examined the following threats: Climate change and climate condition (Factor E) and habitat loss and fragmentation (Factor A), including cumulative effects.

We found a concentration of threats, *i.e.,* the impacts of climate change, urbanization, and invasive species, in the Sonoran Desert Ecoregion, which extends from Arizona south into Sonora, Mexico. Climate change impacts to the pygmy-owl in the Sonoran Desert Ecoregion are likely to include loss of vegetation cover, reduced prey availability, increased predation, reduced nest site availability, and vegetation community change. For example, models predict that the distribution of suitable habitat for saguaros, the primary pygmy-owl nesting substrate within the Sonoran Desert Ecoregion, will substantially decrease over the next 50 years under a moderate climate change scenario (Weiss and Overpeck 2005, p. 2074; Thomas et al. 2012, p. 43).

Climate models project that, by the end of the 21st century, the Sonoran Desert will experience an increase in drought conditions with a transition to a drier and more arid climate (Seager et al. 2007, p. 9; Cook et al. 2015, p. 6; Pascale et al. 2017, p. 806; Williams et al. 2020, p. 317). Given that this portion of the pygmy-owl's overall range is already characterized by arid and hot conditions and is in the midst of an extended drought, the effects from climate change represent a higher concentration of effects than in other portions of the pygmy-owl's range, which generally are characterized by higher precipitation and lower temperatures resulting in a baseline of higher greenness and vegetation health. In general, annual precipitation in the Sonoran Desert is positively correlated to pygmy-owl productivity (Flesch et al. 2015, p. 26). Timing and quantity of precipitation affects lizard and rodent abundance in ways that suggest rainfall is an important driver of prey population and community dynamics. In general, cool-season rainfall is positively correlated with rodent populations and warm-season rainfall is positively correlated with lizard populations. Projected increases in variability and decreases in quantity of precipitation will likely lead to a decrease in prey abundance for the pygmy-owl (Jones 1981, p. 111; Flesch 2008, p. 5; Flesch et al. 2015, p. 26).

Urban expansion and human population growth trends are expected to continue in the Sonoran Desert Ecoregion. The Maricopa-Pima-Pinal County areas of Arizona are expected to see the population grow by as much as 132 percent between 2005 and 2050, creating rural-urban edge effects across thousands of acres of pygmy-owl habitat (AECOM 2011, p. 13).

The population along the U.S.-Mexico border region from Texas to California is expected to double by 2025 (HHS 2017, p. 1). In Arizona, the border counties are projected to increase by 60 percent to 2.5 million by 2050 (OEO 2021, unpaginated). In Sonora the population is projected to reach 3.5 million by 2030 (CONAPO 2014, p. 25). Development is focused along the border and this area of northern Mexico has faster population growth than other Mexican states (Pineiro 2001, pp. 1–2). This development focuses potential barriers or impediments to pygmy-owl movements in a region that is important for demographic support (immigration events and gene flow) of pygmy-owl population groups, including movements such as dispersal. If urban expansion and development continues as expected, it will encompass a substantial portion of the current distribution of the pygmy-owl in the Sonoran Desert Ecoregion.

The invasion of nonnative vegetation, particularly nonnative grasses, has altered the natural fire regime over the Sonoran Desert Ecoregion portion of the pygmy-owl's range. Buffelgrass is prevalent and increasing throughout much of this portion of the pygmy-owl's range, leading to increased fire frequency in a system that is not adapted to fire (Schmid and Rogers 1988, p. 442; D'Antonio and Vitousek 1992, p. 73; Burquez and Quintana 1994, p. 23; Halverson and Guertin 2003, p. 13; Van Devender and Dimmit 2006, p. 5). While a single fire in an area may or may not produce long-term reductions in plant cover or biomass, repeated wildfires in a given area are capable of ecosystem type-conversion from native desertscrub to nonnative annual grassland. These repeated fires may render the area unsuitable for pygmy-owls and other native wildlife due to the loss of trees and columnar cacti, and reduced diversity of cover and prey species (Brooks and Esque 2002, p. 336).

Despite the current concentration of threats and their increasing effects to pygmy-owls and pygmy-owl habitat, the Sonoran Desert Ecoregion currently supports an abundance of pygmy-owls in the high hundreds and a moderate amount of intact, suitable vegetation. Consequently, these factors are currently maintaining an overall moderate level of resiliency in this portion of the range. Additionally, there is currently habitat connectivity with evidence of pygmy-owl movement among population groups, providing redundancy throughout the Sonoran Desert Ecoregion. Representation is also currently being maintained through pygmy-owl occupancy of a variety of vegetation types throughout the Sonoran Desert Ecoregion with gene flow among these population groups. However, under all three future scenarios, this portion of the range is expected to become less resilient due to continued habitat fragmentation and the effects of climate change on habitat conditions, resulting in a reduction of pygmy-owl abundance and occupancy. These deteriorating conditions are also anticipated to result in declines in redundancy and representation through the loss of population groups within the Ecoregion.

Although some threats to the cactus ferruginous pygmy-owl are concentrated in the Sonoran Desert Ecoregion, the best scientific and commercial data available does not indicate that the concentration of threats, or the species' responses to the concentration of threats, are likely to accelerate the time horizon in which the species becomes in danger of extinction in that portion of its range. As a result, the cactus ferruginous pygmy-owl is not in danger of extinction now in the Sonoran Desert Ecoregion. However, we do find that the species is likely to become in danger of extinction within the foreseeable future throughout all of its range. This finding is consistent with the courts' holdings in *Desert Survivors* v. *Department of the Interior,* No. 16–cv–01165–JCS, 2018

WL 4053447 (N.D. Cal. Aug. 24, 2018), and *Center for Biological Diversity* v. *Jewell,* 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017).

Determination of Status

Our review of the best available scientific and commercial information indicates that the cactus ferruginous pygmy-owl meets the Act's definition of a threatened species. Therefore, we propose to list the cactus ferruginous pygmy-owl as a threatened species in accordance with sections 3(20) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Section 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning consists of preparing draft and final recovery plans, beginning with the development of a recovery outline and making it available to the public within 30 days of a final listing determination. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan also identifies recovery criteria for review of when a species may be ready for reclassification from endangered to threatened (''downlisting'') or removal from protected status (''delisting'') and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. If we adopt this rule as proposed, when completed, the recovery outline, draft recovery plan, and the final recovery plan for the cactus ferruginous pygmy-owl will be available on our website (*http://www.fws.gov/endangered*), or from our Arizona Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

If this species is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the States of Arizona and Texas would be eligible for Federal funds to implement management actions that promote the protection or recovery of the cactus ferruginous pygmy-owl. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Section 8(a) of the Act (16 U.S.C. 1537(a)) authorizes the provision of limited financial assistance for the development and management of programs that the Secretary of the Interior determines to be necessary or useful for the conservation of endangered or threatened species in foreign countries. Sections 8(b) and 8(c) of the Act (16 U.S.C. 1537(b) and (c)) authorize the Secretary to encourage conservation programs for foreign listed species, and to provide assistance for such programs, in the form of personnel and the training of personnel.

Although the cactus ferruginous pygmy-owl is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for this subspecies. Additionally, we invite you to submit any new information on this subspecies whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph include management and any other landscape-altering activities on Federal lands administered, or on private lands seeking funding, by Federal agencies, which may include, but are not limited to, the Department of the Interior's U.S. Fish and Wildlife Service, Bureau of Land Management, and National Park Service (Organ Pipe Cactus National Monument and Ironwood Forest National Monument); the Department of Defense's (Barry M. Goldwater Air Force Range) and U.S. Army Corps of Engineers (for issuance of section 404 Clean Water permits); the U.S. Department of Agriculture's U.S. Forest Service, Natural Resources Conservation Service, and Farm Service Agency; and construction and maintenance of roads or highways by the Federal Highway Administration.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR

34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of the species proposed for listing. The discussion below regarding protective regulations under section 4(d) of the Act complies with our policy.

II. Proposed Rule Issued Under Section 4(d) of the Act

Background

Section 4(d) of the Act contains two sentences. The first sentence states that the Secretary shall issue such regulations as he [or she] deems necessary and advisable to provide for the conservation of species listed as threatened. The U.S. Supreme Court has noted that statutory language like ''necessary and advisable'' demonstrates a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592 (1988)). Conservation is defined in the Act to mean the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Additionally, the second sentence of section 4(d) of the Act states that the Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants. Thus, the combination of the two sentences of section 4(d) provides the Secretary with wide latitude of discretion to select and promulgate appropriate regulations tailored to the specific conservation needs of the threatened species. The second sentence grants particularly broad discretion to the Service when adopting the prohibitions under section 9.

The courts have recognized the extent of the Secretary's discretion under this standard to develop rules that are appropriate for the conservation of a species. For example, courts have upheld rules developed under section 4(d) as a valid exercise of agency authority where they prohibited take of threatened wildlife, or include a limited taking prohibition (see *Alsea Valley Alliance* v. *Lautenbacher,* 2007 U.S. Dist. Lexis 60203 (D. Or. 2007); *Washington Environmental Council* v. *National Marine Fisheries Service,* 2002 U.S. Dist. Lexis 5432 (W.D. Wash. 2002)). Courts have also upheld 4(d) rules that do not address all of the threats a species faces (see *State of Louisiana* v. *Verity,* 853 F.2d 322 (5th Cir. 1988)). As noted in the legislative history when the Act was initially enacted, ''once an animal is on the threatened list, the Secretary has an almost infinite number of options available to him [or her] with regard to the permitted activities for those species. He [or she] may, for example, permit taking, but not importation of such species, or he [or she] may choose to forbid both taking and importation but allow the transportation of such species'' (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

Exercising this authority under section 4(d), we have developed a proposed rule that is designed to address the cactus ferruginous pygmy-owl's conservation needs. Although the statute does not require us to make a ''necessary and advisable'' finding with respect to the adoption of specific prohibitions under section 9, we find that this proposed rule as a whole satisfies the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of the cactus ferruginous pygmy-owl. Because of the large geographic range of the cactus ferruginous pygmy-owl, different portions of the geographic range are affected by different types and extent of threats and stressors. Therefore, it is feasible that exceptions under this proposed 4(d) rule may be different for the different analysis units described in the SSA report. We encourage public comment providing support for the potential application of different exceptions in different portions of the cactus ferruginous pygmy-owl's geographic range.

As discussed above under Summary of Biological Status and Threats, we have concluded that the cactus ferruginous pygmy-owl is likely to become in danger of extinction within the foreseeable future primarily due to a loss of vegetation cover, reduced prey availability, increased predation, reduced nest site availability, and vegetation community change resulting from ongoing climate change, particularly increases in drought conditions, as well as due to habitat loss and fragmentation stemming from urbanization, agriculture, deforestation, and invasive species. This proposed 4(d) rule identifies the prohibitions needed to conserve the cactus ferruginous pygmy-owl.

We considered the range of potential activities that may potentially affect the cactus ferruginous pygmy-owl's status and viability. There is a very wide range of such potential activities including, but not limited to, commercial and residential development, infrastructure development and maintenance, utility work, activities related to border infrastructure and enforcement, grazing and ranching activities, activities conducted under Clean Water Act permits, mining, flood control activities, recreation, and activities conducted under land management plans. There is also a wide range of factors that affect the implementation of each of these activity types resulting in unique circumstances that we considered in developing proposed 4(d) rule exceptions. Ultimately, we find that it is appropriate to extend the standard section 9 prohibitions for endangered species to the cactus ferruginous pygmy-owl in order to conserve the subspecies.

However, while developing this proposed 4(d) rule, the Service considered exceptions to the standard section 9 prohibitions for endangered species that would facilitate essential conservation actions needed for the cactus ferruginous pygmy-owl. We consider essential conservation efforts to include facilitating surveys and monitoring of cactus ferruginous pygmy-owl population groups; enabling research to better understand cactus ferruginous pygmy-owl's needs and stressors (including the use of nest boxes and captive breeding); conducting education and outreach activities to increase public awareness and support of cactus ferruginous pygmy-owl conservation and recovery; and encouraging management of the landscape in ways that meet both land management considerations and the conservation needs of the cactus ferruginous pygmy-owl. Such land management considerations potentially include restoration and habitat improvement actions (including nonnative, invasive species management), watershed improvements, and grazing management that is compatible with cactus ferruginous pygmy-owl habitat enhancement and restoration, provided pygmy-owl habitat enhancement and restoration is identified as a significant outcome of the management actions and such actions are coordinated with the Service.

For the purposes of this proposed rule and our SSA analysis, we consider surveying and monitoring activities necessary to understand and implement cactus ferruginous pygmy-owl conservation and recovery. We currently lack data on the current numbers, density, and distribution of the cactus ferruginous pygmy-owl across its defined geographic range in both the United States and Mexico. We also lack comprehensive data on the productivity,

survival, mortality, and other natural-history characteristics of the cactus ferruginous pygmy-owl. Such data have been gathered historically, but only in local areas and primarily only in the United States and northern Sonora. Where we have data on occurrence, numbers, density, and natural-history variables, they allow us to better understand the status of the cactus ferruginous pygmy-owl and what actions are necessary to conserve population groups and enhance status and viability. Surveying and monitoring activities can result in short-term effects to cactus ferruginous pygmy-owls and, potentially, in the take of individuals and nest sites. We want to encourage more comprehensive and widespread surveying and monitoring activities across the geographic range of the cactus ferruginous pygmy-owl, and thus, we are considering providing an exception for this action in the 4(d) rule. This exception could occur by recognizing State authority to issue a permit to conduct call broadcast surveys and monitoring and nest monitoring for listed species. This state permitting would ensure oversight for surveyor and monitor qualifications, as well as data submission to the State agencies. Thus, an exception to the prohibitions of take could be granted under the 4(d) rule if the surveyors and monitors possessed a valid state permit, if required. If a State permit is not required to conduct call broadcast surveys and monitoring and nest monitoring, such activities could require a Federal 10(a)(1)(A) permit. We are considering this approach to recognize State authorities and streamline permitting processes. This exception would not cover any activities that involve the handling of pygmy-owls. We encourage public and agency comments related to our consideration of using the State permitting process in the 4(d) rule as the basis of an exception to the prohibitions on take related to pygmy-owl survey and monitoring activities.

Similar to surveying and monitoring, research related to all aspects of cactus ferruginous pygmy-owl natural history are needed to fill in information gaps and improve our understanding of the needs and stressors of the cactus ferruginous pygmy-owl to be able to identify and implement effective conservation and recovery actions. This includes research into the effectiveness of a managed breeding program for the pygmy-owl.

Because research that involves the capture, handling, marking, human care, tissue sample collection, etc., of pygmy-owls may result in the direct take of cactus ferruginous pygmy-owls, it is necessary to require those implementing these actions to have the appropriate background, expertise, and equipment and materials to implement these activities. We find that these activities are best administered through our section 10 permitting process (under the Act's section 10(a)(1)(A)). This permitting process allows us to assess the appropriateness of the proposed projects and activities with regard to promoting the conservation of the cactus ferruginous pygmy-owl; ensure the competency of those conducting the activities; reduce the potential for redundancy of effort and overlapping effects to cactus ferruginous pygmy-owls; and facilitate the opportunity to receive, analyze, and incorporate the most current information into conservation and recovery actions.

Restoration and habitat improvement actions are those actions that convert areas that are otherwise not habitat for the cactus ferruginous pygmy-owl to areas that are cactus ferruginous pygmy-owl habitat or actions that improve areas of lesser quality cactus ferruginous pygmy-owl habitat to areas of higher quality cactus ferruginous pygmy-owl habitat. These actions are essential for the subspecies, as this is the only way to offset habitat loss and fragmentation. For the cactus ferruginous pygmy-owl, the primary restoration or habitat improvement actions include, but are not limited to, placement of nest boxes, restoration of native species, establishment or protection of nesting substrates (large trees and columnar cacti), invasive species control, riparian enhancement, water developments, watershed improvements, improved habitat connectivity, and fire management. Because we want to encourage the implementation of cactus ferruginous pygmy-owl habitat restoration and enhancement, we are proposing in the 4(d) rule an exemption to the take of cactus ferruginous pygmy-owls that may result from such activities, as described below. In order to receive this exemption, the habitat restoration and improvement projects must be coordinated with, and receive approval from, the Service prior to work commencing.

Education and outreach activities allow cactus ferruginous pygmy-owl conservation partners to present information to various segments of the public related to ongoing conservation and management activities and programs. Public awareness of the cactus ferruginous pygmy-owl's biology, ecology, and threats helps foster support for recovery program activities across the geographic range of the cactus ferruginous pygmy-owl. Increasing the prevailing understanding of how recovery activities for the cactus ferruginous pygmy-owl improve the health, function, and quality of the environments where they are found, as well as the human communities located in proximity to occupied cactus ferruginous pygmy-owl habitat, will strengthen support for continued conservation of the pygmy-owl and for the habitats upon which it depends. Education and outreach will also serve to counteract incorrect narratives that conservation of the cactus ferruginous pygmy-owl is responsible for preventing activities and development that positively affect the area's social and economic well-being. Allowing the public to personally see pygmy-owls through the use of educational animals can result in take of individuals. The potential for this type of take is already addressed through the issuance of a Migratory Bird Treaty Act (MBTA) permit and we are proposing to streamline permitting by acknowledging the existing MBTA process in this proposed 4(d) rule. Such education and outreach programs can increase public awareness, engagement, and support for cactus ferruginous pygmy-owl conservation and recovery. Such benefits outweigh the effects to individual pygmy-owls.

Finally, we considered the need for compatibly managed grazing activities that result in the vegetation structure and composition needed to support the cactus ferruginous pygmy-owl. The habitat needs for the cactus ferruginous pygmy-owl vary across the subspecies' geographic range, and grazing can affect these habitats in different ways. It is important that grazing is managed at a given site to account for a variety of factors specific to the local ecological site, including past management, soils, precipitation, and other factors, to ensure that the resulting vegetative composition and structure will support the cactus ferruginous pygmy-owl. Grazing management that has altered the vegetation community to a point where the composition and structure are no longer suitable for cactus ferruginous pygmy-owls can contribute to habitat loss and fragmentation within the landscape, even though these areas may remain as open space on the landscape. Livestock grazing, however, is not inherently detrimental to the cactus ferruginous pygmy-owl, provided that grazing management results in a plant community with species and structural diversity suitable for the cactus ferruginous pygmy-owl. When livestock grazing is managed compatibly, it can be an invaluable tool for managing healthy

vegetation communities benefiting the cactus ferruginous pygmy-owl.

While developing this proposed 4(d) rule, we determined that grazing management has to occur on the local level, and thus broad determinations within this proposed 4(d) rule would not be beneficial to the species or local land managers. While the 4(d) rule was one approach considered to promote conservation of the cactus ferruginous pygmy-owl by encouraging management of vegetation communities in ways that support both long-term viability of livestock enterprises and concurrent conservation of pygmy-owls, we determined that other mechanisms under our authorities would be more appropriate to support this action. Besides a 4(d) rule, other mechanisms supporting conservation opportunities exist in other portions of the Act and our policies, including under the Act's section 7(a) (Federal Agency Actions and Consultations), the Act's section 10(a) (Permits), and our conservation banking program. We recognize the value of compatibly managed grazing for the cactus ferruginous pygmy-owl, and we look forward to working with our partners and local land managers to ensure there are viable conservation options that provide regulatory coverage for interested landowners. We encourage public comments related to the issue of properly managed grazing and the appropriate best approach for addressing livestock grazing and management within the range of tools available.

As indicated above, the provisions of this proposed 4(d) rule are one of many tools that we would use to promote the conservation of the cactus ferruginous pygmy-owl. This proposed 4(d) rule would apply only if and when we make final the listing of the cactus ferruginous pygmy-owl as a threatened species.

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, Tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat—and actions on State, Tribal, local, or private lands that are not federally funded, authorized, or carried out by a Federal agency—do not require section 7 consultation.

This obligation does not change in any way for a threatened species with a species-specific 4(d) rule. Actions that result in a determination by a Federal agency of ''not likely to adversely affect'' continue to require the Service's written concurrence and actions that are ''likely to adversely affect'' a species require formal consultation and the formulation of a biological opinion.

Provisions of the Proposed 4(d) Rule

This proposed 4(d) rule would provide for the conservation of the cactus ferruginous pygmy-owl by prohibiting the following activities, except as otherwise authorized or permitted: Importing or exporting; take; possession and other acts with unlawfully taken specimens; delivering, receiving, transporting, or shipping in interstate or foreign commerce in the course of commercial activity; or selling or offering for sale in interstate or foreign commerce. In addition, anyone taking, attempting to take, or otherwise possessing a cactus ferruginous pygmy-owl, or parts thereof, in violation of section 9 of the Act would be subject to a penalty under section 11 of the Act, with certain exceptions (discussed below).

Under the Act, ''take'' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Some of these provisions have been further defined in regulations at 50 CFR 17.3. Take can result knowingly or otherwise, by direct and indirect impacts, intentionally or incidentally. Regulating take that occurs incidental to otherwise lawful activities (section 7 consultations with Federal action agencies) would help to conserve and recover the cactus ferruginous pygmy-owl by evaluating the potential of various activities to adversely affect or otherwise decrease the viability of the cactus ferruginous pygmy-owl. As mentioned above, a wide variety of lawful activities and projects have the potential to negatively affect the viability of this subspecies: Disturbance, loss and fragmentation of habitat, reduction of prey species, loss of nesting substrates, introduction of nonnative predators and competitors, and other similar effects. By regulating these types of activities and projects, we can conserve the subspecies' remaining habitat and populations; slow the rate of habitat loss and fragmentation; slow the subspecies' rate of decline; and decrease synergistic, negative effects from other ongoing future threats.

Conversely, allowing incidental and intentional take for certain activities allow us to promote pygmy-owl conservation and improve pygmy-owl habitat. For example, habitat restoration and improvement works to offset losses and fragmentation of habitat from factors related to climate change and human land uses on the landscape. Education and outreach efforts help to increase public awareness and understanding and to garner support for conservation and recovery of the cactus ferruginous pygmy-owl. Thus, benefits to the cactus ferruginous pygmy-owl are derived both from regulating certain sources of potential take and by excepting certain take for activities where benefits outweigh the short-term effects of the take on cactus ferruginous pygmy-owl populations.

As discussed above under Summary of Biological Status and Threats, the loss of vegetation cover, reduced prey availability, increased predation, reduced nest site availability, and vegetation community change resulting from ongoing climate change, particularly increases in drought conditions, and habitat loss and fragmentation stemming from urbanization, agriculture, deforestation, and invasive species are affecting the status of the cactus ferruginous pygmy-owl. We have identified various activities that have the potential to help us understand and offset the activities affecting the cactus ferruginous pygmy-owl's viability. Therefore, a range of conservation activities, including education and outreach related to cactus ferruginous pygmy-owl recovery, and management of the landscape in ways that meet both land management considerations and the conservation needs of the cactus ferruginous pygmy-owl, have the potential to benefit the cactus ferruginous pygmy-owl. Such land management considerations potentially include restoration and habitat improvement actions, watershed

improvements, and grazing management that is compatible with cactus ferruginous pygmy-owl habitat enhancement and restoration, provided such habitat enhancement and restoration is identified as a significant outcome of the management actions and such actions are coordinated with the Service and appropriate State and Tribal agencies and landowners. Accordingly, this proposed 4(d) rule addresses activities to facilitate conservation and management of the cactus ferruginous pygmy-owl where the activities currently occur and may occur in the future by excepting the activities from the Act's take prohibition under certain specific conditions. These activities are intended to increase management flexibility and encourage support for conservation of, habitat restoration for, and habitat improvement for the cactus ferruginous pygmy-owl.

Under this proposed 4(d) rule, most take would be prohibited. Exceptions to the prohibitions on take would include some of the general exceptions allowed for take of endangered wildlife as set forth is 50 CFR 17.21 (see the rule portion of this document) and certain other specific activities that we propose for exception, as described below. The excepted activities would require approval by the Service or would have to be conducted under an existing, appropriate, valid permit issued under part 21 of title 50 of the Code of Federal Regulations, which governs species protected under the MBTA, as described below. These activities should be conducted in coordination with appropriate land management agencies; State, Tribal, and local agencies; and private landowners, as appropriate, and in support of any existing or future designated recovery programs guiding the conservation and recovery of the cactus ferruginous pygmy-owl. The following activities would be excepted from the take prohibitions for the pygmy-owl (*i.e.,* take would be allowed for these activities) under this proposed 4(d) rule.

Education and Outreach

Education and outreach are a vital part of cactus ferruginous pygmy-owl recovery and progress towards achieving and maintaining viable populations of cactus ferruginous pygmy-owls. This proposed 4(d) rule excepts from take prohibitions those cactus ferruginous pygmy-owl education and outreach activities undertaken for the purposes of increasing public awareness of cactus ferruginous pygmy-owl biology, ecology, or recovery needs, as well as of the positive effects of having pygmy-owls as a viable part of the local ecosystems on the local society, economy, and quality of life for communities. Such educational activities may include use of educational captive-reared cactus ferruginous pygmy-owls, pygmy-owl skins, or parts of pygmy-owls. These activities raptors are typically covered by a permit issued under 50 CFR part 21, which governs species protected under the MBTA. To remove redundant permitting, this proposed 4(d) rule will cover incidental take resulting from educational and outreach activities, provided the researcher already holds an appropriate and valid MBTA permit issued under 50 CFR part 21. These activities can increase public awareness, engagement, and support for cactus ferruginous pygmy-owl conservation and recovery.

Education and outreach activities must be coordinated with the Service prior to commencing work. Coordination can occur in person, by phone, or through written communications. Education and outreach activities covered by this proposed 4(d) rule would have to be consistent with an existing designated recovery program, such as a final recovery plan, and benefit cactus ferruginous pygmy-owl conservation through increased public awareness and engagement, which supports cactus ferruginous pygmy-owl recovery. Education and outreach qualifying under this exception would not require a permit issued under section 10(a) of the Act.

Habitat Restoration and Enhancement

Incidental take resulting from habitat restoration or enhancement projects that improve the viability of cactus ferruginous pygmy-owl populations and population groups, and have been coordinated and approved by the Service, is excepted from the take prohibitions under this proposed 4(d) rule. Habitat restoration and enhancement projects are needed to increase nest site (cavity) availability; improve habitat connectivity among cactus ferruginous pygmy-owl population groups; increase prey availability; improve vegetation structure and health; and decrease nonnative species, watershed degradation and erosion, and habitat loss or reduction due to extreme weather events and wildfire.

This proposed 4(d) rule excepts from take prohibitions those habitat restoration or enhancement activities with the primary or secondary purpose of improving cactus ferruginous pygmy-owl habitat conditions across the subspecies' geographical range. Specific habitat restoration or enhancement actions could include nest box installation; establishment or protection of nesting substrates (large trees or columnar cacti) to increase the availability of nest cavities; restoration or enhancement of native vegetation structure and species; control or eradication of invasive, nonnative species; riparian enhancement or restoration; water developments; watershed improvements; improved habitat connectivity; and fire management.

Prescribed fire within Sonoran Desert vegetation communities is not excepted in the proposed 4(d) rule. Fire can be an effective tool in maintaining ecosystem health, which is beneficial to the cactus ferruginous pygmy-owl, but Sonoran Desert vegetation communities are not fire-adapted, and use of fire in these vegetation communities must be carefully implemented or important pygmy-owl habitat elements can be lost or altered. Therefore, because of the risks associated with the loss or alteration of pygmy-owl habitat, the use of fire in Sonoran Desert vegetation communities is not excepted from the take prohibitions under this proposed 4(d) rule.

Woody vegetation communities provide the most important pygmy-owl habitat factors, particularly woodland tree canopy cover. Pygmy-owl habitat is not typically enhanced by actions that would remove woodland tree cover. Such actions would normally reduce vegetation cover diversity, pygmy-owl prey diversity, and important predator avoidance and thermoregulatory cover for the pygmy-owl. Therefore, any action that would result in more than a minimal reduction or removal of tree cover (as determined during coordination with the Service) is not included under the habitat restoration or enhancement take exception in the proposed 4(d) rule.

Actions that promote the use of, or encourage the growth of, nonnative vegetation species are not exempted in the proposed 4(d) rule. Nonnative vegetation species can outcompete and replace native species that provide important habitat factors for the pygmy-owl. This outcome is particularly true when nonnative species form monocultures, resulting in low diversity and dense ground cover that alters natural fire regimes and reduces pygmy-owl prey diversity and availability.

In order to fall under the activities included under the habitat restoration or enhancement take exception in the proposed 4(d) rule, those persons implementing cactus ferruginous

pygmy-owl habitat enhancement and restoration activities need written approval from the Service. Prior to approving proposed activities, the Service will coordinate with the appropriate entities (land management agencies, Tribal entities, private landowners, etc.).

For all forms of allowable take in the proposed 4(d) rule, reasonable care will be practiced to minimize the impacts from the actions. Reasonable care means limiting the impacts to cactus ferruginous pygmy-owl individuals and populations by complying with all applicable Federal, State, and Tribal regulations for the activity in question; using methods and techniques that result in the least harm, injury, or death, as feasible; undertaking activities at the least impactful times (*e.g.,* conducting activities that might impact nesting cactus ferruginous pygmy-owls or nesting habitat only after nesting is concluded for the year) and locations, as feasible; procuring and implementing technical assistance from a qualified biologist on projects regarding all methods prior to the implementation of those methods; minimizing the number of individuals disturbed in the existing wild population; implementing best management practices to ensure no disease or parasites are introduced or spread in pygmy-owl populations, including the proper use of quarantine and health evaluations; and preserving the genetic diversity of wild populations.

Permitting and Other Regulations To Cover Take

We may issue permits to carry out otherwise prohibited activities, including those described above, involving threatened wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.32. With regard to threatened wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance propagation or survival, for economic hardship, for zoological exhibition, for educational purposes, for incidental taking, or for special purposes consistent with the purposes of the Act. The statute also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

We recognize the special and unique relationship with our State natural resource agency partners in contributing to conservation of listed species. State agencies often possess scientific data and valuable expertise on the status and distribution of endangered, threatened, and candidate species of wildlife and plants. State agencies, because of their authorities and their close working relationships with local governments and landowners, are in a unique position to assist the Service in implementing all aspects of the Act. In this regard, section 6 of the Act provides that the Service shall cooperate to the maximum extent practicable with the States in carrying out programs authorized by the Act. Therefore, any qualified employee or agent of a State conservation agency that is a party to a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by his or her agency for such purposes, would be able to conduct activities designed to conserve cactus ferruginous pygmy-owl that may result in otherwise prohibited take without additional authorization.

As described above, take can result by direct and indirect impacts, intentionally or incidentally. Section 7 of the Act regulates incidental take that occurs incidental to otherwise lawful activities, which have a nexus to a Federal action agency. Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. The Section 7 process helps to conserve and recover the cactus ferruginous pygmy-owl by evaluating the potential of various activities to adversely affect the cactus ferruginous pygmy-owl. Section 7 consultations ensure that Federal actions do not jeopardize the continued existence of the pygmy-owl and that proposed project activities include appropriate conservation measures or that reasonable and prudent measures are included to minimize the impacts of incidental take that is anticipated to result from implementing a project.

Nothing in this proposed 4(d) rule would change in any way the recovery planning provisions of section 4(f) of the Act, the consultation requirements under section 7 of the Act, or the ability of the Service to enter into partnerships for the management and protection of the cactus ferruginous pygmy-owl. However, interagency cooperation may be further streamlined through planned programmatic consultations for the species between Federal agencies and the Service, where appropriate. We ask the public, particularly State agencies and other interested stakeholders that may be affected by the proposed 4(d) rule, to provide comments and suggestions regarding additional guidance and methods that the Service could provide or use, respectively, to streamline the implementation of this proposed 4(d) rule (see Information Requested, above).

III. Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features.

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals). Additionally, our regulations at 50 CFR 424.02 define the word ''habitat,'' for the purposes of designating critical habitat only, as the abiotic and biotic setting that currently or periodically contains the resources and conditions necessary to support one or more life processes of a species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies

ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation also does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the Federal agency would be required to consult with the Service under section 7(a)(2) of the Act. However, even if the Service were to conclude that the proposed activity would result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement ''reasonable and prudent alternatives'' to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical or biological features that occur in specific occupied areas, we focus on the specific features that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. The implementing regulations at 50 CFR 424.12(b)(2) further delineate unoccupied critical habitat by setting out three specific parameters: (1) When designating critical habitat, the Secretary will first evaluate areas occupied by the species; (2) the Secretary will consider unoccupied areas to be essential only where a critical habitat designation limited to geographical areas occupied by the species would be inadequate to ensure the conservation of the species; and (3) for an unoccupied area to be considered essential, the Secretary must determine that there is a reasonable certainty both that the area will contribute to the conservation of the species and that the area contains one or more of those physical or biological features essential to the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information from the SSA report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge.

As the regulatory definition of ''habitat'' (50 CFR 424.02) reflects, habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act; (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and (3) the prohibitions found in section 9 of the Act. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of the species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, HCPs, or other species conservation planning efforts if new information available at the time of those planning efforts calls for a different outcome.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the Secretary may, but is not required to, determine that a designation would not be prudent in the following circumstances:

(i) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(ii) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through

management actions resulting from consultations under section 7(a)(2) of the Act;

(iii) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States;

(iv) No areas meet the definition of critical habitat; or

(v) The Secretary otherwise determines that designation of critical habitat would not be prudent based on the best scientific data available.

As discussed earlier in this document, there is currently no imminent threat of collection or vandalism identified under Factor B for this species, and identification and mapping of critical habitat is not expected to initiate any such threat. In our SSA report and proposed listing determination for the cactus ferruginous pygmy-owl, we determined that the present or threatened destruction, modification, or curtailment of habitat or range is a threat to cactus ferruginous pygmy-owl and that those threats in some way can be addressed by section 7(a)(2) consultation measures. Therefore, because none of the circumstances enumerated in our regulations at 50 CFR 424.12(a)(1) have been met and because the Secretary has not identified other circumstances for which this designation of critical habitat would be not prudent, we have determined that the designation of critical habitat is prudent for the cactus ferruginous pygmy-owl.

Critical Habitat Determinability

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for the cactus ferruginous pygmy-owl is determinable. Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Data sufficient to perform required analyses are lacking, or

(ii) The biological needs of the species are not sufficiently well known to identify any area that meets the definition of ''critical habitat.''

When critical habitat is not determinable, the Act allows the Service an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)).

We reviewed the available information pertaining to the biological needs of the species and habitat characteristics where this species is located. Careful assessments of the economic and environmental impacts that may occur due to a critical habitat designation are not yet complete, and we are in the process of working with the States and other partners in acquiring the complex information needed to perform those assessments. The information sufficient to perform a required analysis of the impacts of the designation is lacking. Therefore, we conclude that the designation of critical habitat for the cactus ferruginous pygmy-owl is not determinable at this time. As mentioned above, the Act allows the Service an additional year to publish a critical habitat designation that is not determinable at the time of listing (16 U.S.C. 1533(b)(6)(C)(ii)).

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act (42 U.S.C. 4321 *et seq.*)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes.

We contacted the Ak Chin Indian Community, Apache Tribe of Oklahoma, Cocopah Indian Tribe, Comanche Nation, Gila River Indian Community, Hopi Tribe, Pascua Yaqui Tribe, San Carlos Apache Tribe, Salt River Pima-Maricopa Indian Community, Tohono O'odam Nation, Tonkawa Tribe of Indians, White Mountain Apache Tribe, Wichita and Affiliated Tribes, and Yavapai Apache Nation regarding the SSA process by mail and invited them to provide information and comments to inform the SSA. Our interactions with these Tribes are part of our government-to-government consultation with Tribes regarding the pygmy-owl and the Act. The Tohono O'odham Nation was invited to participate as a member of the SSA team because they have historically participated on issues related to the cactus ferruginous pygmy-owl and they have extensive acreage of pygmy-owl habitat. They accepted the invitation and have participated in development of the SSA, as well as with pygmy-owls surveys and monitoring. We will continue to work with Tribal entities during the rulemaking process.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *http://www.regulations.gov* and upon request from the Arizona Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Arizona Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h) by adding an entry for ''Pygmy-owl, cactus ferruginous'' to the List of Endangered and Threatened Wildlife, in alphabetical order under Birds, to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
BIRDS				
*	*	*	*	*
Pygmy-owl, cactus ferruginous.	*Glaucidium brasilianum cactorum.*	Wherever found	T	[**Federal Register** citation when published as a final rule]; 50 CFR 17.41(l).[4d]
*	*	*	*	*

■ 3. As proposed to be amended at 83 FR 50560 (October 9, 2018), 85 FR 63474 (October 8, 2020), 86 FR 15855 (March 25, 2021), 86 FR 31668 (June 15, 2021), and 86 FR 41917 (August 4, 2021), § 17.41 is further amended by adding paragraph (l) to read as follows:

§ 17.41 Special rules—birds.

* * * * *

(l) Cactus ferruginous pygmy-owl *(Glaucidium brasilianum cactorum).* (1) *Prohibitions.* The following prohibitions that apply to endangered wildlife also apply to cactus ferruginous pygmy-owl. Except as provided under paragraphs (l)(2) and (3) of this section and §§ 17.4, 17.5, and 17.7, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or cause to be committed, any of the following acts in regard to this species:

(i) Import or export, as set forth at § 17.21(b) for endangered wildlife.

(ii) Take, as set forth at § 17.21(c)(1) for endangered wildlife.

(iii) Possession and other acts with unlawfully taken specimens, as set forth at § 17.21(d)(1) for endangered wildlife.

(iv) Interstate or foreign commerce in the course of commercial activity, as set forth at § 17.21(e) for endangered wildlife.

(v) Sale or offer for sale, as set forth at § 17.21(f) for endangered wildlife.

(2) *General exceptions from prohibitions.* In regard to this species, you may:

(i) Conduct activities as authorized by a permit under § 17.32.

(ii) Take, as set forth at § 17.21(c)(2) through (4) for endangered wildlife, and (c)(6) and (7) for endangered migratory birds.

(iii) Take as set forth at § 17.31(b).

(iv) Possess and engage in other acts with unlawfully taken wildlife, as set forth at § 17.21(d)(2) for endangered wildlife, and (d)(3) and (4) for endangered migratory birds.

(3) *Exceptions from prohibitions for specific types of incidental take.* You may take cactus ferruginous pygmy-owl while carrying out the following legally conducted activities in accordance with this paragraph (l)(3):

(i) Educational and outreach activities, provided the researcher already holds an appropriate, valid permit issued under part 21 of this chapter, which governs species protected under the Migratory Bird Treaty Act, for educational activities involving the use of live pygmy-owls, pygmy-owl skins, or parts of pygmy-owls or other raptors.

(ii) Habitat restoration and enhancement activities and projects that are approved by the Service prior to commencing work.

(A) These activities and projects may include activities that enhance cactus ferruginous pygmy-owl habitat conditions; improve habitat connectivity; increase availability of nest cavities; increase prey availability; reduce invasive, nonnative plant species; and enhance native plant communities, particularly woodland riparian communities.

(B) These activities and projects do not include prescribed fire within Sonoran Desert vegetation communities, any actions that would result in more than a minimal reduction or removal of tree cover (as determined by the Service), and actions that use or promote nonnative vegetation species.

(iii) For all forms of allowable take, reasonable care must be practiced to minimize the impacts from the actions. Reasonable care means:

(A) Limiting the impacts to cactus ferruginous pygmy-owl individuals and populations by complying with all applicable Federal, State, and Tribal regulations for the activity in question;

(B) Using methods and techniques that result in the least harm, injury, or death, as feasible;

(C) Undertaking activities at the least impactful times (*e.g.,* conducting activities that might impact nesting cactus ferruginous pygmy-owls or nesting habitat only after nesting is concluded for the year) and locations, as feasible;

(D) Procuring and implementing technical assistance from a qualified biologist on projects regarding all methods prior to the implementation of those methods;

(E) Minimizing the number of individuals disturbed in the existing wild population;

(F) Implementing best management practices to ensure no diseases or parasites are introduced into existing cactus ferruginous pygmy-owl populations; and

(G) Preserving the genetic diversity of wild populations.

Martha Williams,

Principal Deputy Director, Exercising the Delegated Authority of the Director, U.S. Fish and Wildlife Service.

[FR Doc. 2021–27516 Filed 12–21–21; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 86, No. 243
Wednesday, December 22, 2021

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Domestic Sugar Program—2022-Crop Overall Sugar Marketing Allotment, Cane Sugar and Beet Sugar Marketing Allotments and Company Allocations

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Notice.

SUMMARY: The United States Department of Agriculture (USDA) is issuing this notice to increase the fiscal year (FY) 2022 overall sugar marketing allotment quantity (OAQ), State cane sugar allotments, and revise company allocations to sugar beet and sugar cane processors, which apply to all domestic beet and cane sugar marketed for human consumption in the United States from October 1, 2021, through September 30, 2022.

FOR FURTHER INFORMATION CONTACT: Kent Lanclos, telephone, (202) 720–0114; or email, *kent.lanclos@usda.gov.* Persons with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice).

SUPPLEMENTARY INFORMATION: On September 30, 2021, USDA announced the initial fiscal year 2022 OAQ, which was established at 10,370,000 short tons, raw value, (STRV) equal to 85 percent of the estimated quantity of sugar for domestic human consumption for the fiscal year of 12,200,000 STRV as forecast in the September 2021 World Agricultural Supply and Demand Estimates report. The Agricultural Adjustment Act of 1938, as amended, requires that 54.35 percent of the OAQ be distributed among beet processors and 45.65 percent be distributed among the sugarcane States and cane processors.

Some beet processors anticipate that their FY 2022 beet sugar supplies will exceed their FY 2022 marketing allocation, a phenomenon known as ''blocked stocks.'' Given the expected large amount of blocked beet sugar stocks and current high sugar prices, USDA is increasing the FY 2022 OAQ to 10,802,657 STRV. The revised beet sector allotment is 5,871,244 STRV (an increase of 235,149) and the revised cane sector allotment is 4,931,413 STRV (an increase of 197,508). The revised beet and cane sector allotments are distributed to individual processors according to formulas contained in the authorizing legislation for the Sugar Program,[1] as shown in the Table below (see the column titled ''Preliminary Adjusted Allocation'').

FY 2022 Overall Beet/Cane Allotments and Allocations

[Short tons, raw values]

Distribution	Increase in OAQ			Reassignments	
	Initial FY 2022 allocation	Amount of allocation increase	Preliminary adjusted allocation	Reassigned amount	Adjusted FY 2022 allocation as of December 2021
Beet Sugars	5,636,095	235,149	5,871,244	0	5,871,244
Cane Sugar	4,733,905	197,508	4,931,413	0	4,931,413
Total OAQ	10,370,000	432,657	10,802,657	0	10,802,657
Beet Processors Marketing Allocations:					
Amalgamated Sugar Co	1,206,731	50,347	1,257,078	30,761	1,287,839
American Crystal Sugar Co	2,072,759	86,480	2,159,239	-86,480	2,072,759
Michigan Sugar Co	582,071	24,285	606,356	107,669	714,025
Minn-Dak Farmers Co-op	391,421	16,331	407,752	64,580	472,332
So. Minn Beet Sugar Co-op	760,693	31,738	792,431	-77,422	715,009
Western Sugar Co	575,228	24,000	599,228	-47,840	551,388
Wyoming Sugar Co. LLC	47,192	1,969	49,161	8,732	57,893
Total Beet Sugar	5,636,095	235,149	5,871,244	0	5,871,244
State Cane Sugar Allotments:					
Florida	2,544,366	106,156	2,650,522	0	2,650,522
Louisiana	1,968,353	82,124	2,050,477	0	2,050,477
Texas	221,186	9,228	230,414	0	230,414
Total Cane Sugar	4,733,905	197,508	4,931,413	0	4,931,413
Cane Processors' Marketing Allocation:					

[1] The authority for the Sugar Program is in 7 U.S.C. 1359aa–1359jj, 7272, and 8110; and 15 U.S.C. 714b and 714c.

FY 2022 OVERALL BEET/CANE ALLOTMENTS AND ALLOCATIONS—Continued

[Short tons, raw values]

Distribution	Increase in OAQ			Reassignments	
	Initial FY 2022 allocation	Amount of allocation increase	Preliminary adjusted allocation	Reassigned amount	Adjusted FY 2022 allocation as of December 2021
Florida					
Florida Crystals	1,047,582	43,707	1,091,290	0	1,091,290
Growers Co-op of FL	457,694	19,096	476,790	0	476,790
U.S. Sugar Crop	1,039,090	43,353	1,082,443	0	1082,443
Total	2,544,366	106,156	2,650,522	0	2,650,522
Louisiana					
Louisiana Sugar Cane Products, Inc	1,366,493	57,013	1,423,506	0	1,423,506
M.A. Patout & Sons	601,860	25,111	626,971	0	626,971
Total	1,968,353	82,124	2,050,477	0	2,050,477
Texas					
Rio Grande Valley	221,186	9,228	230,414	0	230,414

In accordance with section 359e of the Agricultural Adjustment Act of 1938, as amended, after evaluating each sugar beet processor's ability to market its full allocation after the OAQ increase, USDA is transferring allocations from beet sugar processors with surplus allocation to those with deficit allocation as shown in the Table above, in the column titled ''Adjusted FY 2022 Allocations as of December 2021.''

These actions will result in a transfer of 304,674 STRV of allocation to beet processors with a deficit allocation, an amount sufficient to allow them to market their entire FY 2022 beet sugar supply. USDA has determined that no reassignment of allotments among sugarcane States and allocations among cane processors is necessary at this time.

USDA will closely monitor stocks, consumption, imports and all sugar market and program variables on an ongoing basis and may make further program adjustments during FY 2022 if needed.

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and USDA civil rights regulations and policies, USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family or parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (for example, braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA TARGET Center at (202) 720–2600 (voice and TTY) or (844) 433–2774 (toll-free nationwide). Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint* and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410 or email: *OAC@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

Robert Ibarra,

Acting Executive Vice President, Commodity Credit Corporation.

[FR Doc. 2021–27766 Filed 12–21–21; 8:45 am]

BILLING CODE 3410–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the California Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the California Advisory Committee (Committee) will hold a series of meetings via web video conference on the dates and times listed below for the purpose of finalizing their project proposal on gig worker rights.

DATES: These meetings will be held on:

- Wednesday, January 12, 2022, from 12:30 p.m.–2:00 p.m. Pacific Time
- Friday, February 4, 2022, from 12:30 p.m.–2:00 p.m. Pacific Time

Wednesday, January 12th Webex Registration Link: https://tinyurl.com/b9evx4a9

Friday, February 4th Webex Registration Link: https://tinyurl.com/mv7vn8as

FOR FURTHER INFORMATION CONTACT: Brooke Peery, Designated Federal

Officer (DFO), at *bpeery@usccr.gov* or by phone at (202) 701–1376.

SUPPLEMENTARY INFORMATION: Members of the public may listen to the discussion. This meeting is available to the public through the public WebEx registration link listed above. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Brooke Peery at *bpeery@usccr.gov*. Persons who desire additional information may contact the Regional Programs Unit Office/Advisory Committee Management Unit at (202) 701–1376.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available at: *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzkUAAQ.*

Please click on the ''Meeting Details'' and ''Documents'' links. Persons interested in the work of this Committee are also directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit office at the above email address.

Agenda

I. Welcome & Roll Call
II. Discussion
III. Public Comment
IV. Adjournment

Dated: December 16, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–27694 Filed 12–21–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–82–2021]

Foreign-Trade Zone (FTZ) 75—Phoenix, Arizona; Notification of Proposed Production Activity; LCY Electronic Materials Inc. (Specialty Chemicals for Microchip Production); Casa Grande, Arizona

LCY Electronic Materials Inc., submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Casa Grande, Arizona, within FTZ 75. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on December 10, 2021.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status materials/components and specific finished products described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz.*

The proposed finished products include electronic-grade isopropyl alcohol, photoresist stripper, polysilicon cleaner, photosensitive polyimide, and ammonium hydroxide diluted with water (duty rate ranges from duty-free to 6.5%).

The proposed foreign-status materials and components include technical-grade isopropyl alcohol, diethylene glycol dimethyl ether, ethanolamine, gamma-butyrolactone, and ammonia (duty rate ranges from duty-free to 6.5%). The request indicates that certain materials/components are subject to duties under Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is January 31, 2022.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact Juanita Chen at *juanita.chen@trade.gov.*

Dated: December 16, 2021.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2021–27716 Filed 12–21–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–81–2021]

Foreign-Trade Zone (FTZ) 75—Phoenix, Arizona; Notification of Proposed Production Activity; Chang Chun (Arizona) LLC (Specialty Chemicals for Microchip Production); Casa Grande, Arizona

Chang Chun (Arizona) LLC submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Casa Grande, Arizona, within FTZ 75. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on December 9, 2021.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status materials/components and specific finished products described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz.*

The proposed finished products include high purity hydrogen peroxide, propylene glycol monomethyl ether, propylene glycol monomethyl ether acetate, and liquid developer (duty rate ranges from 3.7% to 6.2%).

The proposed foreign-status materials and components include: Hydrochloric acid; sodium hydroxide; sodium fluoride; sodium hydrogen carbonate; hydrogen peroxide; ethylene glycol; propylene glycol monomethyl ether; propylene glycol monomethyl ether acetate; tetramethylammonium hydroxide; and, 2, 4, 7, 9—tetramethyldec-5-yne-4, 7-diol, ethoxylated (surfactant) (duty rate ranges from duty free to 6.2%). The request indicates that certain materials/components are subject to duties under Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive

Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is January 31, 2022.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact Juanita Chen at *juanita.chen@trade.gov.*

Dated: December 16, 2021.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2021–27715 Filed 12–21–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–821–809]

Certain Hot-Rolled Flat-Rolled Carbon-Quality Steel Products From the Russian Federation: Final Results of the Expedited Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this expedited sunset review, the Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on certain hot-rolled flat-rolled carbon-quality steel products (hot-rolled steel) from the Russian Federation (Russia) would be likely to lead to continuation or recurrence of dumping at the rates identified in the ''Final Results of Review'' section of this notice.

DATES: Applicable December 22, 2021.

FOR FURTHER INFORMATION CONTACT: James Hepburn, AD/CVD Operations, Office VI, Enforcement and Compliance, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1882.

SUPPLEMENTARY INFORMATION:

Background

On December 24, 2014, Commerce published the AD order on hot-rolled steel from Russia.[1] On September 1, 2021, Commerce published the notice of initiation of the second sunset review of the *Order* in accordance with section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On September 16, 2021, Commerce received notices of intent to participate from Nucor Corporation, California Steel Industries, Cleveland-Cliffs Inc., Steel Dynamics Inc., and United States Steel Corporation (collectively, domestic interested parties), within the 15-day deadline specified in 19 CFR 351.218(d)(1)(i). Domestic interested parties claimed interested party status under section 771(9)(C) of the Act.

On September 30, 2021, Commerce received an adequate substantive response to the notice of initiation from domestic interested parties within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[3] Commerce did not receive a substantive response from any respondent interested parties. On October 20, 2021 Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties.[4] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C), Commerce conducted an expedited, *i.e.,* 120-day, sunset review of the *Order.*

Scope of the Order

The merchandise subject to the *Order* is hot-rolled steel. These imports are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings 7208.10.15.00, 7208.10.30.00, 7208.10.60.00, 7208.25.30.00, 7208.25.60.00, 7208.26.00.30, 7208.26.00.60, 7208.27.00.30, 7208.27.00.60, 7208.36.00.30, 7208.36.00.60, 7208.37.00.30, 7208.37.00.60, 7208.38.00.15, 7208.38.00.30, 7208.38.00.90, 7208.39.00.15, 7208.39.00.30, 7208.39.00.90, 7208.40.60.30, 7208.40.60.60, 7208.53.00.00, 7208.54.00.00, 7208.90.00.00, 7210.70.30.00, 7210.90.90.00, 7211.14.00.30, 7211.14.00.90, 7211.19.15.00, 7211.19.20.00, 7211.19.30.00, 7211.19.45.00, 7211.19.60.00, 7211.19.75.30, 7211.19.75.60, 7211.19.75.90, 7212.40.10.00, 7212.40.50.00, 7212.50.00.00, 7225.11.00.00, 7225.19.00.00, 7225.30.30.50, 7225.30.70.00, 7225.40.70.00, 7225.99.00.90, 7226.11.10.00, 7226.11.90.30, 7226.11.90.60, 7226.19.10.00, 7226.19.90.00, 7226.91.50.00, 7226.91.70.00, 7226.91.80.00, and 7226.99.00.00.

The HTSUS subheadings are provided for convenience and customs purposes. A full description of the scopes of the *Order* is contained in the Issues and Decision Memorandum.[5] The written descriptions are dispositive.

Analysis of Comments Received

All issues raised in this review are addressed in the Issues and Decision Memorandum,[6] including the likelihood of continuation or recurrence of dumping, and the magnitude of the margins of dumping likely to prevail if this order was revoked. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to continuation or recurrence of dumping at weighted-average margins up to 184.56.[7]

Administrative Protective Order

This notice also serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective orders is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

[1] *See Termination of the Suspension Agreement on Hot-Rolled Flat-Rolled Carbon-Quality Steel Products from the Russian Federation, Rescission of 2013–2014 Administrative Review, and Issuance of Antidumping Duty Order,* 79 FR 77455 (December 24, 2014) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 86 FR 48983 (September 1, 2021).

[3] *See* Domestic Interested Parties' Letter, ''Certain Hot-Rolled Carbon Steel Flat Products from the Russian Federation: Substantive Response to the Notice of Initiation of Sunset Review,'' dated September 30, 2021.

[4] *See* Commerce's Letter, ''Sunset Reviews Initiated on September 1, 2021,'' dated October 20, 2021.

[5] *See* Memorandum, ''Issues and Decision Memorandum for the Expedited Sunset Review of the Antidumping Duty Order on Certain Hot-Rolled Flat-Rolled Carbon-Quality Steel Products from the Russian Federation,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum) at 3.

[6] *See* Issues and Decision Memorandum.

[7] *See Notice of Final Determination of Sales at Less than Fair Value: Hot-Rolled Flat-Rolled Carbon-Quality Steel Products from the Russian Federation,* 64 FR 38626 (July 19, 1999).

Notification to Interested Parties

We are issuing and publishing the final results and this notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218.

Dated: December 15, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2021–27717 Filed 12–21–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB650]

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will hold a three-day hybrid meeting for both in-person and virtual participation of its Standing, Reef Fish, Socioeconomic, and Ecosystem Scientific and Statistical Committees (SSC).

DATES: The meeting will take place Tuesday, January 11 to Thursday, January 13, 2022, from 9 a.m. to 5 p.m., EST daily.

ADDRESSES: Those who prefer to attend the meeting in-person may do so at the Gulf Council office. If you are unable or do not wish to travel, you may participate in the meeting via webinar. Registration information will be available on the Council's website by visiting *www.gulfcouncil.org* and clicking on the ''meeting tab''.

Council address: Gulf of Mexico Fishery Management Council, 4107 W. Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Mr. Ryan Rindone, Lead Fishery Biologist, Gulf of Mexico Fishery Management Council; *ryan.rindone@gulfcouncil.org,* telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION:

Tuesday, January 11, 2022; 9 a.m.–5 p.m., EST

The meeting will begin with Introductions and Adoption of Agenda, Approval of Verbatim Minutes and Meeting Summary from the November 18, 2021 meeting, and review of Scope of Work. The Committees will select an SSC Representative for the January 24–27, 2022 Gulf Council Meeting. Following, Committees will review the Absolute Abundance Estimates for Red Snapper, Greater Amberjack and other Federally Managed Fish on Offshore Petroleum Platforms in the Gulf of Mexico, evaluate Access-Point Angler Intercept Survey (APAIS) Intercepts for Yellowtail Snapper in the Gulf of Mexico and review the National Academics of Science Report on the Impacts of Limited Access Privilege Programs in Mixed-use Fisheries, including presentations, reports, and SSC discussion.

The Committees will also review Spatial Coverage and Severity of the 2020/21 Red Tide on the West Florida Shelf, Simulation of the Effect of Marine Recreational Information Program Fishing Effort Survey (MRIP–FES) Data on Catch Advice for a Historical King Mackerel Stock Assessment and discuss Draft Essential Fish Habitat Amendment and Data; including presentations, reports, a draft amendment, and SSC discussion.

Wednesday, January 12, 2022; 9 a.m.–5 p.m., EST

The Committees will receive a status update on Red Snapper Management and Outstanding Council Motion, and a summary of SSC Discussion and Recommendations on Great Red Snapper Count Report (GSRC) Report from March/April 2020 and September 2020 Meetings. The Committees will review the GRSC: Re-analysis of the Florida natural/unconsolidated bottom-type data to include the random forest design stratification; Discussion of Results of Post-stratification Analysis by SEFSC, FWC, and GRSC Teams for Florida Absolute Abundance Data; Fishery-Independent Indices Updates for Red Snapper; review Estimated Commercial and Recreational Effort over Uncharacterized Bottom in the Gulf of Mexico; including presentations, supporting documentation, and SSC discussions.

Thursday, January 13, 2022; 9 a.m.–5 p.m., EST

The Committees will hold a summary discussion and review potential requests for Updated SEFSC Red Snapper Interim Analysis for Catch Advice for the March 2022 SSC Meeting and review National Marine Fisheries Service's (NMFS) Standardized Bycatch Reporting Methodology. Lastly, the Committees will receive public comment before addressing any items under Other Business.

Meeting Adjourns

The meeting will also be broadcast via webinar. You may register for the webinar by visiting *www.gulfcouncil.org* and clicking on the SSC meeting on the calendar.

The Agenda is subject to change, and the latest version along with other meeting materials will be posted on *www.gulfcouncil.org* as they become available.

Although other non-emergency issues not on the agenda may come before the Scientific and Statistical Committees for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Actions of the Scientific and Statistical Committee will be restricted to those issues specifically identified in the agenda and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take-action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Kathy Pereira, (813) 348–1630, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 16, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–27679 Filed 12–21–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB648]

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of South Atlantic Fishery Management Council (Council) Seminar Series presentation.

SUMMARY: The Council will host a presentation on managing a multispecies fishery with management complexities similar to the Snapper Grouper Fishery Management Plan via webinar on January 11, 2022.

DATES: The webinar presentation will be held on Tuesday, January 11, 2022, from 1 p.m. until 2:30 p.m.

ADDRESSES:

Meeting address: The presentation will be provided via webinar. The webinar is open to members of the public. Information, including a link to webinar registration will be posted on the Council's website at: *https://safmc.net/safmc-meetings/other-meetings/* as it becomes available.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 302–8439 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: The Council will host a presentation from the Pacific Fishery Management Council on management of groundfish species, including more than 65 rock fish species; flatfish, such as petrale sole and Dover sole; and roundfish, such as sablefish and Pacific whiting (hake). Management of the Pacific groundfish fishery has addressed issues similar to those identified in managing the multi-species Snapper Grouper Fishery Management Complex within the South Atlantic region. A question-and-answer session will follow the presentation. Members of the public will have the opportunity to participate in the discussion. The presentation is for informational purposes only and no management actions will be taken.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 17, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–27734 Filed 12–21–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB641]

Permits; Foreign Fishing

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of application for transshipment permit; request for comments.

SUMMARY: NMFS publishes for public review and comment information regarding a permit application for transshipment of farmed salmon from aquaculture operations in Maine waters to processing plants in Canada by Canadian flagged vessels. The application for a transshipment permit is submitted under provisions of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). This action is necessary for NMFS to make a determination that the permit application can be approved.

DATES: Written comments must be received by January 5, 2022.

ADDRESSES: Written comments on this action, identified by ''RTID 0648–XB641'' should be sent to Kent Laborde in the NMFS Office of International Affairs and Seafood Inspection by email at *kent.laborde@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Kent Laborde at (301) 427–8364 or by email at *kent.laborde@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 204(d) of the Magnuson-Stevens Act (16 U.S.C. 1824(d)) authorizes the Secretary of Commerce (Secretary) to issue a transshipment permit authorizing a vessel other than a vessel of the United States to engage in fishing consisting solely of transporting fish or fish products at sea from a point within the United States Exclusive Economic Zone (EEZ) or, with the concurrence of a state, within the boundaries of that state, to a point outside the United States.

Section 204(d)(3)(D) of the Magnuson-Stevens Act provides that an application to transship from U.S. waters to another country using non-U.S. vessels may not be approved until the Secretary determines that ''no owner or operator of a vessel of the United States which has adequate capacity to perform the transportation for which the application is submitted has indicated . . . an interest in performing the transportation at fair and reasonable rates.'' NMFS is publishing this notice as part of its effort to make such a determination with respect to the application described below.

Summary of Application

NMFS received an application from True North Salmon Limited Partnership and 697002 NB, Inc, requesting authorization to transfer salmon from United States farm pens in Maine waters to four Canadian vessels for the purpose of transporting the salmon to Black's Harbour, Canada for processing. The transshipment operations will occur within the boundaries of the State of Maine, and within 12 nautical miles from Maine's seaward boundary. NMFS issued permits for the same vessels for use in calendar year 2021. Those permits will expire December 31, 2021.

Dated: December 17, 2021.

Alexa Cole,

Director, Office for International Affairs and Seafood Inspection, National Marine Fisheries Service.

[FR Doc. 2021–27729 Filed 12–21–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2021–HQ–0006]

Submission for OMB Review; Comment Request

AGENCY: Department of the Air Force, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by January 21, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, (571) 372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Web-based Legal Information Online System; OMB Control Number 0701–0161.

Type of Request: Extension.

Number of Respondents: 191,000.

Responses per Respondent: 1.

Annual Responses: 191,000.

Average Burden per Response: 3 minutes.

Annual Burden Hours: 9,550 hours.

Needs and Uses: The information collection requirement is necessary to obtain personal identifiable information to provide efficient and competent legal assistance to individuals with personal civil legal issues. Legal assistance records assist Air Force attorneys with tracking and managing cases, performing conflict checks, and generating legal documents for clients. The system optimizes the use of information technology and streamlines the legal assistance process by eliminating manual case tracking requirements and physical storage requirements, as well as assisting the Air Force in compiling and analyzing statistical data related to providing legal assistance to clients.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: December 16, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27665 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–05–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID USA–2021–HQ–0024]

Proposed Collection; Comment Request

AGENCY: Department of the Army, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the U.S. Army Corps of Engineers announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 22, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to U.S. Army Corps of Engineers, 441 G Street NW, Washington, DC 20314–1000, Kathryn Nevins, 703–428–6440.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Application for Department of the Army Permit and Nationwide Permit Pre-Construction Notification Forms; ENG Form 4345, ENG Form 6082; OMB Control Number 0710–0003.

Needs and Uses: The information collected is used to evaluate, as required by law, proposed construction or filing in waters of the United States that result in impacts to the aquatic environment and nearby properties, and to determine which type of permit would be required if one was needed. Respondents are private landowners, businesses, non-profit organizations, and government agencies. Respondents also include sponsors of proposed and approved mitigation banks and in-lieu fee programs.

Affected Public: Business or other for-profit; individuals or households.

Annual Burden Hours: 682,000.

Number of Respondents: 62,000.

Responses per Respondent: 1.

Annual Responses: 62,000.

Average Burden per Response: 11 hours.

Frequency: On occasion.

The Corps of Engineers is required by three federal laws, passed by Congress, to regulate construction-related activities in waters of the United States. This is accomplished through the review of applications for permits to do this work. There are five types of permits that may be used. The ENG 4345 form used for standard permit applications has been in use since the 1970s and the request to extend the expiration date is being provided in this notice. In addition, the Corps is now proposing a form specific to their nationwide permit program. Nationwide Permits (NWPs) are one type of permit authorization that involves a streamlined review process to ensure that no more than minimal individual or cumulative adverse environmental effect result from construction of the proposed activity. NWPs authorize

discharges of dredged or fill material into waters of the United States pursuant to Section 404 of the Clean Water Act and structures or work in navigable waters under Section 10 of the Rivers and Harbors Act of 1899. This form is optional, but allows the Corps to collect the information needed to evaluate the applicants' proposal to determine eligibility for authorization. The Corps will provide outreach materials to guide the public in which of the forms should be used and how using the form and providing the information requested can reduce the time it takes to review whether an application is complete.

Dated: December 16, 2021.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27687 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2021–HQ–0022]

Submission for OMB Review; Comment Request

AGENCY: Department of the Army, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by January 21, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, (571) 372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Application for Survivor Access Card; IMCOM Form 44; OMB Control Number 0702–SACA.

Type of Request: New collection.

Number of Respondents: 670.

Responses per Respondent: 1.

Annual Responses: 670.

Average Burden per Response: 60 minutes.

Annual Burden Hours: 670.

Needs and Uses: In accordance with AR 190–13, the Army Physical Security Program permits surviving family members to have unescorted access to Army installations via the Survivor Access Card, in order for them to receive services, attend events, view memorials, and similar activities. Eligible survivors are those who meet the eligibility criteria to receive the Gold Star Lapel Button or Next of Kin Lapel Button. Eligible survivors must first contact the installation level Survivor Outreach Services (SOS) support coordinator to verify eligibility and coordinate issuance of an installation access credential. The application for Survivor Access Card (IMCOM Form 44) is obtained by eligible surviving family members from SOS staff members. Eligible family members complete the form to obtain the Survivor Access Card which grants survivors ease of access to military installations.

Affected Public: Individuals or households.

Frequency: As required.

Respondent's Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: December 16, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27666 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2021–OS–0122]

Proposed Collection; Comment Request

AGENCY: The Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 22, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Human

Resources Activity, 4800 Mark Center Drive, Suite 08F05, Alexandria, VA 22350, LaTarsha Yeargins, 571–372–2089.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Police Records Check; DD Form 369; OMB Control Number 0704–0007.

Needs and Uses: Title 10, U.S. Code, Sections 504, 505 and 12102 establish minimal standards for enlistment into the Armed Forces. Among other items, these sections specifically prohibit the enlistment of those convicted of a felony. The Services have therefore developed standards which address the acceptability for Service persons with police records, adverse juvenile adjudications or court convictions. The standards are designed to screen out categories of persons who have probability of either becoming serious disciplinary problems or may not be able to adjust to the disciplinary demands of the Armed Forces. This information collection is needed to identify persons who may be undesirable for military service. The existence of a police record is one of the factors considered in establishing eligibility for enlistment or entry into highly sensitive career fields. Therefore, verification data from the individual and law enforcement agencies must be obtained before enlistment can occur. The form associated with this information collection is DD Form 369, ''Police Record Check.'' It is used by recruiters to inquire on applicants' backgrounds prior to acceptance to the Armed Forces, when, in the judgment of the recruiter, an applicant may be withholding information of prior offense history.

Affected Public: Individuals or households.

Annual Burden Hours: 78,750 hours.

Number of Respondents: 175,000.

Responses per Respondent: 1.

Annual Responses: 175,000.

Average Burden per Response: 27 minutes.

Frequency: On occasion.

Dated: December 16, 2021.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27682 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2021–OS–0109]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by January 21, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, (571) 372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Defense Manufacturing Community Support Program Grant Proposals; OMB Control Number 0704–0606.

Type of Request: Revision.

Number of Respondents: 75.

Responses per Respondent: 1.

Annual Responses: 75.

Average Burden per Response: 7 hours.

Annual Burden Hours: 525.

Needs and Uses: The Defense Manufacturing Community Support Program (DMCSP) is designed to undertake long-term investments in critical skills, facilities, research and development, and small business support in order to strengthen the national security innovation and manufacturing base. The program also seeks to ensure complementarity of those communities so designated with existing Defense Manufacturing Institutes. Defense Manufacturing Institutes are manufacturing ecosystems with common manufacturing and design challenges revolving around specific technologies. The DMCSP is designed to recognize communities that demonstrate best practices in attracting and expanding defense manufacturing. This information collection is necessary to facilitate the identification of new Defense Manufacturing Communities and the awarding of grants under the DMCSP via a grant proposal package. The proposal package is prepared in accordance to a Federal Funding Opportunity Announcement posted on the *Grants.gov* website.

Affected Public: Businesses or other for-profit; Not-for-profit Institutions; State, Local or Tribal Government.

Frequency: Annually.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: December 16, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27674 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2021–OS–0108]

Submission for OMB Review; Comment Request

AGENCY: The Office of the Under Secretary of Defense for Research and Engineering, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information

under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by January 21, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, (571) 372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Defense User Registration System; OMB Control Number 0704–0546.

Type of Request: Revision.

Number of Respondents: 5,836.

Responses per Respondent: 1.

Annual Responses: 5,836.

Average Burden per Response: 10 minutes.

Annual Burden Hours: 973.

Needs and Uses: The Defense Technical Information Center (DTIC) requires all eligible users to be registered for access to DTIC's repository of access-controlled scientific and technical information documents. The Defense User Registration System (DURS) collects registration requests from respondents, validates their eligibility, and maintains an official registry that identifies individuals who apply for, and are granted access privileges to DTIC owned or controlled databases, products, services, and electronic information systems. The registration of a user enforces validation of an individual's identity, as well as that individual's persona (*i.e.,* whether the individual is DoD, Federal government, or a contractor supporting the DoD or another federal agency) and authority to access limited and classified documents with distribution controls. A role-based environment based on a user's identification ensures security for DTIC's electronic information collection while the online systems increase availability of information to each user based on his or her mission needs.

Affected Public: Individuals or Households; Business or Other For-Profit; Not-For-Profit Institutions.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: December 16, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27675 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2021–OS–0123]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Policy, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Security Cooperation Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 22, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Security Cooperation Agency, 2800 Defense Pentagon, Washington, DC 20301, Robert Weber, 937–713–3275.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: The Defense Institute of Security Assistance Management Information Technology Mission System; Defense Institute of Security Assistance Management Form GSI–001; OMB Control Number 0704–0548.

Needs and Uses: The Defense Institute of Security Assistance Management (DISAM) Information Technology Mission System: Is a web based portal designed to hold several web applications for the purposes of efficient administration of U.S. and international students, and the effective management of DISAM personnel and guest lecturers. The portal provides DISAM personnel the ability to submit travel requests and travel arrangements. Finally, the web based portal uses a relational database to record, manage and report information about students, personnel, and travel. Reports of annual training of foreign nationals to Congress as required by 22 U.S. Code 2394 (Foreign Assistance Act (FAA)) and 22 U.S. Code 2770A (Arms Export Control Act (AECA)).

Affected Public: Individuals and households.

Annual Burden Hours: 2,512.

Number of Respondents: 5,024.

Responses per Respondent: 2.

Annual Responses: 10,048.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

Dated: December 16, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27728 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2021–HA–0127]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Health Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 22, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Health Agency, 7700 Arlington Blvd., Falls Church, VA 22042, Terry McDavid, 703–681–3645.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: TRICARE Select Survey of Civilian Providers; OMB Control Number 0720–0031.

Needs and Uses: As mandated by Congress, the information collection requirement is necessary to determine how many providers are aware of the TRICARE health benefits program, and specifically accept new TRICARE Select patients in each market area. The original requirement is outlined in Section 711 Fiscal Year (FY) 2015 National Defense Authorization Act (NDAA) (Pub. L. 110–181) and was reaffirmed in Section 721 FY12 NDAA (Pub. L. 112–81). Section 712 of FY15 NDAA extended the requirement to conduct the survey from 2017 through 2020. Surveys of civilian physician and non-physician behavioral health care providers will be conducted in a number of locations in the United States each year. Respondents include civilian physicians (M.D.s & D.O.s) and non-physician behavioral health providers (clinical psychologists, clinical social workers and other TRICARE authorized behavioral health providers). The locations surveyed will include areas where the TRICARE Prime benefit is offered (known as TRICARE PRIME Service Areas) and geographic areas where TRICARE Prime is not offered. Respondents will be contacted by mail with a telephone follow-up to complete the survey.

Affected Public: Individuals or households.

Annual Burden Hours: 1,667.

Number of Respondents: 20,000.

Responses per Respondent: 1.

Annual Responses: 20,000.

Average Burden per Response: 5 minutes.

Frequency: Annually.

Dated: December 16, 2021.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27686 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2021–HA–0106]

Submission for OMB Review; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by January 21, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, (571) 372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: TRICARE Young Adult Application; DD Form 2947; OMB Control Number 0720–0049.

Type of Request: Extension.

Number of Respondents: 2,709.

Responses per Respondent: 1.

Annual Responses: 2,709.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 677.

Needs and Uses: The Ike Skelton National Defense Authorization Act for Fiscal Year 2011 (FY11), Section 702, aligns TRICARE Program eligibility by providing a means to extend the age of eligibility of TRICARE dependents from age 21 or 23 up to age 26 to allow the purchase of extended dependent medical coverage across existing TRICARE program options (Select and Prime). This is consistent with the intent of the Patient Protection and Affordable Care Act, the implementing Health and Human Services regulations, and the limitations of Chapter 55 of Title 10. Section 702 allows qualified adult children not eligible for medical coverage at age 21 (23 if enrolled in a full-time course of study at an institution of higher learning approved by the Secretary of Defense) and are

under age 26 to qualify to purchase medical coverage unless the dependent is enrolled in or eligible to purchase employer sponsored insurance per section 5000A(f)(2) of the Internal Revenue Code of 1986 or is married. The dependents shall be able to purchase either the TRICARE Prime or Select benefits depending on if they meet specific program requirements and the availability of a desired plan in their geographic location.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Julie Wise.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: December 16, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27678 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2021–OS–0124]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Logistics Agency (DLA) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 22, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Logistics Agency, Morale Welfare and Recreation, Child and Youth Program, 8725 John J. Kingman Road, Suite 1134, Fort Belvoir, VA 22060–6221, Lauren Langhan, 571–767–6675.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Defense Logistics Agency Child and Youth Program; DLA Forms 1849, 1849–1, 1849–2, 1849–3, 1849–4, 1855, 1855–1, 1855–1A, 1855–1B, 1855–1C, 1855–1D (Parts I and II), 1855–1E, 1855–1F; OMB Control Number 0704–0582.

Needs and Uses: The Department of Defense requires the information in the proposed collection in support of the Defense Logistics Agency Child and Youth Programs (CYPs). This collection includes fourteen DLA forms, some of which are used by all of the collection respondents and some of which are used under specific circumstances. The information collected is used for program planning, management, and health and safety purposes. More specifically, the information in the proposed collection allows CYP staff to provide safe, developmentally appropriate day care services and to ensure proper, effective response in the event of an emergency. Respondents include patrons enrolling their children in a CYP; these patrons may include active duty military, DoD civilian employees, or DoD contractors.

Affected Public: Individuals or households.

Annual Burden Hours: 1,003.33 hours.

Number of Respondents: 860.

Responses per Respondent: 14.

Annual Responses: 12,040.

Average Burden per Response: 5 minutes.

Frequency: On occasion.

Dated: December 16, 2021.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27683 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2021–OS–0125]

Proposed Collection; Comment Request

AGENCY: The Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use

of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 22, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Human Resources Activity, 4800 Mark Center Drive, Suite 08F05, Alexandria, VA 22350, LaTarsha Yeargins, 571–372–2089.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Innovative Readiness Training Community Application; OMB Control Number 0704–0583.

Needs and Uses: This information collection is necessary to support the Department of Defense's Innovative Readiness Training (IRT) program. Each year the military collects voluntary applications from communities to participate in IRT missions. Communities respond to the collection as they will have a chance to receive incidental support and services from the DoD during the conduct of the IRT mission and training. Currently the majority of missions are in the form of civil engineering projects or medical care. IRT, however, is not limited to this, and any application is considered for its potential training value and incidental community benefit. This information allows the best possible match between the community and military training requirements while ensuring each applicant is eligible to receive support and services under 10 U.S.C. 2012.

Affected Public: State, local, and tribal governments.

Annual Burden Hours: 550 hours.

Number of Respondents: 100.

Responses per Respondent: 1.

Annual Responses: 100.

Average Burden per Response: 5.5 hours.

Frequency: On occasion.

Dated: December 16, 2021.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27684 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2021–OS–0128]

Privacy Act of 1974; System of Records

AGENCY: Department of Defense (DoD).

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the DoD proposes to establish a new Department-wide system of records titled, ''Freedom of Information Act and Privacy Act Records,'' DoD–0008. This system of records covers DoD's maintenance of records about individuals who submit access requests and administrative appeals under the Freedom of Information Act, and who submit access and amendment requests and administrative appeals under the Privacy Act. This system of records data includes information regarding the individual requesters and their attorneys or representatives, the original request for access and any administrative appeal, and other supporting documentation to include related memoranda, correspondence, notes, and, in some instances, copies of requested records and records under administrative appeal. Additionally, DoD is issuing a Notice of Proposed Rulemaking, which proposes to exempt this system of records from certain provisions of the Privacy Act, elsewhere in today's issue of the **Federal Register**.

DATES: This system of records is effective upon publication; however, comments on the Routine Uses will be accepted on or before January 21, 2022. The Routine Uses are effective at the close of the comment period.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

** Federal Rulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

** Mail:* DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *https://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Rahwa Keleta, Defense Privacy, Civil Liberties, and FOIA Directorate, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Department of Defense, 1155 Defense Pentagon, Washington, DC 20301–1155, *OSD.DPCLTD@mail.mil;* (703) 571–0070.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is establishing the ''Freedom of Information Act and Privacy Act Records'' system of records as a DoD-wide Privacy Act system of records. A DoD-wide system of records notice (SORN) supports multiple DoD paper or electronic recordkeeping systems operated by more than one DoD component that maintain the same kind of information about individuals for the same purpose. Establishment of DoD-wide SORNs help DoD standardize the rules governing the collection, maintenance, use, and sharing of personal information in key areas across the enterprise. DoD-wide SORNs also reduce duplicative and overlapping SORNs published by separate DoD components. The creation of DoD-wide SORNs is expected to make locating relevant SORNs easier for DoD personnel and the public, and create efficiencies in the operation of the DoD privacy program.

This system of records concerns access requests and administrative appeals under the Freedom of Information Act (FOIA), and access and amendment requests and administrative appeals under the Privacy Act. The system consists of both electronic and paper records and will be used by DoD components and offices to maintain records about individuals who submit FOIA access requests, Privacy Act access and amendment requests,

administrative appeals to the Department under either the FOIA or Privacy Act, and FOIA and Privacy Act requests referred to DoD by other agencies. These records may include information regarding the individual requesters and their attorneys or representatives, the original request for access, amendment, or administrative appeal, and other supporting documentation to include related memoranda, correspondence, notes, statements of disagreement, and, in some instances, copies of requested records and records under administrative appeal.

Additionally, DoD is issuing a Notice of Proposed Rulemaking to exempt this system of records from certain provisions of the Privacy Act elsewhere in today's issue of the **Federal Register**. DoD SORNs have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at the Defense Privacy, Civil Liberties, and Transparency Division website at *https://dpcld.defense.gov.*

II. Privacy Act

Under the Privacy Act, a ''system of records'' is a group of records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined as a U.S. citizen or lawful permanent resident.

In accordance with 5 U.S.C. 552a(r) and Office of Management and Budget (OMB) Circular No. A–108, DoD has provided a report of this system of records to the OMB and to Congress.

Dated: December 16, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

SYSTEM NAME AND NUMBER:

Freedom of Information Act and Privacy Act Records (FOIA/PA Records) DoD–0008.

SECURITY CLASSIFICATION:

Unclassified; Classified

SYSTEM LOCATION:

Department of Defense (Department or DoD), located at 1000 Defense Pentagon, Washington, DC 20301–1000, and other Department installations, offices, or mission locations. Information may also be stored within a government-certified cloud, implemented and overseen by the Department's Chief Information Officer (CIO), 6000 Defense Pentagon, Washington, DC 20301–6000.

SYSTEM MANAGER(S):

A. Chief, Defense Privacy, Civil Liberties, and Transparency Division, Office of the Director of Administration and Management, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700; *OSD.DPCLTD@mail.mil;* phone (703) 571–0070.

B. The contact information for the DoD Component FOIA Offices is found on the *FOIA.gov* website. The contact information for individual DoD Component Privacy Offices is found at this website: *https://dpcld.defense.gov/Privacy/Privacy-Contacts/.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 113, Secretary of Defense; 5 U.S.C. 552, Freedom of Information Act, as amended; 5 U.S.C. 552a, Privacy Act of 1974, as amended; 32 CFR part 286, DoD Freedom of Information Act (FOIA) Program; 32 CFR part 310, Protection of Privacy and Access and Amendment of Individual Records Under the Privacy Act of 1974; DoD Directive, 5400.07, DoD Freedom of Information Act (FOIA) Program; DoD Instruction 5400.11, DoD Privacy and Civil Liberties Programs; DoD Manual 5400.07, DoD Freedom of Information Act (FOIA) Program; DoD 5400.11–R, DoD Privacy Program; and Executive Order 9397 (SSN), as amended.

PURPOSE(S) OF THE SYSTEM:

A. To report, track, and process access requests and administrative appeals under the FOIA, and access and amendment requests and administrative appeals under the Privacy Act.

B. To participate in and support litigation that may arise from a FOIA and/or Privacy Act access request, amendment request, or administrative appeal.

C. To assist DoD in carrying out any other responsibilities under the FOIA or the access or amendment provisions of the Privacy Act.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

(a) Individuals who submit access requests and appeals to the DoD for records under the provisions of the FOIA and the Privacy Act; (b) individuals who submit access requests to other Federal agencies whose requests have been referred to the DoD for processing or consultation; (c) individuals who request amendment of their records in a DoD system of records under the provisions of the Privacy Act and related appeals; and (d) attorneys or other representatives of the individuals listed above who carry out all or some of these activities on the individuals' behalf.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records created or compiled in response to FOIA access and Privacy Act access and amendment requests, and administrative appeals, including:

A. Original requests and administrative appeals (including requester's name, mailing address, case number, date and subject of the request, with some requesters also voluntarily submitting additional information such as SSNs, telephone numbers, email addresses, and other identifying information) and responses to such requests and administrative appeals.

B. Correspondence with the individuals or entities that submitted the requested records and copies of the requested records, including records that might contain confidential business information or personal information.

C. Intra or interagency memoranda, referrals, correspondence, notes, fee schedules, assessments, cost calculations, and other documentation related to the processing of the FOIA and/or Privacy Act request or appeal.

D. Correspondence related to fee determinations and collection of fees owed under the FOIA or Privacy Act.

E. All related memoranda, correspondence, notes, statements of disagreement following a denial of an appeal of a Privacy Act record amendment request, and other related or supporting documentation;

F. Records concerning lawsuits brought under the FOIA and the Privacy Act including those obtained from the Department of Justice (DOJ) and other government attorneys; and

G. Types of personal information in the records may include: (1) Requesters' and their attorneys' or representatives' identifying and contact information, such as name, address, email, telephone numbers, facsimile numbers, and FOIA/PA case numbers; (2) names and other identifying, descriptive, or contextual information about the individual(s) who is the subject of the request(s); (3) fee category, payment or non-payment information; (4) explanations or justifications provided in support of amendment requests, including supporting documentation; (5) other identifiers that may be provided by or on behalf of a requester or appellant, such as Social Security number (SSN), driver's license number, DoD ID Number (EDI–PI), or other DoD-assigned number.

H. In some instances, copies of the requested records, if any; records subject to an amendment request; or such records when reviewed under administrative appeal. *Note:* Depending on the nature of the records subject to the appeal request, these may not be

''records'' under the Privacy Act or alternatively, may be covered by a separate system of records.

Note 1: This System of Records may contain individually identifiable health information. DoD Instruction 6025.18 and DoD Manual 6025.18 or any successor DoD issuances issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and 45 CFR parts 160 and 164, Health and Human Services, General Administrative Requirements and Security and Privacy, respectively, apply to most such health information. DoD Manual 6025.18 or a successor issuance may place additional procedural requirements on the uses and disclosures of such information beyond those found in the Privacy Act of 1974, as amended, or mentioned in this System of Records Notice (SORN).

Note 2: Individuals who file access or amendment requests may provide their SSN unsolicited to DoD within their request or appeal, or other materials they provide related to their request. In some cases, DoD may request an SSN to properly search for a record subject to a request for access or amendment if the SSN is a unique identifier used to retrieve information from that system of records.

Note 3: In general, this system of records will not be deemed to cover the underlying records that are responsive to an access or amendment request or administrative appeal. Rather, this system of records covers initial access and amendment requests and administrative appeals; all related correspondence, notes, and memoranda created as a result of such requests and appeals; and the other categories of records itemized in paragraphs (A)–(G). In the case of a first-party Privacy Act request, underlying responsive records will typically be covered by a separate system of records.

RECORD SOURCE CATEGORIES:

A. Individuals who submit initial access requests and administrative appeals pursuant to the FOIA and individuals submitting access or amendment requests and administrative appeals under the Privacy Act;

B. DoD personnel assigned to handle such requests and appeals, or related litigation arising therefrom;

C. Other agencies that have referred to DoD requests or consultations concerning DoD records or who have consulted with DOJ regarding the handling of an access or amendment request; and

D. Submitters of or subjects of information reflected in records subject to access requests that have provided assistance to the DoD in making access or amendment determinations.

In addition, copies of records subject to the access or amendment request are obtained from agency systems of records and/or other paper and electronic record-keeping systems containing records searched or otherwise relevant to such requests.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, all or a portion of the records or information contained herein may specifically be disclosed outside the DoD as a Routine Use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government when necessary to accomplish an agency function related to this system of records.

B. To the appropriate Federal, State, local, territorial, tribal, foreign, or international law enforcement authority or other appropriate entity where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether criminal, civil, or regulatory in nature.

C. To any component of the DOJ for the purpose of representing the DoD, or its components, officers, employees, or members in pending or potential litigation to which the record is pertinent.

D. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body or official, when the DoD or other Agency representing the DoD determines that the records are relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

E. To the National Archives and Records Administration (NARA) for the purpose of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

F. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

G. To appropriate agencies, entities, and persons when (1) the DoD suspects or confirms a breach of the system of records; (2) the DoD determines as a result of the suspected or confirmed breach there is a risk of harm to individuals, the DoD (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the DoD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

H. To another Federal agency or Federal entity, when the DoD determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

I. To such recipients and under such circumstances and procedures as are mandated by Federal statute or treaty.

J. To the NARA, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(h), to review administrative agency policies, procedures and compliance with the FOIA, and to facilitate OGIS's offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies.

K. To a Federal agency or other Federal entity that furnished the record or information for the purpose of permitting that agency or entity to make a decision regarding access to or correction of the record or information, or to a Federal agency or entity for purposes of providing guidance or advice regarding the handling of particular requests.

L. To the DOJ, to the Department of the Treasury, or to a consumer reporting agency for collection action on any delinquent debt when circumstances warrant.

M. To the Office of Management and Budget (OMB) or the DOJ to obtain advice regarding statutory and other requirements under the FOIA or Privacy Act.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records may be stored electronically or on paper in secure facilities in a locked drawer behind a locked door. Electronic records may be stored locally on digital media; in agency-owned cloud environments; or in vendor Cloud Service Offerings certified under the Federal Risk and Authorization Management Program (FedRAMP).

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by full name of requestor; FOIA or Privacy Act case

number or appeal number; date and/or year of request or appeal; subject matter; and in some instances may be retrieved by other identifiers assigned by the component.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Retention and disposal of records in this system of records is governed by General Records Schedule 4.2, Information Access and Protection Records, as follows:

A. *Access request files.* Case files created in response to requests for records under the FOIA and Privacy Act, including administrative appeals, are destroyed six years after final agency action (initial response or appeal) or three years after final adjudication by the courts if applicable, whichever is later. (*Note:* National Security Agency documents and supporting files created in response to FOIA requests and appeals are destroyed when 50 years old.)

B. *Privacy Act amendment request files.* Files relating to an individual's request to amend a record subject to the Privacy Act and any appeal or civil action that follows are destroyed with the records for which amendment was requested or four years after the final determination by agency or final adjudication by the courts if applicable, whichever is later.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

DoD safeguards records in this system of records according to applicable rules, policies, and procedures, including all applicable DoD automated systems security and access policies. DoD policies require the use of controls to minimize the risk of compromise of personally identifiable information (PII) in paper and electronic form and to enforce access by those with a need to know and with appropriate clearances. Additionally, DoD has established security audit and accountability policies and procedures which support the safeguarding of PII and detection of potential PII incidents. DoD routinely employs safeguards such as the following to information systems and paper recordkeeping systems: Multifactor log-in authentication including Common Access Card (CAC) authentication and password; Secret internet Protocol Router (SIPR) token as required; physical and technological access controls governing access to data; network encryption to protect data transmitted over the network; disk encryption securing disks storing data; key management services to safeguard encryption keys; masking of sensitive data as practicable; mandatory information assurance and privacy training for individuals who will have access; identification, marking, and safeguarding of PII; physical access safeguards including multifactor identification physical access controls, detection and electronic alert systems for access to servers and other network infrastructure; and electronic intrusion detection systems in DoD facilities.

RECORD ACCESS PROCEDURES:

Individuals seeking access to their records should follow the procedures in 32 CFR part 310. Individuals should address written inquiries to the DoD office with oversight of the records. The public may identify the contact information for the appropriate DoD office through the following website: *www.FOIA.gov.* Signed written requests should contain the name and number of this system of records notice along with the full name, current address, email address, and telephone number of the individual. The individual should also include the FOIA or Privacy Act case identification number, if available. In addition, the requester must provide either a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the appropriate format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

Note 4: In general, this system of records will not be deemed to cover the underlying records that are responsive to an access or amendment request. Rather, this system of records covers the access, amendment, or appeal requests themselves, correspondence created as a result of such requests, and the other categories of records itemized in paragraphs (A)–(G) of the Categories of Records section. In the case of a first-party Privacy Act request, underlying responsive records will typically be covered by a separate system of records. Consistent with paragraph (H) in the Categories of Records section, this system of records does not confer to a FOIA requester access rights under the Privacy Act to copies of the requested records.

CONTESTING RECORD PROCEDURES:

Individuals seeking to amend or correct the content of records about them should follow the procedures in 32 CFR part 310.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system of records should follow the instructions for Records Access Procedures above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(j)(2), portions of this system are exempt from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3) and (4); (d); (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(4)(I), (e)(5), (e)(8); (f); and (g). Additionally, pursuant to 5 U.S.C. 552a(k)(1), (k)(2), (k)(3), (k)(5), (k)(6), and (k)(7) portions of this system are exempt from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d); (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I); and (f). When DoD is processing Privacy Act and/or FOIA requests, responding to appeals, or participating in FOIA or Privacy Act litigation, exempt materials from other systems of record may become part of the records in this system. When exempt records received from other systems of records become part of this system, DoD also claims the same exemptions for those records that are claimed for the prior system(s) of records from which they originated and claims any additional exemptions set forth here. Exemption rules for this system have been promulgated in accordance with requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c), and (e) and published in 32 CFR part 310.

HISTORY:

None.

[FR Doc. 2021–27710 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2021–OS–0110]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by January 21, 2022.

ADDRESSES: Written comments and recommendations for the proposed

information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, (571) 372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Defense Community Infrastructure Program Grant Proposals; OMB Control Number 0704–0607.

Type of Request: Revision.

Number of Respondents: 150.

Responses per Respondent: 1.

Annual Responses: 150.

Average Burden per Response: 15 hours.

Annual Burden Hours: 2,250.

Needs and Uses: Section 2391(d) of Title 10, United States Code (10 U.S.C. 2391), authorizes the Secretary of Defense to, ''make grants, conclude cooperative agreements, and supplement funds available under Federal programs administered by agencies other than the Department of Defense, for projects owned by a State or local government, or a not-for-profit, member-owned utility service to address deficiencies in community infrastructure supportive of a military installation.'' The Consolidated Appropriations Act for Fiscal Year 2021 (Pub. L. 116–260) provided $60 million to the Office of Local Defense Community Cooperation (OLDCC) for the Defense Community Infrastructure Program (DCIP). This information collection supports the awarding of grants under DCIP via the initial grant proposal package prepared in accordance to a Federal Funding Opportunity Announcement posted on the *Grants.gov* website. The criteria established for the selection of community infrastructure projects reflects projects consisting of some combination of attributes that will enhance: (i) Military value; (ii) military installation resilience; and/or, (iii) military family quality of life at a military installation. Respondents can be State or local governments and not-for-profit, member-owned utility services owning infrastructure outside of, but supporting, a military installation.

Affected Public: State, Local or Tribal Government; Not-for-profit Institutions.

Frequency: Annually.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: December 16, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27677 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2021–OS–0126]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 22, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Human Resources Activity, 4800 Mark Center Drive, Suite 08F05, Alexandria, VA 22350, LaTarsha Yeargins, 571–372–2089.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: COVID–19 Vaccination Attestation Form; DD Form 3150; OMB Control Number 0704–0613.

Needs and Uses: DoD is seeking approval of the collection of information addressed by DD Form 3150 ''Certification of Vaccination''. This information is being requested in order to promote the safety of individuals in Federal buildings and on DoD installations, consistent with the COVID–19 Workplace Safety: Agency Model Safety Principles established by the Safer Federal Workforce Task Force and guidance from the CDC and the Occupational Safety and Health Administration and all applicable government FAQs pertaining to the government's response to COVID 19. This information will be used by DoD staff charged with implementing and enforcing workplace safety protocols and is required for ensuring compliance with the requirement for attestation by all civilian employees, on-site contractors, and official visitors. Individuals who refuse to comply with any associated requirements based on the responses to DD Form 3150 may be

refused access to the Federal or DoD installation or facility to which access is sought.

Affected Public: Individuals or households.

Annual Burden Hours: 116,667 hours.

Number of Respondents: 3,500,000.

Responses per Respondent: 1.

Annual Responses: 3,500,000.

Average Burden per Response: 2 minutes.

Frequency: On occasion.

Dated: December 16, 2021.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27685 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2021–OS–0096]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by January 21, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, (571) 372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Mandatory Disclosures as Part of Limitations on Terms of Consumer Credit Extended to Service Members and Dependents; OMB Control Number 0704–0444.

Type of Request: Extension.

Number of Respondents: 37,500.

Responses per Respondent: 6,347 average (varies widely by type of respondent).

Annual Responses: 238,012,500.

Average Burden per Response: 30 seconds.

Annual Burden Hours: 1,983,438 hours.

Needs and Uses: Title 10 U.S.C. 987, as established by section 670 of the National Defense Authorization Act for Fiscal Year 2007 and as amended by sections 661–663 of the National Defense Authorization Act for Fiscal Year 2013, establishes limitations on terms of consumer credit extended to members of the Armed Forces and their dependents. The purpose of this information collection is to ensure disclosures required by 10 U.S.C. 987(c)(1) and discretionary checks of covered-borrower status stipulated in 32 CFR 232.5(b)(2) by creditors in the process of extending consumer credit.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: December 16, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27676 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

ELECTION ASSISTANCE COMMISSION

Sunshine Act Meetings

AGENCY: Election Assistance Commission.

ACTION: Sunshine Act notice; notice of public meeting agenda.

SUMMARY: Public Meeting: U.S. Election Assistance Commission Local Leadership Council Meeting.

DATES: Tuesday, January 11, 2022 1:00 p.m.–2:30 p.m. Eastern.

ADDRESSES: Virtual via Zoom.

The meeting is open to the public and will be livestreamed on the U.S. Election Assistance Commission YouTube Channel: *https://www.youtube.com/channel/UCpN6i0g2rlF4ITWhwvBwwZw.*

FOR FURTHER INFORMATION CONTACT: Kristen Muthig, Telephone: (202) 897–9285, Email: *kmuthig@eac.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: In accordance with the Government in the Sunshine Act (Sunshine Act), Public Law 94–409, as amended (5 U.S.C. 552b), the U.S. Election Assistance Commission (EAC) will conduct a virtual meeting of the EAC Local Leadership Council.

Agenda: The U.S. Election Assistance Commission (EAC) Local Leadership Council will be discussing National Poll Worker Recruitment Day and soliciting feedback to make this effort as effective as possible. The Members will also be discussing the organization structure of the Local Leadership Council, EAC resources, and the Election Administration and Voting Survey (EAVS).

Background: The Local Leadership Council was established in June 2021 under agency authority pursuant to and in accordance with the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2). The Advisory Committee is governed by the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees. The Advisory Committee shall advise the EAC on how best to fulfill the EAC's statutory duties set forth in 52 U.S.C. 20922 as well as such other matters as the EAC determines. It shall provide a relevant and comprehensive source of expert, unbiased analysis and recommendations to the EAC on local election administration topics to include but not limited to voter registration, voting system user practices, ballot administration (programming, printing, and logistics), processing, accounting, canvassing, chain of custody, certifying results, and auditing.

The Local Leadership Council consists of 100 members. The Election Assistance Commission appoints two members from each state after soliciting nominations from each state's election official professional association. At the time of submission, the Local Leadership Council has 88 appointed

members. Upon appointment, Advisory Committee members must be serving or have previously served in a leadership role in a state election official professional association.

The full agenda will be posted in advance on the EAC website: *https://www.eac.gov.*

Status: This meeting will be open to the public.

Kevin Rayburn,

General Counsel, U.S. Election Assistance Commission.

[FR Doc. 2021–27888 Filed 12–20–21; 4:15 pm]

BILLING CODE P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Privacy Act of 1974; System of Records

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of a modified system of records.

SUMMARY: The Federal Energy Regulatory Commission (FERC) is publishing notice of modifications to an existing FERC system of records, FERC–31 titled *Commission Parking Records.* This notice adds 10 new routine uses, including two prescribed by the Office of Management and Budget (OMB) Memorandum M–17–12, *Preparing for and Responding to a Breach of Personally Identifiable Information,* January 3, 2017, that will permit FERC to disclose information as necessary in response to an actual or suspected breach of its own records or to assist another agency in its efforts to respond to a breach. This System of Records Notice (SORN) also describes the Commission's system's manager and location change.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this system of records notice is effective upon publication, with the exception of the routine uses, which will go into effect 30 days after publication of this notice, on December 22, 2021, unless comments have been received from interested members of the public requiring modification and republication of the notice. Please submit any comments by January 21, 2022.

ADDRESSES: Any person interested in commenting on the establishment of this modified system of records may do so by submitting comments electronically to: *Privacy@ferc.gov*. (Include reference to ''FERC–31 Commission Parking Records'' in the subject line of the message.)

For United States Postal Service-delivered mail: Federal Energy Regulatory Commission, Director, Office of External Affairs, 888 First Street NE, Room 4A–05, Washington, DC 20426.

For hand-delivered or courier-delivered mail: Federal Energy Regulatory Commission, Director, Office of External Affairs, 12225 Wilkins Avenue, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Mittal Desai, Chief Information Officer & Senior Agency Official for Privacy, Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6432.

SUPPLEMENTARY INFORMATION: The Commission Parking Records notice includes 10 new routine uses, including two prescribed routine uses that will permit FERC to disclose information as necessary in response to an actual or suspected breach of its own records or to assist another agency in its efforts to respond to a breach. This notice also addresses the system's manager and location change.

SYSTEM NAME AND NUMBER:

Commission Parking Records: FERC–31.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Federal Energy Regulatory Commission, Logistics Operations, Logistics Management Division, 888 First Street NE, Washington, DC 20426.

SYSTEM MANAGER(S):

Logistics Operations Branch Chief, Federal Energy Regulatory Commission, Logistics Operations, Logistics Management Division, 888 First Street NE, Washington, DC 20426.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

41 CFR 101–20.104 *Parking Facilities*.

PURPOSE(S) OF THE SYSTEM:

The Commission Parking Records program supports the overall management of parking operations at the FERC Headquarters garage. The application is managed and controlled by the Commission's Logistics Management Division and is utilized by authorized users to submit applications for parking permits; authorized users are able to electronically register their vehicles and request a parking permit. Information is used to assign parking spaces; to monitor parking expenses and the program budget; to notify drivers of emergencies or parking violations; and to match employees in the same zip code area to existing or potential carpools. The information will also be used for administrative purposes to ensure quality control, performance, and improving management process.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The categories of individuals covered by the system are employees of FERC, vendors and members of the public who park at the FERC Headquarters garage are covered by the Commission Parking Records program.

CATEGORIES OF RECORDS IN THE SYSTEM:

The Commission Parking Records program system maintains records on employee's name, office and home address, office and home phone number, vehicle description and license plate number.

RECORD SOURCE CATEGORIES:

Information is obtained from current employees, vendors and members of the public seeking parking within the FERC Headquarters garage.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, information maintained in this system may be disclosed to authorized entities outside FERC for purposes determined to be relevant and necessary as a routine use pursuant to 5 U.S.C. 552a(b)(3) are as follows:

1. To appropriate agencies, entities, and persons when (a) FERC suspects or has confirmed that there has been a breach of the system of records; (b) FERC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Commission (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To another Federal agency or Federal entity, when FERC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information

systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

3. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of that individual.

4. To the Equal Employment Opportunity Commission (EEOC) when requested in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or other functions of the Commission as authorized by law or regulation.

5. To the Federal Labor Relations Authority or its General Counsel when requested in connection with investigations of allegations of unfair labor practices or matters before the Federal Service Impasses Panel.

6. To disclose information to another Federal agency, to a court, or a party in litigation before a court or in an administrative proceeding being conducted by a Federal agency, where the record is relevant and necessary to proceeding and the Government is a party to the judicial or administrative proceeding. In those cases where the Government is not a party to the proceeding, records may be disclosed if a subpoena has been signed by a judge.

7. To the Department of Justice (DOJ) for its use in providing legal advice to FERC or in representing FERC in a proceeding before a court, adjudicative body, or other administrative body, where the use of such information by the DOJ is deemed by FERC to be relevant and necessary to the advice or proceeding, and such proceeding names as a party in interest: (a) FERC; (b) any employee of FERC in his or her official capacity; (c) any employee of FERC in his or her individual capacity where DOJ has agreed to represent the employee; or (d) the United States, where FERC determines that litigation is likely to affect FERC or any of its components.

8. To non-Federal Personnel, such as contractors, agents, or other authorized individuals performing work on a contract, service, cooperative agreement, job, or other activity on behalf of FERC or Federal Government and who have a need to access the information in the performance of their duties or activities.

9. To the National Archives and Records Administration in records management inspections and its role as Archivist, as permitted by 44 U.S.C. 2904 and 2906.

10. To appropriate Federal, State, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, where the record indicates a violation or potential violation of civil or criminal law, rule, regulation, order.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic format and stored by individuals first and last name, city, zip code and vehicle license plate numbers. In addition, all FERC employees and contractors with authorized access have undergone a thorough background security investigation. Data access is restricted to agency personnel or contractors whose responsibilities require access. Access to electronic records is controlled by user ID and password combination and/or other network access or security controls (*e.g.,* firewalls). Role based access is used to restrict electronic data access and the organization employs the principle of least privilege, allowing only authorized users with access (or processes acting on behalf of users) necessary to accomplish assigned tasks in accordance with organizational missions and business functions.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by employee's or member of the public's name, plate number, or vehicle license plate number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained in accordance with the NARA-approved FERC Comprehensive Records Disposition Schedule, at FERC Records Schedule VII, Administrative Program Records, Part III, Finance, Accounting and Operations, Item 1, Commuter Support Program Records. Temporary, Destroy after subsequent open season, and General Records Schedule (GRS) 5.2: Transitory and Intermediary Records (GRS 5.2 Item 020 Intermediary Records: *https://www.archives.gov/files/records-mgmt/grs/grs05-2.pdf*).'' Materials, including hard copy printouts derived from electronic records created on an ad hoc basis for reference purposes or to meet day-to-day business needs, are destroyed when the Commission determines that they are no longer needed for administrative, legal, audit, or other operational purposes.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Physical access to FERC is controlled by security guards and admission is limited to those individuals possessing a valid identification card or being escorted by an authorized FERC representative. Data center buildings are guarded and monitored by security personnel, cameras, ID checks, and other physical security measures. Physical access to the server rooms is limited to authorized personnel only. Records are maintained in lockable file cabinets in a lockable room with access limited to those employees whose official duties require access; servers are stored in secured facilities in cipher locked server rooms. Computer data is secured by password. The system is secured with the safeguards required by FedRAMP and NIST SP 800–53.

RECORD ACCESS PROCEDURES:

Paper records are maintained in lockable file cabinets in a lockable room with access limited to those employees whose official duties require access. Digital records are accessed by authorized employees by using their user ID and password.

Submit a Privacy Act Request:

The Privacy Act permits access to records about yourself that are maintained by FERC in a Privacy Act system of records. In addition, you may request that incorrect or incomplete information be changed or amended. Privacy requests follow FERC's *Freedom of Information Act (FOIA) request process.* You may access the FOIA website at *https://www.ferc.gov/freedom-information-act-foia-and-privacy-act.*

For questions: Contact the FOIA Service Center at 202–502–6088 or by email at *foia-ceii@ferc.gov.* Written request for access to records should be directed to:

For United States Postal Service-delivered mail: Federal Energy Regulatory Commission, Director, Office of External Affairs, 888 First Street NE, Washington, DC 20426.

For hand-delivered or courier-delivered mail: Federal Energy Regulatory Commission, Director, Office of External Affairs, 12225 Wilkins Avenue, Rockville, Maryland 20852.

CONTESTING RECORD PROCEDURES:

The Privacy Act permits access to records about yourself that are maintained by FERC in a Privacy Act system of records. In addition, you may request that incorrect or incomplete information be changed or amended. Privacy requests follow FERC's *Freedom of Information Act (FOIA) request process.* You may access the FOIA website at *https://www.ferc.gov/freedom-information-act-foia-and-privacy-act.*

For questions: Contact the FOIA Service Center at 202–502–6088 or by email at *foia-ceii@ferc.gov.*

Written request to contest records should be directed to:

For United States Postal Service-delivered mail: Federal Energy Regulatory Commission, Director, Office of External Affairs, 888 First Street NE, Washington, DC 20426.

For hand-delivered or courier-delivered mail: Federal Energy Regulatory Commission, Director, Office of External Affairs, 12225 Wilkins Avenue, Rockville, Maryland 20852.

NOTIFICATION PROCEDURES:

The Privacy Act permits access to records about yourself that are maintained by FERC in a Privacy Act system of records. In addition, you may request that incorrect or incomplete information be changed or amended. Privacy requests follow FERC's *Freedom of Information Act (FOIA) request process.* You may access the FOIA website at *https://www.ferc.gov/freedom-information-act-foia-and-privacy-act.*

For questions: Contact the FOIA Service Center at 202–502–6088 or by email at *foia-ceii@ferc.gov.*

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For hand-delivered or courier-delivered mail: Federal Energy Regulatory Commission, Director, Office of External Affairs, 12225 Wilkins Avenue, Rockville, Maryland 20852.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

FERC previously published the Commission Parking Records in the **Federal Register** as Commission Parking Records. The previous **Federal Register** notice citation is **Federal Register** Vol.65, No. 79, Monday, April 24, 2000.

Issued: December 15, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–27672 Filed 12–21–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–416–000.
Applicants: ANR Pipeline Company.
Description: § 4(d) Rate Filing: ANR—Citadel Energy Negotiated Rate Agreement No. 136886 to be effective 12/15/2021.
Filed Date: 12/15/21.
Accession Number: 20211215–5092.
Comment Date: 5 p.m. ET 12/27/21.

Docket Numbers: RP22–417–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: TGP PCG Pooling to be effective 1/17/2022.
Filed Date: 12/15/21.
Accession Number: 20211215–5172.
Comment Date: 5 p.m. ET 12/27/21.

Docket Numbers: RP22–418–000.
Applicants: Columbia Gulf Transmission, LLC.
Description: § 4(d) Rate Filing: LAXP Tariff Implementation, Waiver and Request for Shortened Comment Period to be effective 1/7/2022.
Filed Date: 12/15/21.
Accession Number: 20211215–5187.
Comment Date: 5 p.m. ET 12/27/21.

Docket Numbers: RP22–419–000.
Applicants: Total Peaking Services, L. L. C.
Description: Compliance filing: TPS Order No. 587–Z Compliance Filing Changes to be effective 6/1/2022.
Filed Date: 12/15/21.
Accession Number: 20211215–5218.
Comment Date: 5 p.m. ET 12/27/21.

Docket Numbers: RP22–420–000.
Applicants: Portland Natural Gas Transmission System.
Description: Compliance filing: 2021 Fuel Mechanism Report to be effective N/A.
Filed Date: 12/15/21.
Accession Number: 20211215–5261.
Comment Date: 5 p.m. ET 12/27/21.

Docket Numbers: RP22–421–000.
Applicants: NEXUS Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—CNX to Direct Energy 962064 to be effective 12/17/2021.
Filed Date: 12/16/21.
Accession Number: 20211216–5090.
Comment Date: 5 p.m. ET 12/28/21.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 16, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–27738 Filed 12–21–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR21–62–001.
Applicants: Black Hills/Kansas Gas Utility Company, LLC.
Description: Submits tariff filing per 284.123(b),(e)/: BHKG Amended Statement of Rates and SOC to be effective 8/1/2021.
Filed Date: 12/15/2021.
Accession Number: 20211215–5040.
Comments/Protests Due: 5 p.m. ET 12/29/21.

Docket Numbers: PR22–11–000.
Applicants: Houston Pipe Line Company LP.
Description: Submits tariff filing per 284.123(b),(e)/: Houston Pipe Line Company LP Notice of Change in Circumstances in PR08–6–000 to be effective N/A.
Filed Date: 12/13/2021.
Accession Number: 20211213–5121.
Comments/Protests Due: 5 p.m. ET 1/3/22.

Docket Numbers: PR22–12–000.
Applicants: Enable Oklahoma Intrastate Transmission, LLC.
Description: Submits tariff filing per 284.123(b),(e)/: EOIT Notice of Change in Circumstances to be effective N/A.
Filed Date: 12/13/2021.
Accession Number: 20211213–5137.
Comments/Protests Due: 5 p.m. ET 1/3/22.

Docket Numbers: RP22–413–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update (Pioneer Jan–Mar 2022) to be effective 1/1/2022.

Filed Date: 12/14/21.
Accession Number: 20211214–5113.
Comment Date: 5 p.m. ET 12/27/21.

Docket Numbers: RP22–414–000.
Applicants: Cheyenne Plains Gas Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing (Mieco) to be effective 12/14/2021.
Filed Date: 12/14/21.
Accession Number: 20211214–5119.
Comment Date: 5 p.m. ET 12/27/21.

Docket Numbers: RP22–415–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Amendments Effective 1/1/2022 to be effective 1/1/2022.
Filed Date: 12/15/21.
Accession Number: 20211215–5068.
Comment Date: 5 p.m. ET 12/27/21.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding. The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 15, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–27671 Filed 12–21–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2606–014; ER17–815–003; ER17–816–003.
Applicants: Consolidated Water Power Company, Verso Luke LLC, Verso Escanaba LLC.
Description: Supplement to June 24, 2021 Triennial Market Power Analysis for Central Region of Consolidated Water Power Company, et al.
Filed Date: 12/9/21.
Accession Number: 20211209–5212.
Comment Date: 5 p.m. ET 12/30/21.

Docket Numbers: ER14–1818–024.
Applicants: Boston Energy Trading and Marketing LLC.
Description: Triennial Market Power Analysis for Southwest Power Pool Inc. Region of Boston Energy Trading and Marketing LLC.
Filed Date: 12/14/21.
Accession Number: 20211214–5270.
Comment Date: 5 p.m. ET 2/14/22.

Docket Numbers: ER21–673–004.
Applicants: PA Solar Park II, LLC,
Description: Compliance filing: Reactive Power Compliance Filing to be effective 12/18/2020.
Filed Date: 12/14/21.
Accession Number: 20211214–5226.
Comment Date: 5 p.m. ET 1/4/22.

Docket Numbers: ER21–2819–002.
Applicants: South Field Energy LLC.
Description: Compliance filing: Reactive Service Rate Schedule Compliance Filing to be effective 10/5/2021.
Filed Date: 12/15/21.
Accession Number: 20211215–5084.
Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER22–645–000.
Applicants: Ormat Dixie Valley LLC.
Description: § 205(d) Rate Filing: Notice of Succession and Revisions to Market-Based Rate Tariff to be effective 12/15/2021.
Filed Date: 12/14/21.
Accession Number: 20211214–5228.
Comment Date: 5 p.m. ET 1/4/22.

Docket Numbers: ER22–647–000.
Applicants: Midcontinent Independent System Operator, Inc., Ameren Illinois Company.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2021–12–15_SA 3299 Att A_Ameren IL-Norris Electric-Hidalgo Tap Proj. No. 5 to be effective 2/14/2022.
Filed Date: 12/15/21.
Accession Number: 20211215–5038.
Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER22–648–000.
Applicants: Tri-State Generation and Transmission Association, Inc.
Description: § 205(d) Rate Filing: Amendment to Rate Schedule FERC No. 259 to be effective 12/16/2021.
Filed Date: 12/15/21.
Accession Number: 20211215–5056.
Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER22–649–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original ISA, Service Agreement No. 6241 to be effective 11/15/2021.
Filed Date: 12/15/21.
Accession Number: 20211215–5069.
Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER22–650–000.
Applicants: Horizon West Transmission, LLC.
Description: § 205(d) Rate Filing: HWT Revisions to TO Tariff Appendix I TRBAA Annual Update to be effective 1/1/2022.
Filed Date: 12/15/21.
Accession Number: 20211215–5087.
Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER22–651–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: Emergency Energy Transactions Agreement between SPP and PSCo to be effective 2/14/2022.
Filed Date: 12/15/21.
Accession Number: 20211215–5090.
Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER22–652–000.
Applicants: Western Spirit Transmission LLC.
Description: Tariff Amendment: Notice of Cancellation of Facilities Use Agreement to be effective 12/16/2021.
Filed Date: 12/15/21.
Accession Number: 20211215–5095.
Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER22–653–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2021–12–15_SA 3084 St. Joseph Phase II–NIPSCO GIA 2nd Rev (J351) to be effective 12/3/2021.
Filed Date: 12/15/21.
Accession Number: 20211215–5097.
Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER22–654–000.
Applicants: Massachusetts Electric Company.
Description: § 205(d) Rate Filing: 2021 Rate Update Filing for Massachusetts Electric Borderline Sales Agreement to be effective 1/1/2021.
Filed Date: 12/15/21.
Accession Number: 20211215–5105.
Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER22–655–000.
Applicants: Alabama Power Company.
Description: Tariff Amendment: Cane Creek Solar LGIA Termination Filing to be effective 12/15/2021.
Filed Date: 12/15/21.
Accession Number: 20211215–5112.
Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER22–656–000.
Applicants: Alabama Power Company.
Description: Tariff Amendment: Moonshot Solar LGIA Termination Filing to be effective 12/15/2021.

Filed Date: 12/15/21.

Accession Number: 20211215–5113.

Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER22–657–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original ISA, Service Agreement No. 6248; Queue No. AE2–206 to be effective 11/15/2021.

Filed Date: 12/15/21.

Accession Number: 20211215–5208.

Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER22–658–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original ISA No. 6237; Queue No. AE2–290 to be effective 11/15/2021.

Filed Date: 12/15/21.

Accession Number: 20211215–5217.

Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER22–659–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: Transmission Access Charge Balancing Account Adjustment (TACBAA) 2022 to be effective 3/1/2022.

Filed Date: 12/15/21.

Accession Number: 20211215–5228.

Comment Date: 5 p.m. ET 1/5/22.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 15, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–27673 Filed 12–21–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL22–5–000]

Tucson Electric Power Company; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On December 16, 2021, the Commission issued an order in Docket No. EL22–5–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e, instituting an investigation into whether Tucson Electric Power Company's failure of the wholesale market share indicative screen in its change in status filing is unjust, unreasonable, unduly discriminatory or preferential, or otherwise unlawful. *Tucson Electric Power Company,* 177 FERC ¶ 61,191 (2021).

The refund effective date in Docket No. EL22–5–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL22–5–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 (2021), within 21 days of the date of issuance of the order.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFile'' link at *http://www.ferc.gov.* In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Dated: December 16, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–27737 Filed 12–21–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC22–24–000.

Applicants: GridLiance High Plains LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act of GridLiance High Plains LLC.

Filed Date: 12/10/21.

Accession Number: 20211210–5245.

Comment Date: 5 p.m. ET 1/3/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1841–023; ER10–1852–053; ER10–1907–022; ER10–1918–023; ER10–1950–023; ER10–1970–022; ER10–1972–022; ER10–2005–023; ER10–2078–023; ER11–26–023; ER11–4462–055; ER12–1660–022; ER13–2458–017; ER13–2461–017; ER16–1872–013; ER16–2506–014; ER17–838–030; ER17–2270–014; ER18–1771–012; ER18–2224–013; ER18–2246–012; ER19–987–010; ER19–1003–010; ER19–1393–010; ER19–1394–010; ER19–2373–006; ER19–2382–006; ER19–2398–008; ER19–2437–006; ER19–2461–006; ER20–122–004; ER20–1220–004; ER20–1769–004; ER20–1879–005; ER20–1987–005; ER20–2690–004; ER21–1320–001; ER21–1953–001; ER21–2048–001; ER21–2100–001.

Applicants: Point Beach Solar, LLC, Sac County Wind, LLC, Heartland Divide Wind II, LLC, Crystal Lake Wind Energy III, LLC, Jordan Creek Wind Farm LLC, Cerro Gordo Wind, LLC, Oliver Wind I, LLC, Chicot Solar, LLC, Oliver Wind II, LLC, Crowned Ridge Interconnection, LLC, Crowned Ridge Wind, LLC, Emmons-Logan Wind, LLC, Hancock County Wind, LLC, Story County Wind, LLC, Ashtabula Wind I, LLC, Endeavor Wind II, LLC, Endeavor

Wind I, LLC, Crystal Lake Wind Energy II, LLC, Crystal Lake Wind Energy I, LLC, Heartland Divide Wind Project, LLC, Pegasus Wind, LLC, Langdon Renewables, LLC, Stuttgart Solar, LLC, NextEra Energy Marketing, LLC, Oliver Wind III, LLC, Marshall Solar, LLC, Pheasant Run Wind, LLC, Tuscola Wind II, LLC, Tuscola Bay Wind, LLC, NEPM II, LLC, Ashtabula Wind III, LLC, White Oak Energy LLC, Ashtabula Wind II, LLC, NextEra Energy Point Beach, LLC, NextEra Energy Duane Arnold, LLC, Garden Wind, LLC, FPL Energy North Dakota Wind II, LLC, Otay Mesa Energy Center, LLC, Florida Power & Light Company, Butler Ridge Wind Energy Center, LLC.

Description: Triennial Market Power Analysis for Central Region of Butler Ridge Wind Energy Center, LLC, et al.

Filed Date: 12/10/21.

Accession Number: 20211210–5247.

Comment Date: 5 p.m. ET 2/8/22.

Docket Numbers: ER20–1581–001.

Applicants: Midcontinent Independent System Operator, Inc., Republic Transmission, LLC.

Description: Compliance filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35: 2021–12–16_Republic Order 864 Compliance Amendment Filing to be effective 6/12/2020.

Filed Date: 12/16/21.

Accession Number: 20211216–5072.

Comment Date: 5 p.m. ET 1/6/22.

Docket Numbers: ER21–1065–003.

Applicants: TransCanyon Western Development, LLC.

Description: Compliance filing: TransCanyon Formula Rate Compliance Filing to be effective 4/7/2021.

Filed Date: 12/16/21.

Accession Number: 20211216–5186.

Comment Date: 5 p.m. ET 1/6/22.

Docket Numbers: ER21–2348–000.

Applicants: Midcontinent Independent System Operator, Inc., Michigan Public Power Agency.

Description: Refund Report of Midcontinent Independent System Operator, Inc.

Filed Date: 12/16/21.

Accession Number: 20211216–5105.

Comment Date: 5 p.m. ET 1/6/22.

Docket Numbers: ER22–337–000.

Applicants: Bio Energy (Ohio II), LLC.

Description: Supplement to November 4, 2021 Bio Energy (Ohio II), LLC tariff filing per 35.12: Application to be effective 11/5/2021.

Filed Date: 12/15/21.

Accession Number: 20211215–5303.

Comment Date: 5 p.m. ET 12/27/21.

Docket Numbers: ER22–660–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original ISA/CSA, Service Agreement Nos. 6235/6236; Queue No. AE2–342 to be effective 11/15/2021.

Filed Date: 12/15/21.

Accession Number: 20211215–5237.

Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER22–661–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2021–12–15_Attachment X GIP Timeline Reduction Filing to be effective 3/15/2022.

Filed Date: 12/15/21.

Accession Number: 20211215–5260.

Comment Date: 5 p.m. ET 1/14/22.

Docket Numbers: ER22–662–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1518R22 Arkansas Electric Cooperative Corp NITSA NOA to be effective 12/1/2021.

Filed Date: 12/15/21.

Accession Number: 20211215–5269.

Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER22–663–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to ISA and ICSA, SA Nos. 4492 and 4494; Queue No. AA2–060 to be effective 6/30/2016.

Filed Date: 12/16/21.

Accession Number: 20211216–5045.

Comment Date: 5 p.m. ET 1/6/22.

Docket Numbers: ER22–664–000.

Applicants: Power Supply Partners, LLC.

Description: Notice of Cancellation of Market Based Rate Tariff of Power Supply Partners, LLC.

Filed Date: 12/14/21.

Accession Number: 20211214–5281.

Comment Date: 5 p.m. ET 1/4/22.

Docket Numbers: ER22–665–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Attachment AE Revisions to Clarify Auction Revenue Rights Allocation Process to be effective 2/16/2022.

Filed Date: 12/16/21.

Accession Number: 20211216–5069.

Comment Date: 5 p.m. ET 1/6/22.

Docket Numbers: ER22–666–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to ISA and ICSA, SA Nos. 4501 and 4502; Queue No. AA2–061 to be effective 7/1/2016.

Filed Date: 12/16/21.

Accession Number: 20211216–5075.

Comment Date: 5 p.m. ET 1/6/22.

Docket Numbers: ER22–668–000.

Applicants: Duke Energy Progress, LLC.

Description: § 205(d) Rate Filing: DEP–NCEMPA—Revisions to Rate Schedule No. 200 to be effective 3/1/2022.

Filed Date: 12/16/21.

Accession Number: 20211216–5125.

Comment Date: 5 p.m. ET 1/6/22.

Docket Numbers: ER22–669–000.

Applicants: American Electric Power Service Corporation, Ohio Power Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: American Electric Power Service Corporation submits tariff filing per 35.13(a)(2)(iii: AEP submits one Facilities Agreement re: ILDSA, SA No. 1336 to be effective 2/15/2022.

Filed Date: 12/16/21.

Accession Number: 20211216–5140.

Comment Date: 5 p.m. ET 1/6/22.

Docket Numbers: ER22–670–000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: 2021–12–16 PSCo Concurrence to SPP Emergency Energy—ER22–651 to be effective 2/14/2022.

Filed Date: 12/16/21.

Accession Number: 20211216–5172.

Comment Date: 5 p.m. ET 1/6/22.

Docket Numbers: ER22–671–000.

Applicants: Pattern Energy Group LP, SunZia Transmission, LLC.

Description: Application for Confirmation of Negotiated Rate Authority to Accommodate Anticipated Change in Upstream Ownership, et al. of SunZia Transmission, LLC.

Filed Date: 12/14/21.

Accession Number: 20211214–5282.

Comment Date: 5 p.m. ET 1/4/22.

Docket Numbers: ER22–672–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original Interim ISA, Service Agreement No. 6252; Queue AF1–063/AF2–127 to be effective 11/16/2021.

Filed Date: 12/16/21.

Accession Number: 20211216–5194.

Comment Date: 5 p.m. ET 1/6/22.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing

requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 16, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–27739 Filed 12–21–21; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Appointment of Board Member to FASAB

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

SUMMARY: Notice is hereby given that Mr. Raymond Vicks, Jr., has been appointed to the Federal Accounting Standards Advisory Board (FASAB or ''the Board''). Mr. Vicks' five-year term will begin on July 1, 2022.

ADDRESSES: The news release is available on the FASAB website at *https://www.fasab.gov/news-releases/.* Copies can be obtained by contacting FASAB at (202) 512–7350.

FOR FURTHER INFORMATION CONTACT: Ms. Monica R. Valentine, Executive Director, 441 G Street NW, Suite 1155, Washington, DC 20548, or call (202) 512–7350.

Authority: 31 U.S.C. 3511(d), the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and the FASAB Rules of Procedure, as amended in October 2010.

Dated: December 17, 2021.

Monica R. Valentine,

Executive Director.

[FR Doc. 2021–27713 Filed 12–21–21; 8:45 am]

BILLING CODE P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0951; FR ID 62741]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before February 22, 2022. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0951.

Title: Sections 1.204(b) Note and 1.1206(a) Note 1, Service of Petitions for Preemption.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, Individuals or households; Not-for-profit institutions; and State, Local or Tribal Government.

Number of Respondents and Responses: 125 respondents; 125 responses.

Estimated Time per Response: 0.28 hours (17 minutes).

Frequency of Response: On occasion reporting requirements and third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154, and 303.

Total Annual Burden: 35 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: Yes.

Nature and Extent of Confidentiality: The Commission is not requesting respondents to submit confidential information to the Commission. If the Commission requests respondents to submit information which respondents believe is confidential, respondents may request confidential treatment of such information pursuant to section 0.459 of the Commission's rules, 47 CFR 0.459.

The FCC has a system of records, FCC/OGC–5, ''Pending Civil Cases,'' to cover the collection, purpose(s), storage, safeguards, and disposal of the personally identifiable information (PII) that individuals may submit with their petitions for preemption that they file with the Commission.

Needs and Uses: These provisions supplement the procedures for filing petitions seeking Commission preemption of state and local government regulation of telecommunications services. They require that such petitions, whether in the form of a petition for rulemaking or a petition for declaratory ruling, be served on all state and local governments. The actions for which are cited as a basis for requesting preemption. Thus, in accordance with these provisions, persons seeking preemption must serve their petitions not only on the state or local governments whose authority would be preempted, but also on other state or local governments whose actions are cited in the petition.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

[FR Doc. 2021–27723 Filed 12–21–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX, 3060–0207; FR ID 63866]

Information Collections Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before February 22, 2022. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–XXXX.
Title: Wireless Emergency Alerts (WEA) Handset Displays and False Alert Reporting.

Form No.: N/A.

Type of Review: New information collection.

Respondents: Businesses or other for-profits; State, Local, or Tribal Government and Federal Government.

Number of Respondents and Responses: 23,277 respondents; 167 responses.

Estimated Time per Response: 1 hour–150 hours.

Frequency of Response: On occasion and one-time reporting requirement.

Obligation to Respond: Mandatory and Voluntary. Statutory authority for this information collection is contained in 47 U.S.C. 151, 152, 154(i), 154(o), 301, 303(r), 303(v), 307, 309, 335, 403, 544(g), 606, 613, 1201, 1202, 1203, 1204 and 1206.

Total Annual Burden: 22,815 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There are no assurance of confidentiality associated with this collection of information.

Needs and Uses: This is a new request for approval of an information collection for two new regulations under the Commission's part 10 Wireless Emergency Alert (WEA) rules. No other information collections contained in the Commission's regulations will be impacted by the new rules described herein.

The WEA system is a mechanism under which Commercial Mobile Service (CMS) providers may elect to transmit emergency alerts to the public. The Commission created WEA (previously known as the Commercial Mobile Service Alert System) as required by Congress in the Warning Alert and Response Network (WARN) Act and to satisfy the Commission's mandate to promote the safety of life and property through the use of wire and radio communication.

On January 1, 2021, Congress passed the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (NDAA21). Section 9201 of the NDAA21 required the Commission to complete a rulemaking and adopt rules within 180 days to make certain changes to its WEA regulations, and also to its separate Emergency Alert System (EAS) regulations governing broadcast, cable television, and direct satellite media emergency alerts. With respect to the WEA rule changes, section 9201 directed the Commission to ensure that the mobile devices of CMS providers that have elected to participate in WEA cannot opt out of receiving WEA alerts from the Federal Emergency Management Agency (FEMA) Administrator, and to enable reporting by the FEMA Administrator and State, Tribal, or local governments of false WEA alerts. On June 21, 2021, the Commission released its Report and Order in PS Dockets 15–91 and 15–94 (NDAA21 Alerting Order), FCC 21–77, adopting the WEA and EAS changes directed by Congress in the NDAA21. The EAS changes are the subject of a different notice to be published separately.

The NDAA21 Alerting Order implemented Congresses' new directives for WEA, in part, with two new regulations that impose new burdens on respondents: The handset display update, and false alert reporting.

Handset Display Update

In the NDAA21 Alerting Order, the Commission combined the current non-optional class of WEA ''Presidential Alerts'' with FEMA Administrator Alerts into a new renamed alert class named ''National Alerts.'' Participating CMS providers that have chosen to display the phrase ''Presidential Alert'' on their handsets are required to either discontinue the handset's use of that phrase or otherwise change those displays to read ''National Alert'' by July 31, 2022. Network infrastructure that is technically incapable of meeting this requirement, such as legacy devices or networks that cannot be updated to support header display changes, are exempt from this requirement. The handset display changes are necessary to avoid confusion when wireless subscribers receive a non-optional emergency alert from the FEMA Administrator instead of the President.

The handset display update regulation is codified at 47 CFR 10.11(b).

False Alert Reporting

Also in the NDAA21 Alerting Order, the Commission adopted a rule permitting the FEMA Administrator or a State, local, Tribal, or territorial government to voluntarily report WEA false alerts to the FCC Operations Center at *FCCOPS@fcc.gov,* informing the Commission of the event and any relevant details. This rule creates a voluntary mechanism for collection of information so that the Commission can monitor these false alert events which can undermine public confidence in the reliability of emergency alerting and WEA. Email reporting was adopted as a minimally-burdensome way for government entities to report false alerts.

The WEA false alert reporting regulation is codified at 47 CFR 10.520(d)(2).

OMB Control Number: 3060–0207.

Title: Part 11—Emergency Alert System (EAS), Order, FCC 21–77.

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit; Not-for-profit institutions; State, Local, or Tribal Government.

Number of Respondents and Responses: 63,084 respondents; 3,588,845 responses.

Estimated Time per Response: 0.017 hours–112 hours.

Frequency of Response: Annual, on occasion and one-time reporting requirements.

Obligation to Respond: Mandatory and Voluntary. Statutory authority for this information collection is contained in 47 U.S.C. 154(i) and 606 of the Communications Act of 1934, as amended.

Total Annual Burden: 141,414 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: No Impact(s).

Nature and Extent of Confidentiality: The Commission shares aggregated and individual State EAS Plan data on a confidential basis with other Federal agencies and state governmental emergency management agencies that have confidentiality protection at least equal to that provided by the Freedom of Information Act.

Needs and Uses: Part 11 contains rules and regulations addressing the nation's Emergency Alert System (EAS). The EAS provides the President with the capability to provide immediate communications and information to the general public during periods of national emergency over broadcast television and radio, cable, direct broadcast radio and other EAS Participants, as defined in § 11.11(a) of the Commission's rules The EAS also provides state and local governments and the National Weather Service with the capability to provide immediate communications and information to the public concerning emergency situations posing a threat to life and property. Part 11 includes testing requirements to ensure proper and efficient operation of the EAS. State and local use of the EAS, alert processing requirements, and monitoring assignments covering the distribution of EAS alerts within the state, among other things, are required to be described in State EAS Plans that are administered by State Emergency Communications Committees (SECC) and submitted to the FCC annually for approval.

The Order, PS Docket Nos. 15–91 and 15–94, FCC 21–77, pursuant to the directions set forth in Section 9201 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Public Law 116–283, 134 Stat. 3388, section 9201 (NDAA21), among other things, (i) requires the Public Safety and Homeland Security Bureau (Bureau) to establish a State EAS Plan Content Checklist composed of the content set forth in § 11.21 of the Commission's rules, (47 CFR 11.21), post the checklist on the FCC's website, and incorporate it as an appendix in ARS user manual; (ii) amend the State EAS Plan requirements in § 11.21 of the Commission's rules to ensure plans are updated annually, require a certification by the SECC Chairperson or Vice-Chairperson that the SECC met (in person, via teleconference, or via other methods of conducting virtual meetings) at least once in the twelve months prior to submitting the annual updated plan, and require that the Bureau approve or reject State EAS Plans submitted for approval within 60 days of receipt; and (iii) require the Bureau to list the approval dates of State EAS Plans submitted on ARS on the Commission's website, and in the event a final decision is made to deny a plan, directly notify the chief executive of the State to which the plan applies of that determination and the reasons for such denial within 30 days of such decision. The Order also amends § 11.45 of the part 11 rules to enable voluntary reporting to the Commission by the FEMA Administrator and Tribal, State, local or territorial governments of false EAS alerts.

The Commission seeks OMB approval of these rule amendments as a modification of a previously approved information collection. Congress has determined that EAS rule changes are necessary to increase oversight over the distribution of state and local EAS alerts within states, and increase false alert reporting capabilities to help ameliorate confusion or other harmful effects that might result from false EAS alerts. The internal State EAS Plan processing requirements and rule changes adopted in the Order will improve State EAS Plan processing and administration, improving the capabilities and efficacy of EAS as a national system for distributing vital alert information to all Americans, and will do so in a cost-effective manner.

The following information collections contained in Part 11 may be impacted by the rule amendments described herein.

State EAS Plans (47 CFR 11.21)

The establishment of a State EAS Plan Content Checklist for SECCs should have no impact or lessen SECC burdens, and posting it on the FCC's website, and incorporating it as an appendix in the ARS user manual, are routine Bureau activities. The requirement to ensure State EAS Plans are updated annually already was contained in § 11.21, and thus does not represent a new burden.

The amendment to include as a required element in the State EAS Plan, a certification (which will be incorporated into the ARS) by the SECC Chairperson or Vice-Chairperson that the SECC met (in person, via teleconference, or via other methods of conducting virtual meetings) at least once in the twelve months prior to submitting the annual updated plan to review and update their State EAS Plan should promote added diligence in SECC administration of State EAS Plans. The Commission estimates the burden to SECC members in complying with this requirement to be two hours per member.

The rule amendment requiring the Bureau approve or reject State EAS Plans submitted for approval within 60 days of receipt does not impose new burdens on any entity. The Bureau already is charged with reviewing State EAS Plans. The internal requirement that the Bureau list the approval dates of State EAS Plans submitted on ARS on the Commission's website, and in the event a final decision is made to deny a plan, directly notify the chief executive of the State to which the plan applies of that determination and the reasons for such denial within 30 days, does not impose new burdens on any entity. The Bureau already maintains a web page on the Commission's website dedicated to SECC and State EAS Plan information.

False EAS Alert Reporting (47 CFR 11.45)

The amendment enabling the FEMA Administrator and Tribal, State, local or territorial governments to file reports of false EAS alerts provides another mechanism for the Commission to receive information concerning false EAS alerts, does not impose burdens on any entity. Should any permitted government entity voluntarily elect to file a false EAS alert report, the burden associated with this provision amounts to composing an email, which the Commission estimates will take an hour or less to prepare, and falls within the routine activities of government employees. False alert reports help the Commission to identify, investigate, correct and prevent false EAS activations, which enhances the EAS's efficacy and the public trust in the EAS.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison, Office of the Secretary.

[FR Doc. 2021–27882 Filed 12–20–21; 4:15 pm]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[GN Docket No. 19–329; FRS 62899]

Federal Advisory Committee Act; Task Force for Reviewing the Connectivity and Technology Needs of Precision Agriculture in the United States

AGENCY: Federal Communications Commission.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission's (FCC or Commission) Task Force for Reviewing the Connectivity and Technology Needs of Precision Agriculture in the United States (Task Force) will hold its next meeting via live internet link.

DATES: January 13, 2022. The meeting will come to order at 10:00 a.m. EST.

ADDRESSES: The meeting will be held via conference call and be available to the public via live feed from the FCC's web page at *www.fcc.gov/live.*

FOR FURTHER INFORMATION CONTACT: Jesse Jachman, Designated Federal Officer, Federal Communications Commission, Wireline Competition Bureau, (202) 418–2668, or email: *Jesse.Jachman@fcc.gov;* Elizabeth Cuttner, Deputy Designated Federal Officer, Federal Communications Commission, Wireline Competition Bureau, (202) 418–2145, or email *Elizabeth.Cuttner@fcc.gov;* or Stacy Ferraro, Deputy Designated Federal Officer, Wireless Telecommunications Bureau, (202) 418–0795 or email *Stacy.Ferarro@fcc.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be held on January 13, 2022 at 10:00 a.m. EST and may be viewed live, by the public, at *http://www.fcc.gov/live.* Any questions that arise during the meeting should be sent to *PrecisionAgTF@fcc.gov* and will be answered at a later date. Members of the public may submit comments to the Task Force in the FCC's Electronic Comment Filing System, ECFS, at *www.fcc.gov/ecfs.* Comments to the Task Force should be filed in GN Docket No. 19–329.

Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice). Such requests should include a detailed description of the accommodation needed. In addition, please include a way the FCC can contact you if it needs more information. Please allow at least five days' advance notice; last-minute requests will be accepted but may not be possible to fill.

Proposed Agenda: At this meeting, the Task Force plans to introduce members of the Task Force, describe the focus of each working group, review policies relevant to the Task Force's duties, and begin discussing strategies to advance broadband deployment on agricultural land and promote precision agriculture. This agenda may be modified at the discretion of the Task Force Chair and the Designated Federal Officer.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer. Secretary.

[FR Doc. 2021–27725 Filed 12–21–21; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; National Human Trafficking Hotline (NHTH) Performance Indicators

AGENCY: Office on Trafficking in Persons, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting approval for a new information collection: National Human Trafficking Hotline (NHTH) Performance Indicators.

DATES: *Comments due within 30 days of publication.* The Office of Management and Budget (OMB) must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: Section 107(b)(1)(B)(ii) of the Trafficking Victims Protection Act of 2000, as amended at 22 U.S.C. 7105(b)(1)(B)(ii), authorizes the Secretary of Health and Human Services (HHS) to make a grant for a national communication system—the NHTH—to assist victims of severe forms of trafficking in persons in seeking help, receiving referrals, and reporting potential trafficking cases.

HHS made an award in the form of a Cooperative Agreement to a single, competitively selected grantee to maintain and support operation of the NHTH throughout the United States and U.S. territories. The NHTH is a toll-free hotline that operates 24 hours a day, every day of the year.

The Cooperative Agreement delineates the roles and responsibilities for the administration of the grant program, which include:

1. Operating the NHTH with experienced and trained anti-trafficking advocates;

2. Operating the NHTH website and responding to online signals;

3. Promoting NHTH services to increase the identification and protection of victims of severe forms of human trafficking;

4. Providing timely information and service referrals to human trafficking victims using a trauma-informed, person-centered, culturally responsive, and linguistically appropriate approach;

5. Notifying law enforcement agencies of potential cases of human trafficking as well as instances when a trafficking victim is in imminent danger; and

6. Documenting emerging trafficking schemes to assist in the detection and investigation of trafficking cases.

The NHTH grantee collects information about signalers (individuals who contact the hotline) and from signalers regarding potential victims of a severe form of trafficking in persons and human trafficking cases. Given the unique relationship the NHTH has to the public, OTIP is seeking clearance to collect information about and from these signalers that will be summarized and reported to OTIP by the NHTH grantee in the aggregate. The NHTH Performance Indicators information collection will provide data for OTIP to assess the extent to which the grantee meets required program activities to:

- Ensure potential victims of trafficking remain able to access assistance by constantly monitoring and mitigating factors impacting NHTH operations;
- Assist the grantee to assess and improve their project over the course of the project period;

• Disseminate insights related to human trafficking cases and trends to inform anti-trafficking strategies and policies; and

• Provide information to Congress, other federal agencies, stakeholders, the public, and other countries on the aggregate outputs and outcomes of the NHTH operations.

In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13) and OMB regulations at 5 CFR part 1320, ACF published a notice in the **Federal Register** to announce the agency's intention to request OMB review of this information collection activity and provide a sixty-day period for public comment (86 FR 38489). During the notice and comment period, one comment was received from the NHTH grantee. The comment did not pertain to the burden estimate for respondents (signalers to the NHTH), rather the burden on the recordkeeper (the NHTH grantee).

To be responsive to this comment and reduce the burden on the recordkeeper, OTIP modified the collection to remove several of the data elements that were initially proposed. Where OTIP has requested any new data (*e.g.,* data the grantee is not already providing to OTIP as a condition of award), particularly, for existing data to be further disaggregated, it is in the interest of allowing OTIP to:

• Monitor performance and operational issues;

• Generate more timely insights into trends related to victim demographics and service needs, and the impact of particular intra- and inter-agency efforts, messaging campaigns, trainings, and other anti-trafficking efforts on NHTH signals, and;

• Respond to congressional inquiries and other ad hoc inquiries without submitting burdensome individual requests to the NHTH.

Respondents: Potential victims, representatives of governmental entities, law enforcement, first responders, members of the community, representatives of nongovernmental entities providing social, legal, or protective services to individuals in the United States who may have been subjected to severe forms of trafficking in persons utilize the NHTH as signalers.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents (signalers)	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
National Human Trafficking Hotline (NHTH) Performance Indicators	585,300	1	0.43333333	253,630	84,543

Estimated Total Annual Burden Hours: 84,543.

Authority: 22 U.S.C. 7105.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–27646 Filed 12–21–21; 8:45 am]

BILLING CODE 4184–47–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Unaccompanied Children (UC) Program Budget Workbook Template (New Collection)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families' (ACF) Office of Refugee Resettlement (ORR) is requesting clearance for the proposed new collection titled ''UC Program Budget Workbook'' to streamline budget details and justifications of applicants to funding opportunities.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The UC Program Budget Workbook will streamline the budget detail and justification documentation for applicants to any upcoming Notice of Funding Opportunity (NOFO). This new information collection will provide guidance to the applicant as well as a fillable form to insert calculations and budget line items. With the assistance of this template, the review of applications will be expedited since documentation will be clearer and more unified. Additionally, this will facilitate the completion of applications that may not otherwise be completed due to lack of budget documentation guidance in past NOFOs.

Respondents: New and existing applicants to NOFOs for residential services for UC.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
UC Program Budget Form	120	3	90	32,400	10,800

Estimated Total Annual Burden Hours: 10,800.

Authority: 8 U.S.C. 1522 of the Immigration and Nationality Act (the Act) (Title IV, Sec. 412 of the Act) and 45 CFR 400.28(b).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–27767 Filed 12–21–21; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0756]

Validation and Verification of Analytical Testing Methods Used for Tobacco Products; Draft Guidance for Industry; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Validation and Verification of Analytical Testing Methods used for Tobacco Products'' and requesting comments, including scientific and other information, concerning the recommendations set forth in the draft guidance. The draft guidance, when finalized, would provide information and recommendations related to the validation and verification of analytical test methods, including analytical testing of tobacco product constituents, ingredients, and additives, as well as stability testing of tobacco products. This draft guidance would help industry produce more consistent and reliable analytical data used to support regulatory submissions for finished tobacco products.

DATES: Submit either electronic or written comments on the draft guidance by February 22, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–0756 for ''Validation and Verification of Analytical Testing Methods used for Tobacco Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Nathan Mease or Matthew Brenner, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft document entitled ''Validation and Verification of Analytical Testing Methods used for Tobacco Products; Draft Guidance for Industry.'' This draft guidance, when finalized, provides information and recommendations on how tobacco product manufacturers can produce validation and verification data for the analytical procedures and

methods used to support regulatory submissions for finished tobacco products including substantial equivalence (SE) applications, premarket tobacco product applications (PMTA), and modified risk tobacco product applications (MRTPA). These recommendations include analytical testing of tobacco product constituents, ingredients, and additives, as well as stability testing of finished tobacco products. The principles in this guidance may also be used for finished tobacco product testing and reporting of harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke.

The FD&C Act requires, among other things, premarket review for new tobacco products and modified risk tobacco products (see sections 910 and 911 (21 U.S.C. 387j and 21 U.S.C. 387k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), and also reporting of HPHCs under section 904 of the FD&C Act (21 U.S.C. 387d). Information about constituents, for example, might be required by law or otherwise support the findings for premarket authorization. Regulatory submissions often contain data from analytical testing, such as data about ingredients, constituents, and additives. In standard practice, analytical testing is done through validation of the analytical method. In these cases, the applicant will want to use analytical methods that are sufficiently precise, accurate, selective, and sensitive. Validation involves documenting, through the use of specific laboratory investigations, that the performance characteristics of the method are suitable and reliable for the intended analytical applications, in terms of precision, accuracy, selectivity, and sensitivity. When finalized, this guidance is intended to help industry produce more consistent and reliable analytical data used to support regulatory submissions for finished tobacco products, such as SE applications, PMTAs, MRTPAs, and for finished tobacco product testing and reporting of HPHCs in tobacco products and tobacco smoke.

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Validation and Verification of Analytical Testing Methods used for Tobacco Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

We believe that the information collection provisions in the draft guidance do not create a new burden for respondents. We believe the recordkeeping provisions are part of usual and customary business practice. Tobacco manufacturers would have in-house analysts or contractual agreements with outside analytical laboratories and suppliers, as applicable for the type of tobacco product, to address all these information collection provisions.

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in section 910(c)(1)(A)(i) of the FD&C Act have been approved under OMB control number 0910–0768; the collections of information in section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) have been approved under OMB control number 0910–0673; and the collections of information in 21 CFR part 1107 have been approved under OMB control number 0910–0684, the collections of information in section 904(a)(3) of the FD&C Act have been approved under OMB control number 0910–0732.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 16, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27719 Filed 12–21–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1967]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biosimilars User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 21, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0719. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Biosimilars User Fee Program

OMB Control Number 0910–0718—Revision

This information collection supports FDA's Biosimilars User Fee Program. The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) amended the Public Health Service Act (PHS Act) to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, allows a company to apply for licensure of a biosimilar or interchangeable biological product (351(k) application). The BPCI Act also amended section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) to include 351(k) applications as a type of application under ''human drug application'' for the purposes of the prescription drug user fee provisions.

The Biosimilar User Fee Act of 2012 (BsUFA) authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological

product development (BPD). BsUFA was reauthorized for an additional 5 years in August 2017 (BsUFA II). We developed the guidance entitled ''Assessing User Fees Under the Biosimilar User Fee Amendments of 2017'' to assist industry in understanding when fees are incurred and the process by which applicants can submit payments. The guidance also explains how respondents can request discontinuation from the BPD program as well as how respondents can request to move products to the discontinued section of the biosimilar list. Finally, the guidance provides information on the consequences of failing to pay BsUFA II fees as well as processes for submitting reconsideration and appeal requests. The guidance is available on the FDA website at: *https://www.fda.gov/media/134567/download.* The guidance was issued consistent with our good guidance practice regulations in § 10.115 (21 CFR 10.115), which provide for public comment at any time.

We also developed Form FDA 3792, the Biosimilars User Fee Cover Sheet, which is submitted by each new BPD entrant (identified via a new meeting request or investigational new drug (IND) submission) and for new biologics license applications (BLAs). Form FDA 3792 requests the minimum necessary information to identify the request, to determine the amount of the fee to be assessed, and to account for and track user fees. The form provides a cross-reference of the fees submitted for an activity with the actual submission or activity by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research to initiate the administrative screening of biosimilar biological product INDs and BLAs and to account for and track user fees associated with BPD meetings.

In addition to Form FDA 3792, the information collection includes an annual survey of all BsUFA II participants designed to provide information to FDA of anticipated BsUFA II activity in the upcoming fiscal year. This information helps FDA set appropriate annual BsUFA II fees.

For efficiency of Agency operations, we are consolidating related information collection currently approved in OMB control number 0910–0719. Specifically we are including our current commitment goals as set forth in the document ''BsUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022,'' which represents the product of FDA discussions with regulated industry and public stakeholders, as mandated by Congress. The document, referred to as the ''BsUFA II letter,'' is available on our website at: *https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf.* The performance and procedural goals specified in the BsUFA II letter apply to aspects of the biosimilar biological product review program that are important for facilitating timely access to safe and effective biosimilar medicines for patients. Among those considerations is providing feedback to requests from regulated industry. Each year, FDA review staff participate in many meetings with requesters who seek advice relating to the development and review of a biosimilar or interchangeable product. Because these meetings often represent critical points in the regulatory and development process, it is important that there are clear procedures for the timely and effective conduct of such meeting. Accordingly, we issued draft guidance, ''Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products,'' available on our website at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-sponsors-or-applicants-bsufa-products-guidance-industry.* The guidance was issued consistent with Section I, Part 6 of the BsUFA II letter (see p. 25), and with our good guidance practice regulations in § 10.115, which provide for public comment at any time. The guidance provides procedural instruction helpful to respondents and helps us reach what we believe is a more accurate burden estimate for the information collection.

Also available from our website is our Biosimilars Action Plan (BAP), which discusses key actions the Agency is taking to encourage innovation and competition among biologics and the development of biosimilars. The BAP builds on progress in implementing the approval pathway for biosimilar and interchangeable products, and provides interested persons with updates and resource material.

In the **Federal Register** of September 17, 2021 (86 FR 51900), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

FDA form; survey	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Biosimilar User Fee Cover Sheet (Form FDA 3792) ..	60	1	60	0.5 (30 minutes)	30
Annual Survey	60	1	60	1	60
Request for discontinuation from BPD program	10	1	10	1	10
Request to move products to discontinued section of the Biosimilar List.	5	1	5	0.5 (30 minutes)	2.5
Biosimilar product applications (351(k)(2)(A))	4	2.25	9	860	7,740
Interchangeable product applications (351(k)(2)(B)) ...	2	1	2	860	1,720
Patent infringement notifications	4	2.25	9	2	18
Formal Meetings Guidance for Industry Recommendations.	69	2.30	159	21.42	3,405
Total	.....	.....	314	.....	12,985.5

In anticipation of increased participation in the BPD program, we have adjusted our estimate to reflect an increase in the number of respondents since last OMB review. We have also made adjustments to reflect information collection consolidated from OMB control number 0910–0719. We invite comment on our estimates and assumptions.

Dated: December 15, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27680 Filed 12–21–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0375]

Determination That Alcohol and Dextrose Injection, 5 Milliliters/100 Milliliters, 5 Grams/100 Milliliters; and 10 Milliliters/100 Milliliters, 5 Grams/100 Milliliters, Were Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that Alcohol and Dextrose Injection, 5 milliliters (mL)/100 mL, 5 gram (g)/100 mL; and Alcohol and Dextrose Injection, 10 mL/100 mL, 5 g/100 mL, were withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL; and 10 mL/100 mL, 5 g/100 mL.

FOR FURTHER INFORMATION CONTACT: Kaetochi Okemgbo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6272, Silver Spring, MD 20993–0002, 240–825–9944, *Kaetochi.Okemgbo@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) Has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and, with certain exceptions, labeling as the listed drug, which is a version of the drug that was previously approved; and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Between 1938 and 1968, FDA evaluated NDAs solely on the basis of safety information. In 1962, the Kefauver-Harris Drug Amendments (Pub. L. 87–781) amended the FD&C Act to require that new drug products also be shown to be effective in order to obtain approval of an NDA. After the enactment of the Kefauver-Harris Drug Amendments, FDA initiated the Drug Efficacy Study Implementation (DESI) to evaluate the effectiveness of drug products that had been approved between 1938 and 1962 solely on the basis of safety.

FDA introduced the concept of an ''abbreviated new drug application'' in 1968 as a vehicle for approval of certain drugs affected by the DESI review. When a drug product subject to the DESI review was determined to be effective for one or more indications, FDA would issue a **Federal Register** notice for that drug product describing the DESI review findings and stating whether abbreviated new drug applications that met specified criteria could be submitted to FDA (see generally 35 FR 11273 (July 14, 1970); 35 FR 6574 (April 24, 1970)) for products that had not been marketed under an NDA. Such a finding allowed manufacturers to submit an abbreviated new drug application in lieu of an NDA. For approval of these applications, which were submitted before the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) (Pub. L. 98–417) created the current ANDA pathway, FDA relied on the evidence of effectiveness that had been provided, reviewed, and accepted during the DESI process and evaluated the safety of these drug products on the basis of information included in NDAs submitted prior to 1962, as well as the subsequent marketing experience with the drugs. These applications are referred to as pre-Hatch-Waxman abbreviated new drug applications or ''PANDAs''.[1] PANDAs were submitted under section 505(b) of the FD&C Act and approved for safety and effectiveness under section 505(c) of the FD&C Act (see 86 FR 44731 at 44732 (August 13, 2021)).

As explained above, the current ANDA pathway is described in section 505(j) of the FD&C Act. Because of substantive differences in the application approval pathway for PANDAs, which were approved for safety and effectiveness under section 505(c) of the FD&C Act, compared to ANDAs approved under section 505(j) of the FD&C Act, FDA has determined that PANDA products can serve as reference listed drugs for 505(j) ANDA applicants seeking to make generic versions of these products and that there is a finding of safety and effectiveness that may be relied upon for approval by applicants of 505(b)(2) applications.

Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL; and 10 mL/100 mL, 5 g/100 mL, is the subject of NDA 004589, held by B. Braun Medical Inc. The initial application, which included Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL, was allowed to take effect on February 21, 1942. Alcohol and Dextrose Injection, 10 mL/100 mL, 5 g/100 mL, was allowed to take effect in a supplemental application on January 17, 1946. On July 28, 1972, FDA published a **Federal Register** notice regarding the DESI review of NDA 004589 (see 37 FR 15184). Under the DESI review, FDA concluded that there was substantial evidence of efficacy for two formulations of 5 percent Alcohol and 5 percent Dextrose for the indication ''for increasing caloric intake.'' Based on the **Federal Register** notice, FDA approved Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL in three PANDAs: ANDA 083263, held by Hospira, Inc. and initially approved on February 26, 1974; ANDA 083483, held by Miles Laboratories Inc. and originally approved on November 22, 1974; and

[1] See ''Drug Products Approved in Abbreviated New Drug Applications Before the Enactment of the Hatch-Waxman Amendments; Establishment of a Public Docket; Request for Comments,'' 86 FR 44731 (August 13, 2021). Note that the scope of the referenced notice is limited to drug products approved in PANDAs under section 505 of the FD&C Act prior to the Hatch-Waxman Amendments; the notice does not cover applications for antibiotic drug products that were originally submitted under section 507 of the FD&C Act (21 U.S.C. 357).

ANDA 083256, held by Baxter Healthcare Corp. and initially approved on March 12, 1976.[2]

All Alcohol and Dextrose Injection products have been discontinued and moved to the ''Discontinued Product List'' section of the Orange Book. In a letter dated June 23, 1999, Miles Laboratories Inc. notified FDA that Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL, the subject of ANDA 083483, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. In the **Federal Register** of September 22, 1999, FDA announced it was withdrawing approval of ANDA 083256, effective September 22, 1999 (see 64 FR 51325). Approval of ANDA 083256 was withdrawn upon request of Baxter Healthcare Corp. under § 314.150(c) (21 CFR 314.150(c)) because the product was no longer being marketed. In the **Federal Register** of June 19, 2014, FDA announced it was withdrawing approval of ANDA 083263, effective July 21, 2014 (see 79 FR 35170). Approval of ANDA 083263 was withdrawn upon request of Hospira, Inc., under § 314.150(c) because the product was no longer being marketed. In the **Federal Register** of October 13, 2015, FDA announced it was withdrawing approval of NDA 004589, effective November 15, 2015 (see 80 FR 61426). Approval of NDA 004589 was withdrawn upon request of B. Braun Medical Inc. under § 314.150(c) because the products were no longer being marketed.

Celerity Pharmaceuticals, LLC submitted a citizen petition dated April 12, 2021 (Docket No. FDA–2021–P–0375), under 21 CFR 10.30, requesting that the Agency determine whether B. Braun Medical Inc.'s Alcohol and Dextrose Injection, 10 mL/100 mL, 5 g/100 mL, NDA 004589, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 5 mL/100 mL, 5 g/100 mL strength or the PANDAs, that strength and the PANDAs have also been withdrawn from sale. On our own initiative, we have also determined whether the 5 mL/100 mL, 5 g/100 mL strength under NDA 004589 and the PANDAs were withdrawn from sale for safety or effectiveness reasons.

The petitioner has identified no data or other information suggesting that Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL; or 10 mL/100 mL, 5 g/100 mL, were withdrawn for reasons of safety or effectiveness. Specifically, the petitioner states that the Alcohol and Dextrose Injection, 10 mL/100 mL, 5 g/100 mL, was discontinued for unknown reasons. The petitioner also included a letter published on November 15, 2005, in the *American Journal of Health-System Pharmacy,* which describes the use of Alcohol and Dextrose Injection as a treatment for ethylene glycol and methanol poisonings.

We have carefully reviewed our files for records concerning the withdrawal of Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL; and 10 mL/100 mL, 5 g/100 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. Based on a thorough evaluation of the information we have available to us and an evaluation of the latest version of the drug products' approved labeling, we have determined that the drug products would not be considered safe and effective if they were reintroduced to the market today. Therefore, after considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL; and Alcohol and Dextrose Injection, 10 mL/100 mL, 5 g/100 mL were withdrawn for reasons of safety or effectiveness.

Alcohol and Dextrose Injection is indicated to provide increased caloric intake. The use of Alcohol and Dextrose raises several safety concerns because there are many risks associated with the exposure to alcohol. Alcohol is contraindicated for use in patients with neurologic disorders, such as seizures, who have current or past substance abuse problems or who are pregnant. It can cause intoxication, respiratory depression, and disturbances in serum glucose levels. FDA-approved alternatives for intravenous calorie supplementation that do not include alcohol were approved after these Alcohol and Dextrose products and are available today.

In addition to the safety considerations, we have concerns about the appropriateness of Alcohol and Dextrose Injection to provide intravenous nutrition. Alcohol and Dextrose Injection was developed prior to the advent of more physiologically complete intravenous nutrition options. Parenteral nutrition, delivered intravenously, is used as a source of nutrition when oral or enteral nutrition cannot be administered. Parenteral nutrition is an admixture of solutions containing dextrose, amino acids, electrolytes, vitamins, minerals, and trace elements. Lipid emulsions are infused separately or added to the mixture, which allows for high energy supply with iso-osmolar solutions. Providing an adequate proportion of the energy needs as lipids obviates the need for high glucose infusion rates and, therefore, can contribute to the prevention of hepatic steatosis and hyperglycemia. Lipid emulsions are also necessary to supply essential fatty acids. Today, there are several FDA-approved parenteral products that are alternatives to Alcohol and Dextrose for increasing caloric intake and that also address other nutritional needs.

Because new clinical studies would first need to be conducted to address the concerns described above, FDA has determined that these Alcohol and Dextrose products would not be considered safe and effective if they were reintroduced to the market. Therefore, under § 314.161, FDA has determined that Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL; and 10 mL/100 mL, 5 g/100 mL were withdrawn for safety and effectiveness reasons. Accordingly, the Agency will remove B. Braun Medical Inc.'s NDA 004589 for Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL; and 10 mL/100 mL, 5 g/100 mL; Miles Laboratory Inc.'s ANDA 083483 for Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL; Baxter Healthcare Corp's ANDA 083256 for Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL; and Hospira, Inc.'s ANDA 083263 for Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to these drug products.

Dated: December 15, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27696 Filed 12–21–21; 8:45 am]

BILLING CODE 4164–01–P

[2] The Orange Book refers to the Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL products in the three PANDAs (*i.e.,* ANDA 083263, ANDA 083483, and ANDA 083256) as Alcohol ''in'' Dextrose, but these products contain the same concentrations of alcohol and dextrose as Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL, approved under NDA 004589. Our findings are limited to these products, which contain both alcohol and dextrose, and we make no findings about the safety or effectiveness of any product that may contain only one of the active ingredients.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0923]

Determination That ANTIZOL (Fomepizole) Injection, 1.5 Grams/1.5 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that ANTIZOL (fomepizole) Injection, 1.5 grams (g)/1.5 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as the ANDAs meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Kaetochi Okemgbo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6272, Silver Spring, MD 20993–0002, 240–825–9944, *Kaetochi.Okemgbo@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) Has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ANTIZOL (fomepizole) Injection, 1.5 g/1.5 mL, is the subject of NDA 020696, held by Par Pharmaceuticals Inc., and initially approved on December 4, 1997. ANTIZOL is indicated as an antidote for ethylene glycol (such as antifreeze) or methanol poisoning, or for use in suspected ethylene glycol or methanol ingestion, either alone or in combination with hemodialysis. ANTIZOL (fomepizole) Injection, 1.5 g/1.5 mL is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Gland Pharma Ltd. submitted a citizen petition dated August 19, 2021 (Docket No. FDA–2021–P–0923), under 21 CFR 10.30, requesting that the Agency determine whether ANTIZOL (fomepizole) Injection, 1.5 g/1.5 mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ANTIZOL (fomepizole) Injection, 1.5 g/1.5 mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ANTIZOL (fomepizole) Injection, 1.5 g/1.5 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ANTIZOL (fomepizole) Injection, 1.5 g/1.5 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ANTIZOL (fomepizole) Injection, 1.5 g/1.5 mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 15, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27699 Filed 12–21–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the cooperative agreement applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; CTSA.

Date: January 26–27, 2022.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Victor Henriquez, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892, (301) 435–0813, *henriquv@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology,

Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: December 16, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–27691 Filed 12–21–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Mechanism for Time-Sensitive Research Opportunities in Environmental Health Sciences (R21).

Date: January 10, 2022.

Time: 1:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Laura A. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709, 984–287–3328, *laura.thomas@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: December 16, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–27690 Filed 12–21–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods Communities of Practice Webinar on New Approach Methodologies To Assess (Developmental) Neurotoxicity; Notice of Public Webinar; Registration Information

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announces a public webinar ''New Approach Methodologies to Assess (Developmental) Neurotoxicity.'' The webinar is organized on behalf of ICCVAM by the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). Interested persons may participate via the web meeting platform. Time will be allotted for questions from the audience. Information about the webinar and registration are available at *https://ntp.niehs.nih.gov/go/commprac-2022.*

DATES:

Webinar: January 25, 2022, 10:00 a.m. to approximately 11:30 a.m. EST.

Registration for Webinar: January 4, 2022, until 11:30 a.m. EST January 25, 2022.

Registration to view the webinar is required.

ADDRESSES: Webinar web page: *https://ntp.niehs.nih.gov/go/commprac-2022.*

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Kleinstreuer, Acting Director, NICEATM, email: *nicole.kleinstreuer@nih.gov,* telephone: (984) 287–3150.

SUPPLEMENTARY INFORMATION:

Background: ICCVAM promotes the development and validation of toxicity testing methods that protect human health and the environment while replacing, reducing, or refining animal use. ICCVAM also provides guidance to test method developers and facilitates collaborations that promote the development of new test methods. To address these goals, ICCVAM will hold a Communities of Practice webinar on ''New Approach Methodologies to Assess (Developmental) Neurotoxicity.''

The nervous system has unique characteristics and can have different sensitivity to toxic substances compared to other organ systems. Effects of chemicals on the nervous system can be affected by concurrent exposures to other substances. During early life stages, exposure to neuroactive drugs and environmental toxins can interact and/or interfere with developmental processes of the brain, which can in turn result in structural and/or functional alterations. Traditional (developmental) neurotoxicity tests use mammals, but the high cost and low throughput of these tests make them impractical to use for all chemicals of potential concern. In addition, it is challenging to correlate the interpretation of animal data to complex human neurological effects. Therefore, interest is increasing in exploring human cell-based assays, computational systems, and other alternatives to traditional animal tests that can be used to predict chemical effects on the developing and adult nervous system.

''New approach methodologies'' (NAMs) refers to any non-animal technology or approach, or combination of these, that can be used to provide information on chemical hazard and risk assessment. This webinar will discuss NAMs that are being considered or developed for assessing potential effects of chemicals on the nervous system. Key insights and ongoing activities will be described in two presentations featuring speakers from U.S. federal research and regulatory agencies. The preliminary agenda and additional information about presentations will be posted at *https://ntp.niehs.nih.gov/go/commprac-2022* as available.

Webinar and Registration: This webinar is open to the public with time scheduled for questions by participants following each presentation. Registration for the webinar is required and will be open from January 4, 2022, through 11:30 a.m. EST on January 25, 2022. Registration is available at *https://ntp.niehs.nih.gov/go/commprac-2022.* Interested individuals are encouraged to visit this web page to stay abreast of the most current webinar information. Registrants will receive instructions on how to access and participate in the webinar in the email confirming their registration.

Background Information on ICCVAM and NICEATM: ICCVAM is an interagency committee composed of representatives from 17 federal regulatory and research agencies that require, use, generate, or disseminate

toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability. ICCVAM also promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) establishes ICCVAM as a permanent interagency committee of the National Institute of Environmental Health Sciences and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. Additional information about ICCVAM can be found at *https://ntp.niehs.nih.gov/go/iccvam.*

NICEATM administers ICCVAM, provides support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about NICEATM can be found at *https://ntp.niehs.nih.gov/go/niceatm.*

Dated: December 16, 2021.

Brian R. Berridge,

Associate Director, National Toxicology Program.

[FR Doc. 2021–27692 Filed 12–21–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; National Center for Advancing Translational Sciences Special Emphasis Panel.

Date: February 23, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Carol (Chang-Sook) Kim, Ph.D., Scientific Review Administrator, Office of Grants Management and Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892 (301) 827–7940, *carolko@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: December 16, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–27689 Filed 12–21–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Neurological Disorders and Stroke Council.

The meeting will be open to the public. Individuals who plan to participate and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Neurological Disorders and Stroke Council.

Date: February 2–3, 2022.

Open: February 2, 2022, 1:00 p.m. to 6:00 p.m.

Agenda: Report by the Director, NINDS; Report by the Director, Division of Extramural Activities; and Administrative and Program Developments.

Open session will be videocast from this link: https://videocast.nih.gov/.

Closed: February 3, 2022, 1:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Rockville, MD 20852 (Virtual Meeting).

Contact Person: Robert Finkelstein, Ph.D., Director of Extramural Research, National Institute of Neurological Disorders and Stroke, NIH, 6001 Executive Blvd., Suite 3309, MSC 9531, Rockville, MD 20852, (301) 496–9248, *finkelsr@ninds.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice at least 10 days in advance of the meeting. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.ninds.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: December 16, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–27724 Filed 12–21–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Automated Commercial Environment (ACE) Export Manifest for Air Cargo Test: Extension of Test

AGENCY: U.S. Customs and Border Protection; Department of Homeland Security.

ACTION: General notice.

SUMMARY: This notice announces that U.S. Customs and Border Protection

(CBP) is extending its Automated Commercial Environment (ACE) Export Manifest for Air Cargo Test, a National Customs Automation Program (NCAP) test concerning ACE export manifest capability.

DATES: The voluntary pilot initially began on July 10, 2015, and it was modified and extended on August 14, 2017. The extended test will run for an additional two years from the date of publication of this notice in the **Federal Register**.

ADDRESSES: Applications to participate in the ACE Export Manifest for Air Cargo Test must be submitted via email to CBP Export Manifest at *cbpexportmanifest@cbp.dhs.gov.* In the subject line of the email, please write ''ACE Export Manifest for Air Cargo Test Application''. Applications will be accepted at any time during the test period. Written comments concerning program, policy, and technical issues may also be submitted via email to CBP Export Manifest at *cbpexportmanifest@cbp.dhs.gov.* In the subject line of the email, please write ''Comment on ACE Export Manifest for Air Cargo Test''. Comments may be submitted at any time during the test period.

FOR FURTHER INFORMATION CONTACT: Brian Semeraro, Branch Chief, or David Garcia, Program Manager, Outbound Enforcement and Policy Branch, Office of Field Operations, CBP, via email at *cbpexportmanifest@cbp.dhs.gov,* or by telephone, 202–325–4221.

SUPPLEMENTARY INFORMATION:

I. Background

The Automated Commercial Environment (ACE) Export Manifest for Air Cargo Test is a voluntary test in which participants agree to submit export manifest data to U.S. Customs and Border Protection (CBP) electronically at least four hours prior to loading of the cargo onto the aircraft in preparation for departure from the United States. The ACE Export Manifest for Air Cargo Test is authorized under § 101.9(b) of title 19 of the Code of Federal Regulations (19 CFR 101.9(b)), which provides for the testing of National Customs Automation Program (NCAP) programs or procedures.

The ACE Export Manifest for Air Cargo Test examines the functionality of filing export manifest data for air cargo electronically in ACE. The ACE system creates a single automated export processing platform for certain export manifest, commodity, licensing, export control, and export targeting transactions. This will reduce costs for CBP, partner government agencies, and the trade community, as well as improve facilitation of export shipments through the supply chain.

The ACE Export Manifest for Air Cargo Test will also assess the feasibility of requiring the manifest information to be filed electronically in ACE within a specified time before the cargo is loaded on the aircraft. This capability will enable CBP to calculate the risk and effectively identify and inspect shipments prior to the loading of cargo in order to comply with all U.S. export laws.

CBP announced the procedures and criteria related to participation in the ACE Export Manifest for Air Cargo Test in a notice published in the **Federal Register** on July 10, 2015 (80 FR 39790). This test was originally scheduled to run for approximately two years. On August 14, 2017, CBP extended the test period for one additional year (82 FR 37888). At that time, CBP also modified the original notice to make certain data elements optional and opened the test to accept additional applications for all parties who met the eligibility requirements.

The data elements, unless noted otherwise, are mandatory. Data elements which are mandatory must be provided to CBP for every shipment. Data elements which are marked ''conditional'' must be provided to CBP only if the particular information pertains to the cargo. Data elements which are marked ''optional'' may be provided to CBP but are not required to be completed. The data elements are set forth below:

(1) Exporting Carrier
(2) Marks of nationality and registration
(3) Flight number
(4) Port of lading
(5) Port of unlading
(6) Scheduled date of departure
(7) Consolidator (conditional)
(8) De-consolidator (conditional)
(9) Air waybill type (Master, House, Simple or Sub)
(10) Air waybill number
(11) Number of pieces and unit of measure (optional)
(12) Weight (kg./lb.)
(13) Number of house air waybills (optional)
(14) Shipper name and address
(15) Consignee name and address
(16) Cargo description
(17) AES Internal Transaction Number (ITN) or AES Exemption Statement/Exception Classification (per shipment)
(18) Split air waybill indicator (optional)
(19) Hazmat indicator (Yes/No)
(20) UN Number (conditional) (If the hazmat indicator is yes, the four digit UN (United Nations) Number assigned to the hazardous material must be provided.)
(21) In-bond number (optional)
(22) Mode of transportation (containerized air cargo or noncontainerized air cargo) (optional).

For further details on the background and procedures regarding this test, please refer to the July 10, 2015 notice and August 14, 2017 extension and modification.

II. Extension of the ACE Export Manifest for Air Cargo Test Period

CBP will extend the test for another two years to continue evaluating the ACE Export Manifest for Air Cargo Test. This will assist CBP in determining whether electronic submission of manifests will allow for improvements in capabilities at the departure level. The extended test will run for two additional years from the date of publication.

III. Applicability of Initial Test Notice

All provisions in the July 2015 notice and the modifications in the August 2017 extension remain applicable, subject to the time period extension provided herein.

Dated: December 10, 2021.

William Ferrara,

Executive Assistant Commissioner, Office of Field Operations, U.S. Customs and Border Protection.

[FR Doc. 2021–27653 Filed 12–21–21; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0110]

Visa Waiver Program Carrier Agreement (Form I–775)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted no later than

February 22, 2022 to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0110 in the subject line and the agency name. Please use the following method to submit comments:

Email. Submit comments to: *CBP_PRA@cbp.dhs.gov.*

Due to COVID–19-related restrictions, CBP has temporarily suspended its ability to receive public comments by mail.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Visa Waiver Program Carrier Agreement.

OMB Number: 1651–0110.

Form Number: Form I–775.

Current Actions: Extension with change.

Type of Review: Extension (with change).

Affected Public: Businesses.

Abstract: Section 233(a) of the Immigration and Nationality Act (INA) (8 U.S.C. 1223(a)) provides for the necessity of a transportation contract. The statute provides that the Attorney General may enter into contracts with transportation lines for the inspection and admission of noncitizens coming into the United States from a foreign territory or from adjacent islands. No such transportation line shall be allowed to land any such noncitizen in the United States until and unless it has entered into any such contracts which may be required by the Attorney General. Pursuant to the Homeland Security Act of 2002, this authority was transferred to the Secretary of Homeland Security.

The Visa Waiver Program Carrier Agreement (CBP Form I–775) is used by carriers to request acceptance by CBP into the Visa Waiver Program (VWP). This form is an agreement whereby carriers agree to the terms of the VWP as delineated in Section 217(e) of the INA (8 U.S.C. 1187(e)). Once participation is granted, CBP Form I–775 serves to hold carriers liable for certain transportation costs, to ensure the completion of required forms, and to require sharing passenger data, among other requirements. Regulations are promulgated at 8 CFR 217.6, Carrier Agreements. A fillable copy of CBP Form I–775 is accessible at: *https://www.cbp.gov/sites/default/files/assets/documents/2019-Aug/CBP%20Form%20I-775.pdf.*

Proposed Change

The requirement of submitting original documents bearing original signatures of company representatives, has been modified to include electronic wire transfer of CBP Form I–775. This temporary transfer of information will be lifted upon notification from the CDC that COVID–19 restrictions have changed.

Type of Information Collection: Form I–775.

Estimated Number of Respondents: 98.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 98.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 49.

Dated: December 17, 2021.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2021–27747 Filed 12–21–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0023]

Request for Information

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than February 22, 2022) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0023 in the subject line and the agency name. Please use the following method to submit comments:

Email. Submit comments to: *CBP_PRA@cbp.dhs.gov.*

Due to COVID–19-related restrictions, CBP has temporarily suspended its ability to receive public comments by mail.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, telephone number 202–325–0056, or via email

CBP_PRA@cbp.dhs.gov. Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Request for Information.

OMB Number: 1651–0023.

Form Number: CBP Form 28.

Current Actions: Extension with a decrease in burden previously reported.

Type of Review: Extension (with change).

Affected Public: Businesses.

Abstract: U.S. Customs and Border Protection (CBP) is authorized to collect the information requested on this form pursuant to 19 CFR 151.11, 19 CFR 142.3, and 19 CFR 181.72.

Under 19 U.S.C. 1500, and 1401a, Customs and Border Protection (CBP) is responsible for appraising merchandise by ascertaining or estimating its value; fixing the final classification of such merchandise under the tariff schedule; and fixing a rate of duty and final amount of duty to be paid on such merchandise. On occasions when the invoice or other documentation does not provide sufficient information for appraisement or classification, including for import compliance with trade agreements, preference treatment, or special provisions, CBP may request additional information using CBP Form 28, *Request for Information.* This form is sent by CBP personnel to importers, exporters, producers, or their agents, as applicable, requesting additional information. Additional authority to collect this information provided under 19 U.S.C. 1509. CBP Form 28 is provided for by 19 CFR 151.11.

Type of Information Collection: Request for Information (CBP Form 28).

Estimated Number of Respondents: 13,415.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 13,415.

Estimated Time per Response: 2 hours.

Estimated Total Annual Burden Hours: 26,830.

Dated: December 17, 2021.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2021–27768 Filed 12–21–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX22EF000COM00; OMB Control Number 1028–0092]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Topographic and Hydrography Data Grants

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Geological Survey (USGS) are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before February 22, 2022.

ADDRESSES: Send written comments on this information collection request (ICR) to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at *OIRA_Submission@omb.eop.gov*; or via facsimile to (202) 395–5806. Please provide a copy of your comments to the U.S. Geological Survey, Information Collections Clearance Officer, 12201 Sunrise Valley Drive MS 159, Reston, VA 20192; or by email to *gs-info_collections@usgs.gov.* Please reference OMB Control Number 1028–0092 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Susan Buto by email at *sbuto@usgs.gov,* or by telephone at 775–546–3059. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the USGS; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the USGS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the USGS minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you can ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Abstract: The U.S. Geological Survey gathers topographic data through the 3D Elevation Program (3DEP) and, contingent on funding, the 3D Hydrography Program (3DHP). The primary goal of 3DEP is to systematically collect three-dimensional (3D) elevation data in the form of high-quality light detection and ranging (lidar) data for the conterminous United

States, Hawaii, and the U.S. territories, as well as interferometric synthetic aperture radar (IfSAR) data for Alaska. The primary goal of the 3DHP is to leverage 3DEP data to create a high-precision, z-enabled representation of the surface waters of the United States and its territories. The implementation model for 3DEP is based on multi-agency partnership funding for topographic data acquisition, with the USGS leading management of the program to facilitate planning and acquisition, using government contracts and partnership agreements, for the broader community. The USGS issues cooperative agreements with partners to collect topographic data through an annual Broad Agency Announcement (BAA), which is a competitive solicitation issued to facilitate the cooperative collection of lidar and derived elevation data for 3DEP. It has been included in the annual Catalog of Federal Domestic Assistance under USGS 15.8 17. Federal agencies, state and local governments, tribes, academic institutions, and the private sector are eligible to submit proposals. The USGS collects information from applicants about their proposed topographic data collection and cost sharing options? offers? and then uses that information to determine grant awards. Implementation of 3DHP will follow the 3DEP model over time as funding permits. This ICR expands the scope of the collection to include proposals for both the 3DEP and 3DHP BAA activities.

Title of Collection: Topographic Data Grants.

OMB Control Number: 1028–0092.

Form Number: None.

Type of Review: Extension of a currently approved collection with revision.

Respondents/Affected Public: State and local governments, tribes, academic institutions, and the private sector.

Total Estimated Number of Annual Respondents: 80.

Total Estimated Number of Annual Responses: 80.

Estimated Completion Time per Response: 41 hours.

Total Estimated Number of Annual Burden Hours: 3,280.

Respondent's Obligation: Voluntary.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct, sponsor, nor is a person required to respond to, a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Michael Tischler,

Director, National Geospatial Program.

[FR Doc. 2021–27647 Filed 12–21–21; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BAC 4331–11]

Call for Nominations to the Idaho Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The purpose of this notice is to request nominations to fill vacant positions or the positions of members whose terms are scheduled to expire for the Bureau of Land Management's (BLM) Idaho Resource Advisory Council (RAC). The RAC advises the Secretary of the Interior on the issues related to land use, planning, and the management of resources on BLM land in the State of Idaho.

DATES: All nominations must be received no later than January 21, 2022.

ADDRESSES: Nominations and completed applications should be sent to the BLM office listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

FOR FURTHER INFORMATION CONTACT: MJ Byrne, 1387 South Vinnell Way, Boise, Idaho 83709; (208) 373–4006; *mbyrne@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at (800) 877–8339 to contact Ms. Byrne during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Federal Land Policy and Management Act (FLPMA) directs the Secretary of the Interior to involve the public in management planning for lands administered by the BLM through the establishment of citizen-based advisory councils that are consistent with the Federal Advisory Committee Act (FACA). RAC membership is balanced and representative of the various interests concerned with the management of the public lands. The rules governing RACs are found at 43 CFR subpart 1784. The RACs include the following three membership categories:

Category One—Holders of Federal grazing permits or leases within the area for which the RAC is organized; representatives of interests associated with transportation or rights-of-way; representatives for developed outdoor recreation, off-highway vehicle users, or commercial recreation activities; representatives of the commercial timber industry; or representatives of energy and mineral development.

Category Two—Representatives of nationally or regionally recognized environmental organizations; representatives of dispersed recreational activities; representatives of archaeological and historical interests; or representatives of nationally or regionally recognized wild horse and burro interest groups.

Category Three—Individuals holding elected office withing the state, county, or local government; employees of a state agency responsible for the management of natural resources; representatives of Indian Tribes within or adjacent to the area for which the RAC is organized; academicians in natural resource management or the natural sciences; and representatives of the public-at-large.

Individuals may nominate themselves or others. Nominees must be residents of the state of Idaho. The BLM will evaluate nominees based on their education, training, experience, and knowledge of the geographic area of the RAC. Nominees should demonstrate a commitment to collaborative resource decision-making.

The following must accompany all nominations:

—A completed RAC application, which can either be obtained through your local BLM office or online at: *https://www.blm.gov/sites/blm.gov/files/1120-019_0.pdf*

—Letters of reference from represented interests or organizations; and

—Any other information that addresses the nominee's qualifications.

Simultaneous with this notice, BLM state offices will issue press releases providing additional information for submitting nominations.

Before including any address, phone number, email address, or other personal identifying information in the application, nominees should be aware this information may be made publicly available at any time. While the nominee can ask to withhold the personal identifying information from public review, the BLM cannot guarantee that it will be able to do so.

Authority: 43 CFR 1784.4–1

Peter J. Ditton,

Acting Idaho State Director.

[FR Doc. 2021–27744 Filed 12–21–21; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[20X.LLAK980600.L18200000. LXSIARAC0000]

Notice of Public Meetings: Resource Advisory Council Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior's Bureau of Land Management (BLM) Alaska Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Alaska RAC will hold virtual meetings on Tuesday, February 8, 2022, and Tuesday, May 17, 2022. The meetings will be held from 9 a.m. to 5 p.m. and may end earlier or later depending on the needs of group members.

ADDRESSES: The meetings will be held online through the Zoom meeting application. The public can register, watch the meetings, and provide comments through the following links:

On February 8, 2022, *https://blm.zoomgov.com/meeting/register/vJItcu6rrj4iH9m_4eVrtX89DywKTV3o2Lo.*

On May 17, 2022, *https://blm.zoomgov.com/meeting/register/vJIsduirrDkiG3pfi4ZNwpaxFxC0I_OsZbo.*

Written comments can be mailed to: BLM Alaska State Office, Office of Communications, Attn: RAC Coordinator Melinda Bolton; 222 W 7th Avenue #13, Anchorage, AK 99513. Comments can also be submitted by email to *mbolton@blm.gov* with the subject line: BLM AK RAC.

Meeting links, guidance for attendees, and the final agendas will be available 2 weeks in advance of each meeting on the BLM Alaska RAC web page at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/alaska/rac* and linked on BLM Alaska news releases and social media posts.

FOR FURTHER INFORMATION CONTACT: Melinda Bolton, RAC Coordinator, by telephone at (907) 271–3342, or by email at *mbolton@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at (800) 877–8339 to contact Ms. Bolton during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member Alaska RAC serves in an advisory capacity concerning issues relating to land use planning and the management of the public land resources located within the State of Alaska. Meetings are open to the public in their entirety and public comment periods will be held near the end of the day for each meeting. Both the February and May meeting agendas include discussions on lands and cadastral survey, land use planning projects, and recreation; Federal Subsistence Board activity updates; and potential for recommendations to the State Director or his designee.

Interested persons may make verbal presentations to the RAC during the meetings or file written statements. Such requests should be made to RAC Coordinator Melinda Bolton prior to the public comment period. Depending on the number of people who wish to speak, the time for individual comments may be limited. Individuals who need further information about the meetings, or special assistance such as sign language interpretation or other reasonable accommodations, may contact Melinda Bolton (see **FOR FURTHER INFORMATION CONTACT**).

Before including your address, phone number, email address, or other personal identifying information in your comments, please be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 CFR 1784.4–2)

Thomas A. Heinlein,

Acting State Director.

[FR Doc. 2021–27652 Filed 12–21–21; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–5033154; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before December 11, 2021, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by January 6, 2022.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before December 11, 2021. Pursuant to Section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers:

ARKANSAS

Conway County

Chapel of the Transfiguration, 10 Keller Way, Morrillton vicinity, SG100007356

FLORIDA

Jefferson County

Dixie Plantation, 1583 Livingston Road, Greenville vicinity, SG100007362

IOWA

Linn County

Wickiup Hill Late Woodland Village Site (Archaeology of the Wickiup Hill Locality in Linn County, Iowa MPS), Address Restricted, Toddville vicinity, MP100007333

Wickiup Hill Middle to Late Archaic Camp Site (Archaeology of the Wickiup Hill Locality in Linn County, Iowa MPS), Address Restricted, Toddville vicinity, MP100007334

Wickiup Hill Mound Group No. 1 (Archaeology of the Wickiup Hill Locality in Linn County, Iowa MPS), Address Restricted, Toddville vicinity, MP100007335

Wickiup Hill Mound Group No. 2 (Archaeology of the Wickiup Hill Locality in Linn County, Iowa MPS), Address Restricted, Toddville vicinity, MP100007336

Wickiup Hill Mound Group No. 3 (Archaeology of the Wickiup Hill Locality in Linn County, Iowa MPS), Address Restricted, Toddville vicinity, MP100007337

Wickiup Hill Mound Group No. 4 (Archaeology of the Wickiup Hill Locality in Linn County, Iowa MPS), Address Restricted, Toddville vicinity, MP100007338

KANSAS

Douglas County

Oregon-California Trail Segments (Boundary Increase), US 40, Lawrence vicinity, BC100007343

Shawnee County

Kansas State Office Building, 915 SW Harrison Street, Topeka, SG100007341

MASSACHUSETTS

Suffolk County

Walnut Park Historic District, 7–15 Waldren Rd., 348–363, 367 Walnut Ave., 8–81 Walnut Park, 7–20 Wardman Rd., 65–71 Westminster Ave., Boston, SG100007348

MICHIGAN

Wayne County

Most Worshipful Prince Hall Grand Lodge of Michigan (The Civil Rights Movement and the African American Experience in 20th Century, Detroit MPS), 3500 McDougall St., Detroit, MP100007344

MINNESOTA

Hennepin County

Church of the Incarnation and Rectory, 3801–3817 Pleasant Ave., Minneapolis, SG100007352

The Woman's Club of Minneapolis, 410 Oak Grove Dr., Minneapolis, SG100007357

Otter Tail County

Northern Pacific Depot (Railroads in Minnesota MPS), 423 South Cascade St., Fergus Falls, MP100007347

MISSOURI

Jackson County

East Side Apartments Historic District (Working-Class and Middle-Income Apartment Buildings in Kansas City, Missouri MPS), 5212–5314 East 12th St., 1103–1123 Hardesty Ave., 5308–5315 Williamsburg Ct., 5101–5315 Winner Rd., Kansas City, MP100007359

Jasper County

Joplin YMCA (Historic Resources of Joplin, Missouri MPS), 510 South Wall Ave., Joplin, MP100007358

Randolph County

Moberly Municipal Auditorium, 201–299 West Rollins St., Moberly, SG100007361

St. Louis Independent City

Rose Fanning Elementary School (St. Louis Public Schools of William B. Ittner MPS), 3417 Grace Ave., St. Louis, MP100007353

Cook School, 5935 Horton Pl., St. Louis, SG100007360

NEW HAMPSHIRE

Carroll County

Union Railroad Station and Freight Shed, 1 Chapel St., Wakefield, SG100007349

NEW YORK

Monroe County

Gregory Tract Historic District, Portions of Benton, Caroline, Cayuga, Diem, Gregory, Linden, Meigs, Nicholson, Oakland, Seager, South Goodman, and Weider Sts., Carroll and Goebel Pls., Mt. Vernon and South Clinton Aves., Washburn Park, Rochester, SG100007350

PENNSYLVANIA

Philadelphia County

Hoyle, Harrison & Kaye Textile Mill, 118–160 East Indiana Ave., Philadelphia, SG100007364

TEXAS

Galveston County

Parkland Apartments, 3916 Winnie St. (Ave. G), Galveston, SG100007354

Hood County

Granbury Elementary School, 126 North Morgan St., Granbury, SG100007355

A request for removal has been made for the following resource:

VIRGINIA

Botetourt County

Greenfield, Botetourt Center at Greenfield, US HWY 220, Fincastle, OT10000792

Additional documentation has been received for the following resources:

KANSAS

Douglas County

Pinkney I Historic District (Additional Documentation) (Lawrence, Kansas MPS), Roughly bounded by West 5th St., Tennessee St., West 6th St., and Louisiana St., with 501–533 Louisiana St. and 444–445 West 5th St., Lawrence, AD04000688

Pinkney II Historic District (Additional Documentation) (Lawrence, Kansas MPS), Roughly bounded by West 3rd St., Louisiana St., West 4th St., and Mississippi St., Lawrence, AD04000689

Oregon-California Trail Segments (Additional Documentation), US 40, Lawrence vicinity, AD16000132

VIRGINIA

Radford Independent City, East Radford Historic District (Additional Documentation), Norwood, Stockton, and Downey Sts., and Grove Ave., Radford (Independent City), AD00000491

Authority: Section 60.13 of 36 CFR part 60.

Dated: December 11, 2021.

Sherri A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2021–27659 Filed 12–21–21; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Replacement Automotive Lamps, DN 3583*; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The

public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Kia Corporation and Kia America, Inc., on December 16, 2021. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain replacement automotive lamps. The complainant names as respondents: TYC Brother Industrial Co., Ltd of Taiwan; Genera Corporation (d/b/a TYC Genera) of Brea, CA; LKQ Corporation of Chicago IL; and Keystone Automotive Industries, Inc. of Exeter, PA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders and impose a bond upon respondents alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3583'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: December 16, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–27651 Filed 12–21–21; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Replacement Automotive Lamps, DN 3584;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information

System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Hyundai Motor Company and Hyundai Motor America, Inc. on December 16, 2021. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain replacement automotive lamps. The complainant names as respondents: TYC Brother Industrial Co., Ltd of Taiwan; Genera Corporation (d/b/a TYC Genera) of Brea, CA; LKQ Corporation of Chicago IL; and Keystone Automotive Industries, Inc. of Exeter, PA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders and impose a bond upon respondents alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3584'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures).[1] Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: December 17, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–27756 Filed 12–21–21; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1235]

Certain Vehicle Control Systems, Vehicles Containing the Same, and Components Thereof; Notice of a Commission Determination Not To Review an Initial Determination Granting a Joint Motion To Terminate the Investigation Due to a Settlement Agreement; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has

determined not to review an initial determination (''ID'') (Order No. 58) issued by the presiding administrative law judge (''ALJ'') granting a joint motion to terminate the investigation based on a settlement agreement. The investigation is hereby terminated.

FOR FURTHER INFORMATION CONTACT: Carl P. Bretscher, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2382. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on December 29, 2020, based on a complaint, as supplemented, filed by Jaguar Land Rover Ltd. of Coventry, United Kingdom and Jaguar Land Rover North America, LLC of Mahwah, New Jersey (collectively, ''JLR''). 85 FR 85659 (Dec. 29, 2020). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''Section 337''), in the importation into the United States, sale for importation, or sale in the United States after importation of certain vehicle control systems, vehicles containing the same, and components thereof by reason of infringement of certain claims of U.S. Patent No. RE46,828 (''the '828 patent''). The complaint further alleges that a domestic industry exists. *Id.* The Commission's notice of investigation named the following respondents: Dr. Ing. h.c. F. Porsche AG (d/b/a Porsche AG) of Stuttgart, Germany; Porsche Cars North America, Inc. of Atlanta, Georgia; Automobili Lamborghini S.p.A. of Sant'Agata Bolognese, Italy; Automobili Lamborghini America, LLC of Herndon, Virginia; Volkswagen AG of Wolfsburg, Germany; Volkswagen Group of America, Inc. of Herndon, Virginia; Audi AG of Ingolstadt, Germany; and Audi of America, LLC of Herndon, Virginia. *Id.* The Office of Unfair Import Investigations was not named as a party to this investigation. *Id.*

The Commission partially terminated the investigation with respect to certain claims of the '828 patent based on unopposed motions filed by JLR. Order No. 43 (May 3, 2021), *unreviewed by* Comm'n Notice (June 1, 2021); Order No. 47 (Aug. 4, 2021), *unreviewed by* Comm'n Notice (Aug. 18, 2021); Order No. 48 (Aug. 5, 2021), *unreviewed by* Comm'n Notice (Aug. 18, 2021).

On September 27, 2021, JLR and Respondents filed a joint motion to terminate the investigation based on a settlement agreement that settled all of the issues between the parties.

On November 18, 2021, the presiding ALJ issued the subject ID (Order No. 58) granting the joint motion to terminate the investigation. The ID finds that the settlement agreement complies with Commission Rules 210.21(a)(1) and 210.21(b)(1) (19 CFR 210.21(a)(1), 210.21(b)(1)) because it completely resolves the dispute between the parties, and there are no other agreements, written or oral, express or implied, between the parties concerning the subject matter of the investigation. The ID also finds that terminating the investigation is in the public interest and will conserve public and private resources. The ID finds there are no extraordinary circumstances that would prevent the termination of this investigation.

No petition for review of the subject ID was filed.

The Commission has determined not to review the subject ID. Accordingly, the investigation is hereby terminated in its entirety.

The Commission vote for this determination took place on December 17, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: December 17, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–27758 Filed 12–21–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–662 and 731–TA–1554 (Final)]

Pentafluoroethane (R–125) From China; Revised Schedule for the Subject Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: December 17, 2021.

FOR FURTHER INFORMATION CONTACT: Peter Stebbins (202–205–2039), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: Effective August 17, 2021, the Commission established a schedule for the conduct of the final phase of the subject investigations (86 FR 50171, September 7, 2021). The Commission is revising its schedule.

The Commission's revised date in the schedule is as follows: The deadline for filing posthearing briefs is December 28, 2021. Parties may submit supplemental comments not to exceed five (5) pages in length addressing only Commerce's final countervailing and antidumping duty determinations on or before January 7, 2022; the Commission will make its final release of information on January 26, 2022; and final party comments are due on January 28, 2022.

For further information concerning these proceedings, see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.21 of the Commission's rules.

By order of the Commission.

Issued: December 17, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–27759 Filed 12–21–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–308–310 and 520–521 (Fifth Review)]

Scheduling of Expedited Five-Year Reviews; Carbon Steel Butt-Weld Pipe Fittings From Brazil, China, Japan, Taiwan, and Thailand

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty orders on carbon steel butt-weld pipe fittings from Brazil, China, Japan, Taiwan, and Thailand would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: October 4, 2021.

FOR FURTHER INFORMATION CONTACT: Tyler Berard (202–205–3354), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On October 4, 2021, the Commission determined that the domestic interested party group response to its notice of institution (86 FR 35133, July 1, 2021) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.[1] Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*. No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Staff report.—A staff report containing information concerning the subject matter of the reviews has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for these reviews on December 22, 2021. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,[2] and any party other than an interested party to the reviews may file written comments with the Secretary on what determinations the Commission should reach in the reviews. Comments are due on or before January 7, 2022 and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by January 7, 2022. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: December 16, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–27668 Filed 12–21–21; 8:45 am]

BILLING CODE 7020–02–P

[1] A record of the Commissioners' votes is available from the Office of the Secretary and at the Commission's website.

[2] The Commission has found the joint response to its notice of institution filed on behalf of Tube Forgings of America, Inc., Mills Iron Works, Inc., and Hackney Ladish, Inc. (a subsidiary of Precision Castparts Corp.), as well as the separate response by Weldbend Corporation, domestic producers of carbon steel butt-weld pipe fittings, to be adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1196]

Notice of Request for Submissions on the Public Interest; Certain In Vitro Fertilization Products, Components Thereof, and Products Containing the Same

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that on December 15, 2021, the presiding administrative law judge (''ALJ'') issued a Final Initial Determination on Violation of Section 337. The ALJ also issued a Recommended Determination on remedy and bonding should a violation be found in the above-captioned investigation. The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation. This notice is soliciting comments from the public only.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–4716. Copies of non-confidential documents filed in connection with this investigation may be viewed on the

Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that, if the Commission finds a violation, it shall exclude the articles concerned from the United States:

unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation, specifically: (1) A limited exclusion order directed to certain in vitro fertilization products, components thereof, and products containing the same imported, sold for importation, and/or sold after importation by defaulting respondents Fast IVF of Scottsdale, Arizona and Hermes Ezcanesi of Istanbul, Turkey; and (2) a cease and desist order directed against Fast IVF. Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the ALJ's Recommended Determination on Remedy and Bonding issued in this investigation on December 15, 2021. Comments should address whether issuance of the recommended remedial orders in this investigation, should the Commission find a violation, would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the recommended remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;

(iii) identify like or directly competitive articles that complainants, complainants' licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainants, complainants' licensees, and/or third-party suppliers have the capacity to replace the volume of articles potentially subject to the recommended orders within a commercially reasonable time; and

(v) explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on January 14, 2022.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (''Inv. No. 337–TA–1196'') in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: December 16, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–27654 Filed 12–21–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1204]

Certain Chemical Mechanical Planarization Slurries and Components Thereof Notice of the Commission's Final Determination Finding a Violation of Section 337; Issuance of a Limited Exclusion Order and Cease and Desist Orders; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined that there is a violation of section 337 in the above-captioned investigation. The Commission has further determined to issue a limited exclusion order and cease and desist orders and to set a bond rate on the entered value of covered products imported or sold during the period of Presidential review.

FOR FURTHER INFORMATION CONTACT: Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3042. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its

internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On July 7, 2020, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based on a complaint filed by Cabot Microelectronics Corporation (''CMC'') of Aurora, Illinois. 85 FR 40685–86 (July 7, 2020). The complaint, as supplemented, alleged violations of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain chemical mechanical planarization (''CMP'') slurries and components thereof by reason of infringement of one or more of claims 1, 3–6, 10, 11, 13, 14, 18–20, 24, 26–29, 31, 35–37, and 39- 44 of U.S. Patent No. 9,499,721 (''the '721 patent''). *Id.* at 40685. The Commission's notice of investigation named as respondents DuPont de Nemours, Inc. of Wilmington, Delaware; Rohm and Haas Electronic Materials CMP, LLC of Newark, Delaware; Rohm and Haas Electronic Materials CMP Asia Inc. (d/b/a Rohm and Haas Electronic Materials CMP Asia Inc., Taiwan Branch (U.S.A.)) of Taoyuan City, Taiwan; Rohm and Haas Electronic Materials Asia-Pacific Co., Ltd. of Miaoli, Taiwan; Rohm and Haas Electronic Materials K.K. of Tokyo, Japan; and Rohm and Haas Electronic Materials LLC of Marlborough, Massachusetts (collectively, ''Respondents'' or ''DuPont''). *Id.* at 40686. The Office of Unfair Import Investigations (''OUII'') is participating in this investigation. *Id.*

On October 1, 2020, the administrative law judge (''ALJ'') issued an initial determination granting CMC's unopposed motion to amend the complaint and notice of investigation to assert infringement of claims 17 and 46 of the '721 patent. Order No. 7 (Oct. 1, 2020), *unreviewed by* Notice (Oct. 16, 2020).

On November 10, 2020, the ALJ issued an initial determination granting CMC's unopposed motion to amend the complaint and notice of investigation to change the name of Complainant from Cabot Microelectronics Corporation to CMC Materials, Inc. Order No. 8 (Nov. 10, 2020), *unreviewed by* Notice (Nov. 24, 2020).

On January 26, 2021, the ALJ issued an initial determination granting CMC's unopposed motion to amend the complaint and notice of investigation to reflect the conversion of Rohm and Haas Electronic Materials, Inc. to Rohm and Haas Electronic Materials CMP, LLC. Order No. 13 (Jan. 26, 2021), *unreviewed by* Notice (Feb. 11, 2021).

On January 26, 2021, the ALJ issued an initial determination granting CMC's unopposed motion to terminate the investigation as to claim 5 of the '721 patent. Order No. 12 (Jan. 26, 2021), *unreviewed by* Notice (Feb. 16, 2021).

On July 8, 2021, the ALJ issued the subject final initial determination (''ID'') finding a violation of section 337. The ID found that the parties do not contest personal jurisdiction, and that the Commission has *in rem* jurisdiction over the accused products. ID at 11. The ID further found that the importation requirement under 19 U.S.C. 1337(a)(1)(B) is satisfied. ID at 11–30. The ID also found that CMC established the existence of a domestic industry that practices the '721 patent. ID at 144–169, 297–314. The ID concluded that CMC proved that Respondent's accused products infringe the asserted claims of the '721 patent and that Respondents failed to show that the asserted claims are invalid. ID at 87–144. The ID included the ALJ's recommended determination on remedy and bonding (''RD''). The RD recommended that, should the Commission find a violation, issuance of a limited exclusion order and cease and desist orders would be appropriate. ID/RD at 316–331. The RD also recommended imposing a bond in the amount of one hundred percent of the entered value for covered products imported during the period of Presidential review. ID at 331.

On July 15, 2021, OUII filed a motion to extend the time for the parties to file petitions for review from July 20, 2021 (with responses due July 28, 2021) to July 29, 2021 (with responses due August 12, 2021). On July 16, 2021, the Chair granted the motion.

On July 29, 2021, Respondents and OUII filed separate petitions for review of the ID. On August 12, 2021, CMC submitted responses to the petitions filed by DuPont and OUII, and OUII submitted a response to DuPont's petition.

On August 30, 2021, the Commission extended the due date for determining whether to review the final ID from September 8, 2021, to September 22, 2021.

On September 22, 2021, the Commission determined to review the ID in part. 86 FR 53674–76 (Sept. 28, 2021). Specifically, the Commission determined to review the ID's findings on importation, infringement, and domestic industry and requested briefing on the latter issue. *Id.* The Commission also requested briefing from the parties, interested government agencies, and interested persons on the issues of on remedy, the public interest, and bonding. On October 6, 2021, the parties submitted their opening briefs. On October 13, 2021, the parties filed their reply briefs.

On October 6, 2021, non-Party, Intel Corporation (''Intel'') filed a statement on the public interest in response to the Commission's notice. On October 8, 2021, Intel sent a letter to the Chair stating that it is in possession of a document that bears directly on the public interest impact of CMC's requested remedy (''PI Document'') and that it would be in a position to provide the document if ordered to do so. On October 20, 2021, DuPont filed a response requesting that the Commission order Intel to produce the PI document. On October 21, 2021, CMC filed a response in opposition.

On November 2, 2021, the Commission issued a notice requesting additional public interest information from Intel and directing Intel to produce the PI Document. On November 9, 2021, Intel submitted a response to the Commission notice. On November 15, 2021, the parties filed replies to Intel's Submission.

Upon review of the parties' submissions, the ID, the RD, evidence of record, and public interest filings, the Commission has determined that Respondents violated section 337 by reason of importation and sale of articles that infringe asserted claims 1, 3–6, 10, 11, 13, 14, 18–20, 24, 26–29, 31, 35–37, and 39–44 of the '721 patent. The Commission has further determined to issue a limited exclusion order prohibiting further importation of infringing products and cease and desist orders against the domestic respondents. The Commission, however, has determined that the public interest factors warrant an exemption from the remedial orders for up to one year for entities currently using the infringing products in an ongoing semiconductor chip fabrication development project pursuant to terms stated in the concurrently issued opinion and orders. The Commission has determined to set a bond in the amount of one hundred percent (100%) of entered value for covered products imported or sold during the period of Presidential review.

The Commission's vote on this determination took place on December 16, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of

Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: December 16, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–27701 Filed 12–21–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1213]

Certain Light-Emitting Diode Products, Fixtures, and Components Thereof Notice of a Commission Determination Finding a Violation of Section 337; Issuance of Limited Exclusion Order and Cease and Desist Order; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''the Commission'') has determined to affirm a final initial determination (''ID'') of the presiding administrative law judge (''ALJ'') finding a violation of section 337 by the accused products of respondent RAB Lighting Inc. (''RAB'') of Northvale, New Jersey. The Commission has issued a limited exclusion order (''LEO'') directed against infringing light-emitting diode products, fixtures, and components thereof of RAB and a cease and desist order (''CDO'') directed against RAB. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Clint Gerdine, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–2310. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email *EDIS3Help@usitc.gov*. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on August 17, 2020, based on a complaint filed on behalf of Ideal Industries Lighting LLC d/b/a Cree Lighting (''Cree'') of Durham, North Carolina. 85 FR 50047–48 (Aug. 17, 2020). The complaint, as supplemented, alleges violations of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain light-emitting diode products, fixtures, and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 8,403,531 (''the '531 patent''); 8,596,819 (''the '819 patent''); 8,777,449 (''the '449 patent''); 9,261,270 (''the '270 patent''); and 9,476,570 (''the '570 patent''). The complaint further alleges the existence of a domestic industry. The Commission's notice of investigation (''NOI'') named RAB as the sole respondent. The Office of Unfair Import Investigations is not participating in the investigation. The Commission previously terminated the following claims from the investigation: (1) Claims 1–9 and 11–14 of the '449 patent; (2) claims 3–12 of the '270 patent; claims 17, 21, and 24 of the '531 patent; and (3) claims 2, 6–9, and 11–24 of the '570 patent. *See* Order No. 13 (Jan. 8, 2021), *unreviewed by* Comm'n Notice (Jan. 26, 2021); Order No. 25 (May 5, 2021), *unreviewed by* Comm'n Notice (May 21, 2021). The Commission also amended the complaint and NOI to add asserted claim 11 of the '531 patent. *See* Order No. 13 (Jan. 8, 2021), *unreviewed by* Comm'n Notice (Jan. 26, 2021).

On August 17, 2021, the ALJ issued the final ID finding a violation of section 337 based on infringement of the asserted claims of the '270 and '570 patents. The ID finds no violation of section 337 with respect to the '531 and '819 patents on the basis of patent-ineligible subject matter, lack of enablement, and lack of written description. The ID also finds no violation with respect to the '449 patent based on findings that the accused products do not infringe asserted claim 10; the asserted claims are invalid for lack of enablement; and the domestic industry products do not practice one or more claims. The ALJ recommended, should the Commission find a violation, issuing a limited exclusion order directed to RAB's infringing products and a cease and desist order directed to RAB and requiring a bond in the amount of five (5) percent for importation of infringing articles during the period of Presidential review.

On October 25, 2021, the Commission determined to review the final ID in part. Specifically, the Commission determined to review the ID's finding that: (1) The asserted claims of the '531 patent and '819 patent are invalid due to patent-ineligible subject matter, lack of enablement, and lack of written description and (2) the '819 patent is prior art to claims 1, 10–12, and 26 of the '531 patent. The Commission determined not to review the remainder of the ID, including the ID's finding of a violation with respect to the '270 and '570 patents. 86 FR 60071–72 (Oct. 29, 2021). The Commission also requested written submissions from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding. *Id.*

On November 8 and 15, 2021, Cree and RAB each filed a brief and a reply brief, respectively, on remedy, the public interest, and bonding. The Commission received no other submissions.

Having reviewed the record in this investigation, including the final ID and the parties' briefing, the Commission has determined, on review, to: (1) Affirm the ID's finding that the asserted claims of the '531 and '819 patents are patent ineligible; (2) take no position on the ID's finding that the asserted claims of the '531 and '819 patents are invalid due to lack of enablement and lack of written description; and (3) take no position on the ID's finding that the '819 patent is prior art to claims 1, 10–12, and 26 of the '531 patent. Accordingly, the Commission affirms the ID's finding of no violation as to the '531 and '819 patents.

The Commission has adopted the final ID's finding of a violation of section 337 as to the '270 and '570 patents. The Commission has determined that the appropriate form of relief is an LEO prohibiting the entry of unlicensed light-emitting diode products, fixtures, and components thereof that infringe one or more of claims 1–2 of the '270 patent and claims 1, 3–5, and 10 of the '570 patent, and that are manufactured abroad by or on behalf of, or imported by or on behalf of RAB, or any of its affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns (collectively, ''the covered articles''). Appropriate relief also includes a CDO prohibiting RAB from conducting any of the following activities in the United States: Importing, selling, marketing, advertising, distributing, offering for sale, transferring (except for exportation), and soliciting U.S. agents or distributors for light-emitting diode products, fixtures, and components thereof that infringe one or more of claims 1–2 of the '270 patent and claims 1, 3–5, and 10 of the '570 patent.

The Commission has further determined that the public interest factors enumerated in sections 337(d)(1) and 337(f)(1) (19 U.S.C. 1337(d)(1) and 1337(f)(1)) do not warrant denying relief. Finally, the Commission has determined that a bond in the amount of five (5) percent of the entered value of the covered articles is required during the period of Presidential review (19 U.S.C. 1337(j)). The Commission's order was delivered to the President and to the United States Trade Representative on the day of its issuance.

The Commission issues its opinion herewith setting forth its determinations on the remedy issues. The investigation is terminated.

The Commission vote for this determination took place on December 16, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in Part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.

Issued: December 16, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–27702 Filed 12–21–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1206]

Certain Percussive Massage Devices; Issuance of a General Exclusion Order and a Cease and Desist Order; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to issue a general exclusion order (''GEO'') and a cease and desist order (''CDO'') directed to respondent Kinghood International Logistics Inc. (''Kinghood'') in the above-captioned investigation. The investigation is terminated in its entirety.

FOR FURTHER INFORMATION CONTACT: Cathy Chen, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2392. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on July 22, 2020, based on a complaint filed on behalf of Hyper Ice, Inc. (''Hyperice'') of Irvine, California. 85 FR 44322 (July 22, 2020). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain percussive massage devices by reason of infringement of U.S. Design Patent Nos. D855,822 and D886,317 (collectively, ''Asserted Design Patents'') and claims 1–9, 14, and 15 of U.S. Patent No. 10,561,574 (''the '574 patent''). The complaint further alleged that a domestic industry exists. The Commission's notice of investigation named the following nineteen respondents: Laiwushiyu Xinuan Trading Company of Shandong District, China; Shenzhen Let Us Win-Win Technology Co., Ltd. of Guangdong, China; Shenzhen Qifeng Technology Co., Ltd. of Guangdong, China; Shenzhen QingYueTang E-commerce Co., Ltd. of Guangdong, China; and Shenzhen Shiluo Trading Co., Ltd. of Guangdong, China (collectively, the ''Unserved Respondents''); Kinghood of La Mirada, California; Manybo Ecommerce Ltd. (''Manybo'') of Hong Kong, China; Shenzhen Infein Technology Co., Ltd. (''Shenzhen Infein'') of Guangdong, China; Hong Kong Yongxu Capital Management Co., Ltd. (''Hong Kong Yongxu'') of Hong Kong, China; Kula eCommerce Co., Ltd. (''Kula'') of Guangdong, China; Performance Health Systems, LLC (''Performance Health'') of Northbrook, Illinois; Rechar, Inc. (''Rechar'') of Strasburg, Colorado; Ning Chen of Yancheng, Jiangsu China; Opove, Ltd. (''Opove'') of Azusa, California; Shenzhen Shufang E-Commerce Co., Ltd. (''Shufang E-Commerce'') of Shenzhen, China; Fu Si (''Shenzhen Fusi Technology'') of Guangdong, China; [1] WODFitters of Lorton, Virginia; Massimo Motor Sports, LLC (''Massimo'') of Garland, Texas; and Addaday LLC (''Addaday'') of Santa Monica, California. The notice of investigation also named the Office of Unfair Import Investigations (''OUII'') as a party.

On October 16, 2020, the Commission determined not to review Order No. 11 granting motions to intervene by third parties Shenzhen Xinde Technology Co., Ltd. (''Xinde'') and Yongkang Aijiu Industrial & Trade Co., Ltd. (''Aijiu'') in the investigation. *See* Order No. 11 (Sept. 25, 2020), *unreviewed by* Comm'n Notice (Oct. 16, 2020).

Respondents Addaday, WODFitters, Massimo, Performance Health, Rechar, Ning Chen, Opove, Shufang E-Commerce, Xinde, Aijiu, and Shenzhen Fusi Technology were terminated from the investigation based upon settlement agreements. *See* Order No. 10 (Sept. 16, 2020), *unreviewed by* Comm'n Notice (Oct. 15, 2020); Order No. 12 (Nov. 4, 2020), *unreviewed by* Comm'n Notice (Nov. 20, 2020); Order No. 30 (Apr. 8, 2021), *unreviewed by* Comm'n Notice (Apr. 22, 2021).

The Unserved Respondents were terminated from the investigation based upon withdrawal of the Complaint. *See* Order No. 36 at 2 (Aug. 3, 2021), *unreviewed by* Comm'n Notice (Aug. 19, 2021).

Respondents Kinghood, Manybo, Shenzhen Infein, Hong Kong Yongxu, and Kula (collectively, ''the Defaulting Respondents'') were found in default. *See* Order No. 17 (Dec. 17. 2020), *unreviewed by* Comm'n Notice (Jan. 5, 2021).

On May 6, 2021, OUII filed a motion to terminate the Asserted Design Patents from this investigation on the ground that Hyperice did not have sufficient rights to the design patents at the time the investigation was instituted. On May 17, 2021, Hyperice filed its response in opposition to OUII's motion to terminate, which included a cross-motion to amend the Complaint to reflect proper inventorship.

On May 7, 2021, Hyperice filed a motion for summary determination that the Defaulting Respondents have violated section 337 for infringing its three asserted patents. On May 14, 2021, Hyperice supplemented its motion with additional declarations. On May 20, 2021, Hyperice again supplemented its motion with claim charts and exhibits. OUII filed a response in support of the

[1] Respondent Fu Si's full name is Shenzhen Fusi Technology Co., Ltd. *See* Response of Opove Ltd., Shenzhen Shufang E-Commerce Co., Ltd., and Fu Si to the Complaint and Notice of Investigation at ¶ 40, EDIS Doc ID 716966 (Aug. 11, 2020). The principal place of business of Shenzhen Fusi Technology Co., Ltd. was changed to 14E, Building A, Guanghao International Center, No. 441 Meilong Road, Minzhi Street, Longhua District, Shenzhen, China, 518131 effective September 15, 2020. *Id.*

motion with respect to the '574 patent but not with respect to the Asserted Design Patents.

On August 17, 2021, the ALJ issued Order No. 38 denying Hyperice's motion to amend the complaint and the notice of investigation to reflect proper inventorship. That same day, the ALJ issued Order No. 39 granting OUII's motion to terminate the Asserted Design Patents for lack of standing. Hyperice filed a timely petition for review of Order No. 39 and OUII filed a response to the petition.

On November 22, 2021, the Commission determined to review in part Order No. 39 and, on review, affirm with modifications the ALJ's denial of limited relief under section 337(g)(1) as to the Defaulting Respondents. The Commission adopted Order No. 39's finding that Hyperice lacked standing to assert the Asserted Design Patents in this investigation. Accordingly, the Commission terminated the Asserted Design Patents from the investigation.

On August 20, 2021, the ALJ issued the subject ID (Order No. 40) granting in part Hyperice's motion for summary determination of violation of section 337. Specifically, the ID found: (1) That Hyperice established the importation requirement as to Defaulting Respondents Kinghood, Manybo, Shenzhen Infein, and Hong Kong Yongxu, but not Kula; (2) that Defaulting Respondents Kinghood, Manybo, Shenzhen Infein, and Hong Kong Yongxu infringe one or more of claims 1–7, 9, 14, and 15 of the '574 patent; (3) that Hyperice's domestic industry products practice at least one claim of the '574 patent; and (4) that Hyperice has proven that a domestic industry exists within the United States related to articles protected by that patent. Accordingly, the ALJ found that four of the five Defaulting Respondents have infringed one or more of claims 1–7, 9, 14, and 15 of the '574 patent in violation of section 337. No petitions for review of the ID were filed.

The ALJ concurrently issued a Recommended Determination (''RD'') on the issues of remedy and bonding. The RD recommended the issuance of a GEO and a CDO against Kinghood and setting the bond during the period of Presidential review in the amount of one hundred percent (100%) of the entered value.

On October 20, 2021, the Commission determined to review the ID in part and requested briefing on one issue it determined to review, and on remedy, the public interest, and bonding. 86 FR 59187 (Oct. 26, 2021). Specifically, the Commission determined to review the ID's finding that Hyperice satisfied the economic prong of the domestic industry requirement with respect to the '574 patent. The Commission adopted the ID's findings that Hyperice provided undisputed evidence that Kinghood's, Manybo's, and Shenzhen Infein's accused products infringe claims 1–7, 9, 14 and 15 of the '574 patent and that Hong Kong Yongxu's accused products infringe claims 1–7, 14 and 15 of the '574 patent. Although Hyperice provided undisputed evidence that Kula's accused products infringe claims 1–7, 9, 14 and 15 of the '574 patent, the Commission adopted the ID's finding that there is insufficient evidence of importation of Kula's accused products. On November 3, 2021, Hyperice and OUII filed their initial written submissions regarding the issue on review, and on remedy, the public interest, and bonding. OUII further filed a response brief on November 10, 2021.

Having examined the record of this investigation, including the ID and the submissions received, the Commission has determined to affirm the ID's finding that Hyperice satisfied the economic prong of the domestic industry requirement as to the '574 patent.[2] Accordingly, the Commission finds a violation of section 337 as to respondents Kinghood, Manybo, Shenzhen Infein, and Hong Kong Yongxu with respect to the '574 patent.

The Commission has determined that the appropriate remedy in this investigation is: (1) A GEO prohibiting the unlicensed importation of therapeutic handheld percussive massage devices for applying percussive massage to a person's body that infringe one or more of claims 1–7, 9, 14, and 15 of the '574 patent; and (2) a CDO prohibiting respondent Kinghood from further importing, selling, and distributing infringing products in the United States. The Commission has also determined that the public interest factors enumerated in paragraphs 337(d)(1) and (f)(1), 19 U.S.C. 1337(d)(1) and (f)(1), do not preclude issuance of these remedial orders. Finally, the Commission has determined that the bond during the period of Presidential review pursuant to 19 U.S.C. 1337(j) shall be in the amount of one hundred percent (100%) of the entered value of the imported articles. The Commission's order was delivered to the President and to the United States Trade Representative on the day of its issuance. The investigation is hereby terminated.

[2] Chair Kearns does not join his colleagues in finding the economic prong requirement met under section 337(a)(3)(B), and therefore does not find a violation of section 337.

Commissioners Karpel and Schmidtlein would issue CDOs directed to respondents Kinghood, Manybo, Shenzhen Infein, Kula, and Hong Kong Yongxu pursuant to 19 U.S.C. 1337(g)(1).

While temporary remote operating procedures are in place in response to COVID–19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR 201.16(a), 210.7(a)(1)), the Commission orders that the Complainant complete service for any party without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

The Commission vote for this determination took place on December 16, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in Part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.

Issued: December 16, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–27700 Filed 12–21–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1228]

Certain Automated Storage and Retrieval Systems, Robots, and Components Thereof Notice of Request for Submissions on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that on December 13, 2021, the presiding administrative law judge (''ALJ'') issued an Initial Determination on Violation of Section 337. The ALJ also issued a Recommended Determination on remedy and bonding should a violation be found in the above-captioned investigation. The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation. This notice is soliciting comments from the public only.

FOR FURTHER INFORMATION CONTACT: Cathy Chen, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202–205–2392. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that, if the Commission finds a violation, it shall exclude the articles concerned from the United States:

unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1).

The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation, specifically: A limited exclusion order directed to infringing articles imported, sold for importation, and/or sold after importation. The ALJ does not recommend a cease and desist order against Respondents Ocado Group Plc, Ocado Solutions Ltd., Ocado Solutions USA Inc., Ocado Innovation Ltd., Ocado Operating Ltd., and Ocado Central Services Ltd. Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the ALJ's Recommended Determination on Remedy and Bonding issued in this investigation on December 13, 2021. Comments should address whether issuance of the recommended remedial order in this investigation, should the Commission find a violation, would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the recommended remedial order are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended order;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third-party suppliers have the capacity to replace the volume of articles potentially subject to the recommended order within a commercially reasonable time; and

(v) explain how the recommended order would impact consumers in the United States.

Written submissions must be filed no later than by close of business on Friday, January 14, 2022.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (''Inv. No. 337–TA–1228'') in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: December 17, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–27757 Filed 12–21–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0071]

Agency Information Collection Activities; Proposed eCollection of eComments Requested; Extension With Change of a Currently Approved Collection; Notification to Fire Safety Authority of Storage of Explosive Materials

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Department of Justice (DOJ), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for an additional 30 days until January 21, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting

''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and, if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension with change of a currently approved collection.

(2) *The Title of the Form/Collection:* Notification to Fire Safety Authority of Storage of Explosive Materials.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: Individuals or households, Farms, and State, Local or Tribal Government.

Abstract: The Notification to Fire Safety Authority of Storage of Explosive Materials requires both oral and written notifications to local fire safety authority about sites where explosive materials are stored. This collection is necessary to ensure the safety of emergency personnel responding to fires at explosives storage locations.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 653 respondents will respond once to this collection, and it will take each respondent approximately 30 minutes to complete their responses.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 327 hours, which is equal to 653 (total respondents) * 1 (# of response per respondent) * .5 (30 minutes or the time taken to prepare each response).

(7) *An Explanation of the Change in Estimates:* The reduction in total responses and burden hours from 975 and 488 hours in 2018, to 653 and 327 hours respectively, is due to fewer respondents during the current renewal.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Mail Stop 3E.405A, Washington, DC 20530.

Dated: December 17, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–27740 Filed 12–21–21; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0079]

Agency Information Collection Activities; Proposed eCollection of eComments Requested; Extension With Change of a Currently Approved Collection; Transactions Among Licensee/Permittees and Transactions Among Licensees and Holders of User Permits

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Department of Justice (DOJ) will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for an additional 30 days until January 21, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and, if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension with change of a currently approved collection.

(2) *The Title of the Form/Collection:* Transactions Among Licensee/Permittees and Transactions Among Licensees and Holders of User Permits.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: Individuals or households OR Farms.

Abstract: The Transactions Among Licensee/Permittees and Transactions Among Licensees and Holders of User Permits requires that all explosives licensee/permittees and holders of user permits maintain records of all

explosives transactions as outlined in 27 CFR 555.103, for compliance with the Safe Explosives Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 46,500 respondents will prepare explosives transaction records for this collection once annually, and it will take each respondent approximately 30 minutes to complete their responses.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 23,250 hours, which is equal to 46,500 (total respondents) * 1 (# of response per respondent) * .5 (30 minutes or the time taken to prepare each response.

(7) *An Explanation of the Change in Estimates:* Due to fewer respondents, the total responses and burden hours were reduced from 50,000 and 25,000 hours respectively in 2018, to 46,500 and 23,250 hours currently.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Mail Stop 3E.405A, Washington, DC 20530.

Dated: December 17, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–27741 Filed 12–21–21; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to The National Cooperative Research and Production Act of 1993—Undersea Technology Innovation Consortium

Notice is hereby given that, on November 10, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Undersea Technology Innovation Consortium (''UTIC'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Shield AI, Inc., San Diego, CA; AEGIS Power Systems, Inc., Murphy, NC; Southwest Research Institute, San Antonio, TX; ATI Engineering Services LLC, Johnstown, PA; FORCE 3 LLC, Crofton, MD; Composite Energy Technologies dba GOETZ Composites, Bristol, RI; Windings, Inc., New Ulm, MN; MaXentric Technologies LLC, Fort Lee, NJ; Optoknowledge, Torrance, CA; Gird Systems, INC., Cincinnati, OH; Columbia Power Technologies, Inc., Charlottesville, VA; Critical Prism Defense LLC, Ashland, MA; Pandata Tech, Inc., Houston, TX; XR 2 Lead LLC, Dumfries, VA; Sea Machine Robotics, Inc., Boston, MA; Leapfrog AI, Colorado Springs, CO; University of Connecticut, Storrs, CT; Ward Leonard CT LLC, Thomaston, CT; Art Anderson Associates, Inc., Bremerton, WA; Dragonfly Pictures, Inc., Essington, PA; American Defense International, Inc., Washington, DC; Alluvionic, Inc., Melbourne, FL; and Modern Intelligence, Inc., Austin, TX, have been added as parties to this venture.

Also, Allegheny Technologies, Inc., Billerica, MA; Applied Mathematics, Inc., Gales Ferry, CT; Aretec, Inc., Providence, RI; Asymmetric Technologies LLC, Columbus, OH; Aviation & Missile Solutions LLC, Huntsville, AL; BAE Systems Technology Solutions & Services, Inc., Rockville, MD; Clear Carbon And Components, Inc., Bristol, RI; Cognitech Corporation, Salt Lake City, UT; Critical Frequency Design LLC, Melbourne, FL; DE Technologies, Inc., King of Prussia, PA; Design Interactive, Inc., Orlando, FL; Dynexus Technology, Inc., Niwot, CO; Entanglement Research Institute, Inc., Newport, RI; GE Research, Niskayuna, NY; I Square Systems LLC, Middletown, RI; I-Assure LLC, Mandeville, LA; Kern Technology Group LLC, Virginia Beach, VA; L3 Communication Systems-East, Camden, NJ; L3 Harris Maripro, Goleta, CA; Lockheed Martin Sippican, Inc., Marion, MA; Maritime Arresting Technologies LLC, Tarpon Springs, FL; Ocean Acoustical Services & Instrumentation Systems, Inc., Lexington, MA; R&D Technologies, Inc., N Kingstown, RI; Red River Technology LLC, Claremont, NH; Remote Sensing Solutions, Barnstable, MA; Search, Inc., Orlando, FL; Terradepth, Inc., Austin, TX; The Aegis Technologies Group, Inc., Huntsville, AL; VIASAT, Inc., Carlsbad, CA; Voltaig, Inc., Berkeley, CA; VSOLVIT LLC, Ventura, CA; WWM Solutions LLC, Washington, DC; Quickflex, Inc., San Antonio, TX; Raytheon Missle Systems, Fall River, MA; Simventions, Inc., Rome, NY; Aquabotix Technology Corporation, Fall River, MA; HII Fleet Support Group LLC, Virginia Beach, VA; Spatial Intergrated Systems, Inc., Virginia Beach, VA; EDGEONE LLC dba EDGETECH, Boca Raton, FL; OLIS ROBOTICS dba BLUEHAPTICS, Seattle, WA; Analytical Graphics, Inc., Exton, PA; Gavial ITC LLC, Santa Barbara, CA; Parker Hannifin Corporation, Mayfield Heights, OH; Problem Solutions LLC, Johnstown, PA; Savant Financial Technologies, Inc., dba Ariel Partners, New York, NY; Omni Federal, Gainesville, VA; Ceranova Corporation, Marlborough, MA; Triumph Enterprises, Inc., Vienna, VA; Cambridge International Systems, Inc., Arlington, VA; and, SA Photonics, Inc., Los Gatos, CA have withdrawn from this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and UTIC intends to file additional written notifications disclosing all changes in membership.

On October 9, 2018, UTIC filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on November 2, 2018 (83 FR 55203).

The last notification was filed with the Department on February 5, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on March 10, 2021 (86 FR 13752).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–27750 Filed 12–21–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to The National Cooperative Research and Production Act of 1993—America's Datahub Consortium

Notice is hereby given that, on November 11, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), America's DataHub Consortium (''ADC'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the identity of the parties to the venture are: 2Is Inc., Walpole, MA; American Economic Association, Nashville, TN; American Statistical Association, Alexandria, VA; Applied Information Sciences (AIS), Reston, VA; Bowie State University, Bowie, MD; CGI Federal, Fairfax, VA; Columbia University Data Science Institute, New York, NY; Concurrent Technologies Corporation, Johnstown, PA; Council of Professional Organizations on Federal Statistics, Washington, DC; Data Security Technologies LLC, Richardson, TX; Emerging Sun, LLC, Bethesda, MD; FDHint, LLC, Purchase, NY; Malum, Inc., Coralville, IA; MRIGlobal, Kansas City, MO; NanoVMs, Inc., San Francisco, CA; National Opinion Research Center, Chicago, IL; Northeast Information Discovery Inc., Canastota, NY; PitchBook Data, Inc., Seattle, WA; Quantitative Scientific Solutions, LLC, Arlington, VA; SRI International, Menlo Park, CA; The Coleridge Initiative Inc, Chevy Chase, MD; The Informatics Applications Group, Inc (dba TIAG), Reston, VA; Trustees of Tufts College, Inc., Medford, MA; University of Florida Institute of Marine Remote Sensing, St. Petersburg, FL; University of Tennessee, Knoxville, TN; University of Southern Mississippi, Gulfport, MS; Urban Institute, Washington, DC; Vertosoft LLC, Leesburg, VA. The general area of ADC's planned activity is to perform a coordinated research and development program to further the National Center for science and Engineering Statistics' (NCSES) statutory role as a central Federal clearinghouse for the collection, interpretation, analysis, and dissemination of objective data on science, engineering, technology, and research and development. ADC's planned activity is to develop new ways of acquiring, cleaning, and standardizing data; combining multiple data sets; and linking data from various government and private sources to yield valuable insights into critical issues. The consortium was formed effective August 10th, 2021.

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–27742 Filed 12–21–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to The National Cooperative Research and Production Act of 1993—Information Warfare Research Project Consortium

Notice is hereby given that, on November 10, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Information Warfare Research Project Consortium (''IWRP'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, HaloTech Solutions LLC, Charlotte, NC; Northeast Information Discovery, Inc., Canastota, NY; NewSat North America LLC, Indian Harbour Beach, FL; Panasonic Corporation of North America, Newark, NJ; Radiance Technologies, Inc., Huntsville, AL; Virginia Polytechnic Institute and State University, Blacksburg, VA; XSB, Inc., Setauket, NY; G3 Technologies, Inc., Columbia, MD; IoTAI, Inc., Fremont, CA; Hayes Group International LLC, Washington, DC; Raytheon Intelligence & Space, Indianapolis, IN; Simulation Technologies, Inc., Huntsville, AL; Tetrad Digital Integrity LLC, Washington, DC; Unified Experience LLC, Mount Pleasant, SC; Liberty Business Associates LLC, Ladson, SC; RMA Associates, Arlington, VA; Google LLC, Mountain View, CA; Jacobs Technology, Tullahoma, TN; RedShred LLC, Baltimore, MD; Render Security Engineering LLC, Lexington Park, MD; and Trenton Systems, Lawrenceville, GA have been added as parties to this venture.

Also, Knowledge Vortex, Inc., Madison, AL; Intrinsic Enterprises, Inc., Newcastle, WA; Kriaanet, Inc., Quantico, VA; Pi Radio, Inc., Brooklyn, NY; Hawks Nest Solutions, Inc. dba Marjau Systems Corporation, Tampa, FL; and Key Cyber Solutions LLC, Richmond, VA have withdrawn from this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and IWRP intends to file additional written notifications disclosing all changes in membership.

On October 15, 2018, IWRP filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on October 23, 2018 (83 FR 53499).

The last notification was filed with the Department on July 15, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 23, 2021 (86 FR 47155).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–27748 Filed 12–21–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to The National Cooperative Research and Production Act of 1993—R Consortium, Inc.

Notice is hereby given that, on November 9, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), R Consortium, Inc. (''R Consortium'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Biogen, Cambridge, MA, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and R Consortium intends to file additional written notifications disclosing all changes in membership.

On September 15, 2015, R Consortium filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on October 2, 2015 (80 FR 59815).

The last notification was filed with the Department on August 13, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on September 3, 2021 (86 FR 49567).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–27746 Filed 12–21–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0339]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection; Comments Requested: Generic Clearance for Cognitive, Pilot and Field Studies for Bureau of Justice Statistics Data Collection Activities

AGENCY: Office of Justice Programs, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs (OJP), Bureau of Justice Statistics (BJS) intends to request approval from the Office of Management and Budget (OMB) for a generic information collection clearance that will allow BJS to conduct a variety of cognitive, pilot, and field test studies. BJS will submit the request for review and approval in accordance with the Paperwork Reduction Act of 1995.

Over the next three years, BJS anticipates undertaking a variety of new surveys and data collections, as well as reassessing ongoing statistical projects, across a number of areas of criminal justice, including law enforcement, courts, corrections, and victimization. This work will entail development of new survey instruments, redesigning and/or modifying existing surveys, procuring administrative data from state and local government entities, and creating or modifying establishment surveys. In order to inform BJS data collection protocols, to develop accurate estimates of respondent burden, and to minimize respondent burden associated with each new or modified data collection, BJS will engage in cognitive, pilot and field test activities to refine instrumentation and data collection methodologies. BJS envisions using a variety of techniques, including but not limited to tests of different types of survey and data collection operations, focus groups, cognitive testing, pilot testing, exploratory interviews, experiments with questionnaire design, and usability testing of electronic data collection instruments.

Following standard Office of Management and Budget (OMB) requirements, BJS will submit a change request to OMB individually for every group of data collection activities undertaken under this generic clearance. BJS will provide OMB with a copy of the individual instruments or questionnaires (if one is used), as well as other materials describing the project.

DATES: Comments are encouraged and will be accepted for 60 days until February 22, 2022.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Devon Adams, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: *Devon.Adams@usdoj.gov;* telephone: 202–307–0765).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *The Title of the Form/Collection:* Generic Clearance for cognitive, pilot and field studies for Bureau of Justice Statistics data collection Activities.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form numbers not available for generic clearance. The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Administrators or staff of state and local agencies or programs in the relevant fields; administrators or staff of non-government agencies or programs in the relevant fields; individuals; policymakers at various levels of government.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* We estimate that approximately 30,000 respondents will be involved in exploratory, field test, pilot, cognitive, and focus group work conducted under this clearance over the requested 3-year clearance period. The average response time per respondent will be specific to each project covered under the clearance. Specific estimates of the number of respondents and the average response time are not known for each pilot study or development project covered under a generic clearance at this time. Project specific estimates will be submitted to OMB separately for each project conducted under this clearance. An estimate of the overall number of burden hours for activities under this generic

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total respondent burden for identified and future projects covered under this generic clearance over the 3-year clearance period is approximately 20,000 hours.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: December 17, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–27711 Filed 12–21–21; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petition for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of seven petitions for modification submitted to the Mine Safety and Health Administration (MSHA) by the parties listed below.

DATES: All comments on the petitions must be received by MSHA's Office of Standards, Regulations, and Variances on or January 21, 2022.

ADDRESSES: You may submit your comments including the docket number of the petition by any of the following methods:

1. *Email: zzMSHA-comments@dol.gov.* Include the docket number of the petition in the subject line of the message.

2. *Facsimile:* 202–693–9441.

3. *Regular Mail or Hand Delivery:* Regular Mail or Hand Delivery: MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452, Attention: S. Aromie Noe, Acting Director, Office of Standards, Regulations, and Variances. MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above. Before visiting MSHA in person, call 202–693–9455 to make an appointment in keeping with the Department of Labor's COVID–19 policy. Special health precautions may be required.

FOR FURTHER INFORMATION CONTACT: S. Aromie Noe, Office of Standards, Regulations, and Variances at 202–693–9440 (voice), *Noe.Song-Ae.A@dol.gov* (email), or 202–693–9441 (facsimile). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations (CFR) part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. The application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, sections 44.10 and 44.11 of 30 CFR establish the requirements for filing petitions for modification.

II. Petitions for Modification

Docket Number: M–2021–035–C.

Petitioner: Peabody Southeast Mining LLC, 701 Market Street, St. Louis, Missouri 63101.

Mine: Shoal Creek Mine, MSHA ID No. 01–02901, located in Tuscaloosa and Walker Counties, Alabama.

Regulation Affected: 30 CFR 75.500(d) (Permissible electric equipment).

Modification Request: The petitioner requests a modification of the existing standard, 30 CFR 75.500(d), as it relates to the use of low voltage, battery-powered non-permissible testing and diagnostic equipment in or inby the last open crosscut. Specifically, the petitioner requests to use low voltage, battery-powered non-permissible testing and diagnostic equipment, including, but not limited to laptop computers; oscilloscopes; vibration analysis machines; cable fault detectors; point temperature probes; infrared temperature devices; insulation testers (meggers); voltage, current resistance, and power testers; and electronic tachometers, as well as other testing and diagnostic equipment if approved in advance by the MSHA District Manager.

The petitioner states that:

(a) The petitioner utilizes the continuous mining machine and longwall method of mining.

(b) Accurate testing and diagnostic tools for troubleshooting equipment problems in or inby the last open crosscut are critical to the safety of the miners at the Shoal Creek Mine.

(c) Mining equipment sometimes breaks down in areas of a mine where permissible equipment is required and the equipment cannot be moved into intake air to perform diagnosis or repairs as it may not be possible to move the equipment, or it is unsafe to move it.

(d) Permissible diagnostic and testing equipment is not available for all types of testing and diagnostics. While certain types of equipment, such as vibration analysis machines, point temperature and infrared temperature devices, and voltage current and resistance meters are currently on the list of MSHA-approved permissible products, the petitioner includes such devices in the event approved devices may not be readily available on the market.

The petitioner proposes the following alternative method:

(a) Non-permissible electronic testing and diagnostic equipment to be used includes laptop computers; oscilloscopes; vibration analysis machines; cable fault detectors; point temperature probes; infrared temperature devices; insulation testers (meggers); voltage testers, current resistance testers, and power testers; and electronic tachometers. Other testing and diagnostic equipment may be used if approved in advance by the MSHA District Manager.

(b) All non-permissible testing and diagnostic equipment used in or inby the last open crosscut will be examined by a qualified person as defined in 30 CFR 75.153 prior to use to ensure the equipment is being maintained in a safe operating condition. The examination results will be recorded in the weekly examination book and will be made available to MSHA and the miners at the mine.

(c) A qualified person as defined in 30 CFR part 75.151 will continuously monitor for methane immediately before and during the use of non-permissible electronic testing and diagnostic equipment in or inby the last open crosscut.

(d) Non-permissible electronic testing and diagnostic equipment will not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more methane is detected while the non-permissible electronic equipment is being used, the equipment will be de-energized immediately and withdrawn outby the last open crosscut.

(e) All hand-held methane detectors will be MSHA-approved and will be maintained in permissible and proper operating condition as defined in 30 CFR 75.320.

(f) Coal production in the section will cease except for time necessary to troubleshoot under actual mining conditions. However, coal may remain in or on the equipment to test and diagnose the equipment under ''load.''

(g) All electronic testing and diagnostic equipment will be used in accordance with the safe use procedures recommended by the manufacturer.

(h) Qualified personnel who use electronic testing and diagnostic equipment will be properly trained to recognize the hazards and limitations associated with use of the equipment.

The petitioner asserts that the alternative method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Docket Number: M–2021–036–C.

Petitioner: Peabody Southeast Mining LLC, 701 Market Street, St. Louis, Missouri 63101.

Mine: Shoal Creek Mine, MSHA ID No. 01–02901, located in Tuscaloosa and Walker Counties, Alabama.

Regulation Affected: 30 CFR 75.507–1(a) (Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements).

Modification Request: The petitioner requests a modification of the existing standard, 30 CFR 75.507–1(a), as it relates to the use of low voltage, battery-powered nonpermissible testing and diagnostic equipment in return air. Specifically, the petitioner requests to use low voltage, battery-powered non-permissible testing and diagnostic equipment, including, but not limited to laptop computers; oscilloscopes; vibration analysis machines; cable fault detectors; point temperature probes; infrared temperature devices; insulation testers (meggers); voltage, current resistance, and power testers; and electronic tachometers, as well as other testing and diagnostic equipment if approved in advance by the MSHA District Manager.

The petitioner states that:

(a) The petitioner utilizes the continuous mining machine and longwall method of mining.

(b) Accurate testing and diagnostic tools for troubleshooting equipment problems in return air are critical to the safety of the miners at the Shoal Creek Mine.

(c) On occasion mining equipment breaks down in areas of a mine where permissible equipment is required and the equipment cannot be moved into intake air to perform diagnosis or repairs as it may not be possible to move the equipment, or it is unsafe to move it.

(d) Permissible diagnostic and testing equipment is not available for all types of testing and diagnostics. While certain types of equipment, such as vibration analysis machines, point temperature and infrared temperature devices, and voltage current and resistance meters are currently on the list of MSHA-approved permissible products, the petitioner includes such devices in the event approved devices may not be readily available on the market.

The petitioner proposes the following alternative method:

(a) Non-permissible electronic testing and diagnostic equipment to be used includes laptop computers; oscilloscopes; vibration analysis machines; cable fault detectors; point temperature probes; infrared temperature devices; insulation testers (meggers); voltage testers, current resistance testers, and power testers; and electronic tachometers. Other testing and diagnostic equipment may be used if approved in advance by the MSHA District Manager.

(b) All non-permissible testing and diagnostic equipment used in return air outby the last open crosscut will be examined by a qualified person as defined in 30 CFR 75.153 prior to use to ensure the equipment is being maintained in a safe operating condition. The examination results will be recorded in the weekly examination book and will be made available to MSHA and the miners at the mine.

(c) A qualified person as defined in 30 CFR part 75.151 will continuously monitor for methane immediately before and during the use of non-permissible electronic testing and diagnostic equipment in return air outby the last open crosscut.

(d) Non-permissible electronic testing and diagnostic equipment will not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more methane is detected while the non-permissible electronic equipment is being used, the equipment will be de-energized immediately and the non-permissible equipment withdrawn from the return air outby the last open crosscut.

(e) All hand-held methane detectors will be MSHA-approved and will be maintained in permissible and proper operating condition as defined in 30 CFR 75.320.

(f) All electronic testing and diagnostic equipment will be used in accordance with the safe use procedures recommended by the manufacturer.

(g) Qualified personnel who use electronic testing and diagnostic equipment will be properly trained to recognize the hazards and limitations associated with use of the equipment.

The petitioner asserts that the alternative method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Docket Number: M–2021–037–C.

Petitioner: Peabody Southeast Mining LLC, 701 Market Street, St. Louis, Missouri 63101.

Mine: Shoal Creek Mine, MSHA ID No. 01–02901, located in Tuscaloosa and Walker Counties, Alabama.

Regulation Affected: 30 CFR 75.1002(a) (Installation of electric equipment and conductors; permissibility).

Modification Request: The petitioner requests a modification of the existing standard, 30 CFR 75.1002(a) as it relates to the use of low voltage, battery-powered nonpermissible testing and diagnostic equipment on the longwall face or within 150 feet of pillar workings. Specifically, the petitioner requests to use low voltage, battery-powered non-permissible testing and diagnostic equipment, including, but not limited to laptop computers; oscilloscopes; vibration analysis machines; cable fault detectors; point temperature probes; infrared temperature devices; insulation testers (meggers); voltage, current resistance, and power testers; and electronic tachometers, as well as other testing and diagnostic equipment if approved in advance by the MSHA District Manager.

The petitioner states that:

(a) The petitioner utilizes the continuous mining machine and longwall method of mining.

(b) Accurate testing and diagnostic tools for troubleshooting equipment problems on the longwall face or within 150 feet of pillar workings are critical to the safety of the miners at the Shoal Creek Mine.

(c) On occasion mining equipment breaks down in areas of a mine where permissible equipment is required and the equipment cannot be moved into intake air to perform diagnosis or repairs as it may not be possible to move the equipment, or it is unsafe to move it. On a longwall face, the mining equipment cannot be moved to another location.

(d) Permissible diagnostic and testing equipment is not available for all types of testing and diagnostics. While certain types of equipment, such as vibration analysis machines, point temperature and infrared temperature devices, and voltage current and resistance meters are currently on the list of MSHA-approved permissible products, the petitioner includes such devices in the event approved devices may not be readily available on the market.

The petitioner proposes the following alternative method:

(a) Non-permissible electronic testing and diagnostic equipment to be used includes laptop computers; oscilloscopes; vibration analysis machines; cable fault detectors; point temperature probes; infrared temperature devices; insulation testers (meggers); voltage testers, current resistance testers, and power testers; and electronic tachometers. Other testing and diagnostic equipment may be used if approved in advance by the MSHA District Manager.

(b) All non-permissible testing and diagnostic equipment used on the longwall face or within 150 feet of pillar workings will be examined by a qualified person as defined in 30 CFR 75.153 prior to use to ensure the equipment is being maintained in a safe operating condition. The examination results will be recorded in the weekly examination book and will be made

available to MSHA and the miners at the mine.

(c) A qualified person as defined in 30 CFR part 75.151 will continuously monitor for methane immediately before and during the use of non-permissible electronic testing and diagnostic equipment on the longwall face or within 150 feet of pillar workings.

(d) Non-permissible electronic testing and diagnostic equipment will not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more methane is detected while the non-permissible electronic equipment is being used, the equipment will be de-energized immediately and the non-permissible equipment withdrawn from the longwall face or moved more than 150 feet from pillar workings.

(e) All hand-held methane detectors will be MSHA-approved and will be maintained in permissible and proper operating condition as defined in 30 CFR 75.320.

(f) All electronic testing and diagnostic equipment will be used in accordance with the safe use procedures recommended by the manufacturer.

(g) Qualified personnel who use electronic testing and diagnostic equipment will be properly trained to recognize the hazards and limitations associated with use of the equipment.

The petitioner asserts that the alternative method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Docket Number: M–2021–038–C.

Petitioner: Peabody Southeast Mining LLC, 701 Market Street, St. Louis, Missouri 63101.

Mine: Shoal Creek Mine, MSHA ID No. 01–02901, located in Tuscaloosa and Walker Counties, Alabama.

Regulation Affected: 30 CFR 75.500(d) (Permissible electric equipment).

Modification Request: The petitioner requests a modification of the existing standard, 30 CFR 75.500(d) as it pertains to use of battery-powered non-permissible surveying equipment in or inby the last open crosscut. Specifically, the petitioner requests to use battery-powered non-permissible equipment including, but not limited to, portable battery operated mine transits, total station surveying equipment, distance meters, and data loggers.

The petitioner states that:

(a) The petitioner utilizes the continuous mining machine and longwall method of mining.

(b) Accurate surveying is critical to the safety of the miners at the Shoal Creek Mine.

(c) To comply with the requirements of 30 CFR 75.372 and 30 CFR 75.1200, it is necessary to use the most practical and accurate surveying equipment.

(d) Mechanical surveying equipment has been obsolete for a number of years and such equipment of acceptable quality is not commercially available. It is difficult, if not impossible, to service or repair mechanical surveying equipment.

(e) Electronic surveying equipment is, at a minimum, eight to ten times more accurate than mechanical equipment.

(f) Underground mining by its nature, size, and mine plan complexity requires prompt and efficient completion of accurate and precise measurements.

(g) Application of this standard would result in a diminution of safety to miners.

The petitioner proposes the following alternative method:

(a) The operator may use the Leica TS06 total station and similar low voltage battery-operated total stations and theodolites, distance meters, and data loggers if they have an Ingress Protection (IP) rating of 55 or greater in or inby the last open crosscut subject to the conditions of this petition.

(b) The operator shall replace or retire from service any electronic surveying instrument acquired prior to December 31, 2004, within 1 year of this petition becoming final. Within 3 years of that date, the operator shall replace or retire from service any theodolite acquired more than 5 years prior to the date this petition became final and any total station or other electronic surveying equipment acquired more than 10 years prior to the date this petition became final. After 5 years, the operator will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 3 years from date of manufacture, and total stations and other electronic surveying equipment will be no older than 10 years from date of manufacture. All non-permissible electronic total stations and theodolites acquired under this retirement criteria shall have an IP rating of 66 or greater.

(c) The operator is responsible for ensuring that all surveying contractors hired by the operator use electronic equipment in accordance with the requirements of this petition. The conditions of use apply to all non-permissible electronic surveying equipment used in or inby the last open crosscut regardless of whether the equipment is used by the operator or by an independent contractor.

(d) The operator will maintain an electric surveying equipment logbook with the equipment, where mine record books are kept, or where surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each piece of electronic surveying equipment. The logbook shall be made available to MSHA upon request.

(e) All non-permissible electronic surveying equipment to be used in or inby the last open crosscut shall be examined by the person who will operate the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. These examinations shall include:

1. Check the instrument for any physical damage and the integrity of the case;

2. Remove the battery and inspect for corrosion;

3. Inspect the contact points to ensure a secure connection to the battery;

4. Reinsert the battery and power up and shut down to ensure proper connections; and

5. Check the battery compartment cover or battery attachment to ensure it is securely fastened.

(f) The equipment shall be examined at least weekly by a qualified person as defined in 30 CFR 75.153, and the examination results shall be recorded weekly in the equipment's logbook. Examination entries in the logbook will be maintained for at least 1 year.

(g) The operator shall ensure that all non-permissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment's logbook and shall include a description of the work performed.

(h) Non-permissible surveying equipment used in or inby the last open crosscut shall not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of this petition.

(i) Non-permissible surveying equipment shall not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more of methane is detected while the non-permissible surveying equipment is being used, the equipment shall be de-energized immediately and the non-permissible electronic equipment withdrawn outby the last open crosscut. Prior to entering in or inby the last open crosscut, all requirements of 30 CFR 75.323 shall be complied with.

(j) As an additional safety check, prior to setting up and energizing non-permissible electronic surveying equipment in or inby the last open crosscut, the surveyor(s) shall conduct a visual examination of the immediate

area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or accumulated float coal dust is observed, the equipment may not be energized until sufficient rock dust has been applied and/or the accumulation of float coal dust has been cleaned-up. If non-permissible electronic surveying equipment is to be used in an area that is not rock dusted within 40 feet of a working face where a continuous mining machine is used to extract coal, the area shall have sufficient rock dust applied prior to energizing the electronic surveying equipment.

(k) All hand-held methane detectors shall be MSHA-approved and will be maintained in permissible and proper operating condition as defined by 30 CFR 75.320. All methane detectors shall provide visual and audible warnings when methane is detected at or above 1.0 percent.

(l) Prior to energizing any non-permissible surveying equipment in or inby the last open crosscut, methane tests shall be made in accordance with 30 CFR 75.323(a).

(m) All areas to be surveyed shall be pre-shift examined according to 30 CFR 75.360 prior to surveying. If the area was not pre-shift examined, a supplemental examination according to 30 CFR 75.361 shall be performed before any non-certified person enters the area. If the area has been examined according to 30 CFR 75.360 or 30 CFR 75.361, additional examination is not required.

(n) A qualified person as defined in 30 CFR 75.151 shall continuously monitor for methane immediately before and during the use of non-permissible surveying equipment in or inby the last open crosscut. A second person in the surveying crew, if there are two people in the crew, shall also continuously monitor for methane. That person shall either be a qualified person as defined in 30 CFR 75.151, or be in the process of being trained to be a qualified person but have yet to make such tests for a period of 6 months as required by 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew shall become qualified in order to continue on the surveying crew. If the surveying crew consists of only one person, the surveyor shall monitor for methane with two separate devices.

(o) Personnel engaged in the use of surveying equipment shall be properly trained to recognize the hazards and limitations associated with the use of surveying equipment in areas where methane could be present.

(p) Batteries contained in the surveying equipment shall be changed out or charged in intake air outby the last open crosscut. Replacement batteries for the surveying equipment shall be carried only in the compartment provided for a spare battery in the electronic equipment carrying case. Before each shift of surveying, all batteries for the surveying equipment shall be charged sufficiently so that they are not expected to be replaced on that shift.

(q) When using non-permissible electronic surveying equipment in or inby the last open crosscut, the surveyor shall confirm by measurement or by inquiry of the person in charge of the section that the air quantity on the section, on that shift, is at least the minimum quantity that is required by the mine's ventilation plan.

(r) Non-permissible surveying equipment may be used when production is occurring subject to these conditions:

1. On a mechanized mining unit (MMU) where production is occurring, non-permissible electronic surveying equipment shall not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.

2. Production may continue while non-permissible electronic surveying equipment is used if the surveying equipment is used in a separate split of air from where production is occurring.

3. Non-permissible surveying equipment shall not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

4. If, while surveying, a surveyor must disrupt ventilation, the surveyor shall cease surveying and communicate to the section foreman that ventilation must be disrupted. Production shall stop while ventilation is disrupted. Ventilation controls shall be reestablished immediately after the disruption is no longer necessary. Production can only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans and other applicable laws, standards, or regulations.

5. Any disruption in ventilation shall be recorded in the logbook required by this petition. The logbook shall include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption, the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

(s) All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations shall receive training on the terms and conditions of this petition before using non-permissible electronic equipment in or inby the last open crosscut. A record of the training shall be kept with the other training records and provided to MSHA upon request.

(t) Within 60 days after this petition becomes final, the operator shall submit proposed revisions for its approved 30 CFR part 48 training plans to the District Manager. These proposed revisions shall specify initial and refresher training regarding the terms and conditions stated in this petition. When training is conducted, an MSHA Certificate of Training (Form 5000–23) shall be completed indicating surveyor training.

The petitioner asserts that the alternative method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Docket Number: M–2021–039–C.

Petitioner: Peabody Southeast Mining LLC, 701 Market Street, St. Louis, Missouri 63101.

Mine: Shoal Creek Mine, MSHA ID No. 01–02901, located in Tuscaloosa and Walker Counties, Alabama.

Regulation Affected: 30 CFR 75.507–1(a) (Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements).

Modification Request: The petitioner requests a modification of the existing standard, 30 CFR 30 CFR 75.507–1(a) as it pertains to use of battery-powered non-permissible surveying equipment in return air. Specifically, the petitioner requests to use battery-powered non-permissible equipment including, but not limited to portable battery operated mine transits, total station surveying equipment, distance meters, and data loggers.

The petitioner states that:

(a) The petitioner utilizes the continuous mining machine and longwall method of mining.

(b) Accurate surveying is critical to the safety of the miners at the Shoal Creek Mine.

(c) To comply with the requirements of 30 CFR 75.372 and 30 CFR 75.1200, it is necessary to use the most practical and accurate surveying equipment.

(d) Mechanical surveying equipment has been obsolete for a number of years and such equipment of acceptable quality is not commercially available. It is difficult, if not impossible, to service or repair mechanical surveying equipment.

(e) Electronic surveying equipment is, at a minimum, eight to ten times more accurate than mechanical equipment.

(f) Application of this standard would result in a diminution of safety to miners.

(g) Underground mining by its nature, size, and mine plan complexity requires prompt and efficient completion of accurate and precise measurements.

The petitioner proposes the following alternative method:

(a) The operator may use the Leica TS06 total station and similar low voltage battery-operated total stations and theodolites, distance meters, and data loggers if they have an Ingress Protection (IP) rating of 55 or greater in return air subject to the conditions of this petition.

(b) The operator shall replace or retire from service any electronic surveying instrument acquired prior to December 31, 2004, within 1 year of this petition becoming final. Within 3 years of that date, the operator shall replace or retire from service any theodolite acquired more than 5 years prior to the date this petition became final and any total station or other electronic surveying equipment acquired more than 10 years prior to the date this petition became final. After 5 years, the operator will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 3 years from date of manufacture, and total stations and other electronic surveying equipment will be no older than 10 years from date of manufacture. All non-permissible electronic total stations and theodolites acquired under this retirement criteria shall have an IP rating of 66 or greater.

(c) The operator is responsible for ensuring that all surveying contractors hired by the operator use electronic equipment in accordance with the requirements of this petition. The conditions of use apply to all non-permissible electronic surveying equipment used in return air regardless of whether the equipment is used by the operator or by an independent contractor.

(d) The operator will maintain an electric surveying equipment logbook with the equipment, where mine record books are kept, or where surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each piece of electronic surveying equipment. The logbook shall be made available to MSHA upon request.

(e) All non-permissible electronic surveying equipment to be used in return air shall be examined by the person who will operate the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. These examinations shall include:

1. Check the instrument tor any physical damage and the integrity of the case;

2. Remove the battery and inspect for corrosion;

3. Inspect the contact points to ensure a secure connection to the battery;

4. Reinsert the battery and power up and shut down to ensure proper connections; and

5. Check the battery compartment cover or battery attachment to ensure it is securely fastened.

(f) The equipment shall be examined at least weekly by a qualified person as defined in 30 CFR 75.153, and the examination results shall be recorded weekly in the equipment's logbook. Examination entries in the logbook may be expunged after 1 year.

(g) The operator is to ensure that all non-permissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment's logbook and shall include a description of the work performed.

(h) Non-permissible surveying equipment that will be used in return air shall not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of this petition.

(i) Non-permissible surveying equipment shall not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more of methane is detected while the non-permissible surveying equipment is being used, the equipment shall be de-energized immediately and the non-permissible electronic equipment withdrawn out of return air. Prior to entering in return air, all requirements of 30 CFR 75.323 shall be complied with.

(j) As an additional safety check, prior to setting up and energizing non-permissible electronic surveying equipment in return air, the surveyor(s) shall conduct a visual examination of the immediate area for evidence that the areas appear to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or accumulated float coal dust is observed, the equipment may not be energized until sufficient rock dust has been applied and/or the accumulation of float coal dust has been cleaned-up. If non-permissible electronic surveying equipment is to be used in an area that is not rock dusted within 40 feet of a working face where a continuous mining machine is used to extract coal, the area shall have sufficient rock dust applied prior to energizing the electronic surveying equipment.

(k) All hand-held methane detectors shall be MSHA-approved and maintained in permissible and proper operating condition as defined by 30 CFR 75.320. All methane detectors shall provide visual and audible warnings when methane is detected at or above 1.0 percent.

(l) Prior to energizing any non-permissible surveying equipment in return air, methane tests shall be made in accordance with 30 CFR 75.323(a).

(m) All areas to be surveyed shall be pre-shift examined according to 30 CFR 75.360 prior to surveying. If the area was not pre-shift examined, a supplemental examination according to 30 CFR 75.361 shall be performed before any non-certified person enters the area. If the area has been examined according to 30 CFR 75.360 or 30 CFR 75.361, additional examination is not required.

(n) A qualified person as defined in 30 CFR 75.151 shall continuously monitor for methane immediately before and during the use of non-permissible surveying equipment in or inby the last open crosscut. A second person in the surveying crew, if there are two people in the crew, shall also continuously monitor for methane. That person shall either be a qualified person as defined in 30 CFR 75.151, or be in the process of being trained to be a qualified person but have yet to make such tests for a period of 6 months as required by 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew shall become qualified in order to continue on the surveying crew. If the surveying crew consists of only one person, the surveyor shall monitor for methane with two separate devices.

(o) Personnel engaged in the use of surveying equipment shall be properly trained to recognize the hazards and limitations associated with the use of surveying equipment in areas where methane could be present.

(p) Batteries contained in the surveying equipment shall be changed out or charged out of return air. Replacement batteries for the surveying equipment shall be carried only in the compartment provided for a spare

battery in the electronic equipment carrying case. Before each shift of surveying, all batteries for the surveying equipment shall be charged sufficiently that they are not expected to be replaced on that shift.

(q) When using non-permissible electronic surveying equipment in return air, the surveyor shall confirm by measurement or by inquiry of the person in charge of the section that the air quantity on the section, on that shift, is at least the minimum quantity that is required by the mine's ventilation plan.

(r) Non-permissible surveying equipment may be used when production is occurring subject to these conditions:

1. On a mechanized mining unit (MMU) where production is occurring, non-permissible electronic surveying equipment shall not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.

2. Production may continue while non-permissible electronic surveying equipment is used if the surveying equipment is used in a separate split of air from where production is occurring.

3. Non-permissible surveying equipment shall not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

4. If, while surveying, a surveyor must disrupt ventilation, the surveyor shall cease surveying and communicate to the section foreman that ventilation must be disrupted. Production shall stop while ventilation is disrupted. Ventilation controls shall be reestablished immediately after the disruption is no longer necessary. Production can only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans and other applicable laws, standards, or regulations.

5. Any disruption in ventilation shall be recorded in the logbook required by this petition. The logbook shall include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption, the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

(s) All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations shall receive training on the terms and conditions of the petition before using non-permissible electronic equipment in return air. A record of the training shall be kept with the other training records and provided to MSHA upon request.

(t) Within 60 days after this petition becomes final, the operator shall submit proposed revisions for its approved 30 CFR part 48 training plans to the District Manager. These proposed revisions shall specify initial and refresher training regarding the terms and conditions stated in this petition. When training is conducted, an MSHA Certificate of Training (Form 5000–23) shall be completed indicating surveyor training.

The petitioner asserts that the alternative method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Docket Number: M–2021–040–C.

Petitioner: Peabody Southeast Mining LLC, 701 Market Street, St. Louis, Missouri 63101.

Mine: Shoal Creek Mine, MSHA ID No. 01–02901, located in Tuscaloosa and Walker Counties, Alabama.

Regulation Affected: 30 CFR 75.1002(a) (Installation of electric equipment and conductors; permissibility).

Modification Request: The petitioner requests a modification of the existing standard, 30 CFR 75.1002(a) as it pertains to use of battery-powered non-permissible surveying equipment on the longwall face or within 150 feet of pillar workings. Specifically, the petitioner requests to use battery-powered non-permissible equipment including, but not limited to portable battery operated mine transits, total station surveying equipment, distance meters, and data loggers.

The petitioner states that:

(a) The petitioner utilizes the continuous mining machine and longwall method of mining.

(b) Accurate surveying is critical to the safety of the miners at the Shoal Creek Mine.

(c) To comply with the requirements of 30 CFR 75.372 and 30 CFR 75.1200, it is necessary to use the most practical and accurate surveying equipment. In order to ensure the safety of the miners in active mines and to protect miners in future mines which may mine in close proximity to these same active mines, it is necessary to determine the exact location and extent of the mine workings.

(d) Mechanical surveying equipment has been obsolete for a number of years and such equipment of acceptable quality is not commercially available. It is difficult, if not impossible, to service or repair mechanical surveying equipment.

(e) Electronic surveying equipment is, at a minimum, eight to ten times more accurate than mechanical equipment.

(f) Application of this standard would result in a diminution of safety to miners.

(g) Underground mining by its nature, size, and mine plan complexity requires prompt and efficient completion of accurate and precise measurements.

The petitioner proposes the following alternative method:

(a) The operator may use the Leica TS06 total station and similar low voltage battery-operated total stations and theodolites, distance meters, and data loggers if they have an Ingress Protection (IP) rating of 55 or greater within 150 feet of pillar workings subject to the conditions of this petition.

(b) The operator shall replace or retire from service any electronic surveying instrument acquired prior to December 31, 2004, within 1 year of this petition becoming final. Within 3 years of that date, the operator shall replace or retire from service any theodolite acquired more than 5 years prior to the date this petition became final and any total station or other electronic surveying equipment acquired more than 10 years prior to the date this petition became final. After 5 years, the operator will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 3 years from date of manufacture, and total stations and other electronic surveying equipment will be no older than 10 years from date of manufacture. All non-permissible electronic total stations and theodolites acquired under this retirement criteria shall have an IP rating of 66 or greater.

(c) The operator is responsible for ensuring that all surveying contractors hired by the operator use electronic equipment in accordance with the requirements of this petition. The conditions of use apply to all non-permissible electronic surveying equipment within 150 feet of pillar workings regardless of whether the equipment is used by the operator or by an independent contractor.

(d) The operator will maintain an electric surveying equipment logbook with the equipment, where mine record books are kept, or where surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each piece of electronic

surveying equipment. The logbook shall be made available to MSHA upon request.

(e) All non-permissible electronic surveying equipment to be used within 150 feet of pillar workings shall be examined by the person who will operate the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. These examinations shall include:

1. Check the instrument for any physical damage and the integrity of the case;

2. Remove the battery and inspect for corrosion;

3. Inspect the contact points to ensure a secure connection to the battery;

4. Reinsert the battery and power up and shut down to ensure proper connections; and

5. Check the battery compartment cover or battery attachment to ensure it is securely fastened.

(f) The equipment shall be examined at least weekly by a qualified person as defined in 30 CFR 75.153, and the examination results shall be recorded weekly in the equipment's logbook. Examination entries in the logbook may be expunged after 1 year.

(g) The operator is to ensure that all non-permissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment's logbook and shall include a description of the work performed.

(h) Non-permissible surveying equipment that will be used within 150 feet of pillar workings shall not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of this petition.

(i) Non-permissible surveying equipment shall not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more of methane is detected while the non-permissible surveying equipment is being used, the equipment shall be de-energized immediately and the non-permissible electronic equipment withdrawn more than 150 feet from pillar workings. Prior to entering within 150 feet of pillar workings, all requirements of 30 CFR 75.323 shall be complied with.

(j) As an additional safety check, prior to setting up and energizing non-permissible electronic surveying equipment within 150 feet of pillar workings, the surveyor(s) shall conduct a visual examination of the immediate area for evidence that the areas appear to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or accumulated float coal dust is observed, the equipment may not be energized until sufficient rock dust has been applied and/or the accumulation of float coal dust has been cleaned-up. If non-permissible electronic surveying equipment is to be used in an area that is not rock dusted within 40 feet of a working face where a continuous mining machine is used to extract coal, the area shall have sufficient rock dust applied prior to energizing the electronic surveying equipment.

(k) All hand-held methane detectors shall be MSHA-approved and will be maintained in permissible and proper operating condition as defined by 30 CFR 75.320. All methane detectors shall provide visual and audible warnings when methane is detected at or above 1.0 percent.

(l) Prior to energizing any non-permissible surveying equipment within 150 feet of pillar workings, methane tests shall be made in accordance with 30 CFR 75.323(a).

(m) All areas to be surveyed shall be pre-shift examined according to 30 CFR 75.360 prior to surveying. If the area was not pre-shift examined, a supplemental examination according to 30 CFR 75.361 shall be performed before any non-certified person enters the area. If the area has been examined according to 30 CFR 75.360 or 30 CFR 75.361, additional examination is not required.

(n) A qualified person as defined in 30 CFR 75.151 shall continuously monitor for methane immediately before and during the use of non-permissible surveying equipment in or inby the last open crosscut. A second person in the surveying crew, if there are two people in the crew, shall also continuously monitor for methane. That person shall either be a qualified person as defined in 30 CFR 75.151, or be in the process of being trained to be a qualified person but have yet to make such tests for a period of 6 months as required by 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew shall become qualified in order to continue on the surveying crew. If the surveying crew consists of only one person, the surveyor shall monitor for methane with two separate devices.

(o) Personnel engaged in the use of surveying equipment shall be properly trained to recognize the hazards and limitations associated with the use of surveying equipment in areas where methane could be present.

(p) Batteries contained in the surveying equipment shall be changed out or charged more than 150 feet from pillar workings. Replacement batteries for the surveying equipment shall be carried only in the compartment provided for a spare battery in the electronic equipment carrying case. Before each shift of surveying, all batteries for the surveying equipment shall be charged sufficiently that they are not expected to be replaced on that shift.

(q) When using non-permissible electronic surveying equipment within 150 feet of the pillar workings, the surveyor shall confirm by measurement or by inquiry of the person in charge of the section that the air quantity on the section, on that shift, is at least the minimum quantity that is required by the mine's ventilation plan.

(r) Non-permissible surveying equipment may be used when production is occurring subject to these conditions:

1. On a mechanized mining unit (MMU) where production is occurring, non-permissible electronic surveying equipment shall not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.

2. Production may continue while non-permissible electronic surveying equipment is used if the surveying equipment is used in a separate split of air from where production is occurring.

3. Non-permissible surveying equipment shall not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

4. If, while surveying, a surveyor must disrupt ventilation, the surveyor shall cease surveying and communicate to the section foreman that ventilation must be disrupted. Production shall stop while ventilation is disrupted. Ventilation controls shall be reestablished immediately after the disruption is no longer necessary. Production can only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans and other applicable laws, standards, or regulations.

5. Any disruption in ventilation shall be recorded in the logbook required by this petition. The logbook shall include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption, the date and time the surveyor communicated the disruption

to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

(s) All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations shall receive training on the terms and conditions of this petition before using non-permissible electronic equipment within 150 feet of the pillar workings. A record of the training shall be kept with the other training records and provided to MSHA upon request.

(t) Within 60 days after this petition becomes final, the operator shall submit proposed revisions for its approved 30 CFR part 48 training plans to the District Manager. These proposed revisions shall specify initial and refresher training regarding the terms and conditions stated in this petition. When training is conducted, an MSHA Certificate of Training (Form 5000–23) shall be completed indicating surveyor training.

Docket Number: M–2021–041–C.

Petitioner: Bronco Utah Operations LLC, Hwy 10 South 550 West Consol Road, P.O. Box 527, Emery, Utah 84522.

Mine: Emery Mine, MSHA ID No. 42–00079, located in Emery County, Utah.

Regulation Affected: 30 CFR 75.1909(b)(6), Nonpermissible diesel-powered equipment; design and performance requirements.

Modification Request: The petitioner requests a modification of the existing standard to permit the use of the Getman Roadbuilder RGD–1504, serial number 6946, (roadbuilder) a diesel-powered, six-wheeled road grader. It has dual brake systems on the four rear wheels that are designed to prevent loss of braking due to a single component failure; however, it is not equipped with brakes on the front wheels.

The petitioner proposes an alternative method of compliance, in lieu of the front wheel brakes, on the roadbuilder that will be used at the Emery Mine.

(a) The roadbuilder will be modified to ensure that its maximum speed shall be limited to 10 miles per hour (mph) by:

1. Permanently blocking out any gear ratio that allows speeds faster than 10 mph in both forward and reverse; and

2. Using transmission(s) and differential(s) geared in accordance with the equipment manufacturer's instructions that limit(s) the maximum speed to 10 mph.

(b) The roadbuilder operators will be trained to recognize:

1. Appropriate levels of speed for different road conditions and slopes;

2. When to lower the moldboard (grader blade) to provide additional stopping capability in emergencies; and

3. The transmission gear-blocking device, or methods to block gears, and their proper application and requirements.

The petitioner asserts that the alternative method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Song-ae Aromie Noe,

Acting Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2021–27655 Filed 12–21–21; 8:45 am]

BILLING CODE 4520–43–P

LIBRARY OF CONGRESS

Copyright Office

[Docket No. 2021–10]

Technical Measures: Public Consultations

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notification of inquiry: Public consultations.

SUMMARY: The U.S. Copyright Office is announcing a series of consultations on technical measures to identify or protect copyrighted works online. The Office plans to hold a plenary session to launch consultations on this issue on February 22, 2022, to be followed by smaller sectoral consultations thereafter. To aid in this effort, the Office also is seeking public input on a number of questions.

DATES: Written statements of interest to participate in the consultations, along with a response to at least one of the questions in this notice, must be received no later than 11:59 p.m. Eastern Time on February 8, 2022. Written comments may be made for the record without expectation of participating in the consultations by that same deadline. The Office is planning to hold the plenary consultation via Zoom on February 22, 2022. The Office also plans to hold February 23, 2022 as a possible second day for plenary consultations, if needed. Subsequent industry-sector specific consultations will be announced at a later date via *https://www.copyright.gov/policy/technical-measures/*.

ADDRESSES: For reasons of governmental efficiency, the Copyright Office is using the *regulations.gov* system for the submission and posting of public submissions in this proceeding. All submissions are therefore to be submitted electronically through *regulations.gov.* Specific instructions for submitting comments and statements of interest are available on the Copyright Office's website at *https://www.copyright.gov/policy/technical-measures/.* If electronic submission of comments or statements of interest is not feasible due to lack of access to a computer and/or the internet, please contact the Office using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Emily Lanza, Counsel for Policy and International Affairs, by email at *emla@copyright.gov,* or Jenée Iyer, Counsel for Policy and International Affairs, by email at *jiyer@copyright.gov.* They can each be reached by telephone at 202–707–8350.

SUPPLEMENTARY INFORMATION:

I. Background

The U.S. Copyright Office's 2020 Report, *Section 512 of Title 17* (''Section 512 Report''), acknowledged the important role that technologies and technical measures can play in addressing internet piracy. While the infringement of copyrighted material online has evolved alongside technological developments, stakeholders have engaged in a range of voluntary collaborations and developed a number of technical measures that supplement the legislative notice-and-takedown framework.[1]

In a letter dated June 24, 2021, Senators Patrick Leahy and Thom Tillis requested that the Copyright Office ''convene a representative working group of relevant stakeholders to achieve the identification and implementation of technical measures.'' [2] The Senators emphasized that they continue to believe, as the Senate Judiciary Committee noted more than twenty years ago with the passage of the Digital Millennium Copyright Act, ''that voluntary technology is likely to be the solution to many of the issues facing copyright owners and service providers.'' [3]

The Office is now announcing that it will convene a series of consultations on technical measures for identifying or protecting copyrighted works online.

[1] *See* U.S. Copyright Office, Section 512 of Title 17 27–47 (2020) (''Section 512 Report''), *https://www.copyright.gov/policy/section512/section-512-full-report.pdf.*

[2] Letter from Sens. Thom Tillis & Patrick Leahy to Register Shira Perlmutter at 2 (June 24, 2021) (''Request Letter'').

[3] *Id.*

Over the past decade or so, rightsholders across industries have developed and employed various technical measures to assist with the protection of their works. For example, the implementation of digital fingerprinting allows rightsholders to negotiate with service providers specific responses once an exact match to a fingerprint has been identified.[4] Similarly, rightsholders have utilized digital watermarks, standard identifiers, and other tools to facilitate the use of their works, including downstream uses, while maintaining attribution and other copyright management information.[5]

Some technical measures to identify and protect copyrighted works online have been developed and deployed by or for online service providers and other stakeholders. [6] Proprietary systems used internally by platforms to identify and filter potentially infringing uploaded material include Scribd's BookID,[7] Dropbox's unique identifier system,[8] and YouTube's ContentID. YouTube's ContentID program, for example, scans videos that are uploaded to YouTube against a database of files that have been submitted by copyright owners participating in the program. When a match is made, the owner is notified and has the option to block the video from being viewed, monetize it by running advertisements, or track its viewership statistics.[9] Examples of broadly-available technical measures include filtering technologies like Audible Magic, universal data formats, and registries like the Picture Licensing Universal System (PLUS).[10] Audible Magic's filtering technology, which uses Automatic Content Recognition to match uploaded audio and video files against files registered with its database, operates similarly to ContentID but is broadly available for licensing by online platforms.[11]

While these collaborations and technical measures may constitute reasonable, effective, and flexible approaches to curbing online infringement, as the Office noted in its Section 512 Report, their strictly voluntary nature presents inherent limitations.[12] The absence of comprehensive coverage and the exclusion of certain stakeholder interests during the development stages could hinder a measure's sustainable success. One commenter to the Section 512 Study noted that ''voluntary initiatives can create potential for . . . disadvantaging those who are not involved in the relevant discussions or parties to the ultimate agreement, including the public, creators and providers of innovative new services.'' [13] The Office therefore recommended in the Section 512 Report that a ''key feature of any future voluntary measure should . . . involve cooperation among rightsholder organizations, all sizes of OSPs, individual creators, and users.'' [14] In addition to inclusivity, the Office also emphasized the importance of flexibility, accountability, and comprehensive reporting.[15]

II. Consultations

The consultations will address current and forthcoming technologies for identifying or protecting works online, including the technologies' availability, their use-cases, and their limitations. These consultations on the voluntary identification and implementation of technical measures are separate from the Office's forthcoming notice of inquiry on Standard Technical Measures (''STMs''), which will focus specifically on the interpretation of section 512(i) of the DMCA, 17 U.S.C. 512(i), and the definition and identification of STMs within the scope of the statute.

The consultations will consist of one plenary session and a series of smaller, industry-sector specific sessions. The plenary session will occur on February 22, 2022. If a sufficient number of participants appear, the Office will divide the plenary session into multiple breakout rooms. The plenary session, whether it proceeds in one room or several, will be viewable to the public.

Based on the responses received to this notice and the outcome of the plenary session, the Office will identify specific industry-sector based groups that will form the basis for the smaller sessions to follow. Schedules may be adjusted as needed by the Copyright Office, with advance notice given to the participants. At the current time, we anticipate this process continuing through late Spring 2022.

Members of the public who seek to participate in the consultations should submit, via *regulations.gov,* a written statement of interest answering at least one of the questions listed in section III below. The Copyright Office strongly encourages participation by individuals with experience currently using or developing relevant technologies. Both the plenary and industry-sector based sessions will be held virtually over Zoom.

The Office will notify participants of their assigned industry-sector based session not later than one week after the plenary session is held. The Office appreciates the flexibility of potential participants.

The Office will be inviting other government agencies, including but not

[4] *See* Intellectual Property Owners Association, Comments Submitted in Response to U.S. Copyright Office's Dec. 31, 2015, Notice of Inquiry at 7 (Apr. 1, 2016).

[5] *See generally* U.S. Copyright Office, Authors, Attribution, and Integrity: Examining Moral Rights in the United States 87–88 (2019), *https://copyright.gov/policy/moralrights/full-report.pdf* (discussing digital attribution in the context of section 1202 protections).

[6] Stakeholders have also collaborated in developing voluntary measures and best practices to address online infringement. Advertising networks and payment processors, for example, have implemented best practices to cut off payments and advertising revenues for web services offering infringing material. *See, e.g., Anti-Piracy Policy,* Mastercard, *https://www.mastercard.us/en-us/vision/who-we-are/terms-of-use/anti-piracy-policy.html* (last visited Dec. 10, 2021). More formal agreements across industry sectors, like the RogueBlock program and domain name registry ''Trusted Notifier'' programs, have facilitated collaborative programs to address online piracy. *See* Section 512 Study at 39–41; *IACC RogueBlock,* IACC, *http://www.iacc.org/online-initiatives/rogueblock;* Press Release, Motion Picture Association of America, Inc., Donuts and the MPAA Establish New Partnership to Reduce Online Piracy (Feb. 9, 2016), *https://www.mpaa.org/wp-content/uploads/2016/02/Donuts-and-MPAA-Establish-New-Partnership-2.9.16.pdf.* Similar voluntary initiatives to address online piracy have been adopted in the United Kingdom and European Union; for example, in June 2018, content industries, service providers, advertising bodies, and other stakeholder groups signed the European Commission's Memorandum of Understanding on Online Advertising and IPR to limit advertising on websites that infringe copyrights or disseminate counterfeit goods. *See* Eur. Commission, *Memorandum of Understanding on online advertising and IPR* (2018), *reposted at https://ec.europa.eu/docsroom/documents/30226.*

[7] Scribd, a service that provides access to literary works and allows users to self-publish, has established BookID to filter uploaded works. *BookID,* Scribd, *https://www.scribd.com/copyright/bookid.*

[8] Dropbox utilizes a different approach. Upon receiving a takedown notice and disabling access to the file, Dropbox adds the file's unique identifier, or hash, to a blacklist. If a user attempts to share a file with the same hash, it is blocked. *See* Greg Kumparak, *How Dropbox Knows When You're Sharing Copyrighted Stuff (Without Actually Looking at Your Stuff),* TechCrunch (Mar. 30, 2014, 4:38 p.m.), *https://techcrunch.com/2014/03/30/how-dropbox-knows-when-youre-sharing-copyrighted-stuff-without-actually-looking-at-your-stuff/.*

[9] *See How Content ID Works,* YouTube Help, *https://support.google.com/youtube/answer/2797370.*

[10] *The System: What is PLUS?,* PLUS, *https://www.useplus.com/aboutplus/system.asp.*

[11] If there is a match, the database relays to the platform owner information and rules specifying how the rightsholder wants the file to be used. *See Technology,* AudibleMagic, *https://www.audiblemagic.com/technology/.*

[12] *See* Section 512 Report at 173–74.

[13] Independent Film & Television Alliance, Comments Submitted in Response to the U.S. Copyright Office's Dec. 31, 2015, Notice of Inquiry at 11 (Apr. 1, 2016).

[14] Section 512 Report at 174–75.

[15] *See id.* at 175.

limited to the National Telecommunications and Information Agency (NTIA), the National Institute of Standards and Technology (NIST), and the U.S. Patent and Trademark Office (USPTO), to participate in the consultations and provide technical and operational input, as requested by Senators Leahy and Tillis.[16]

III. Statement of Interest Questions

Below are questions to consider ahead of the plenary session, as these topics will underlie the discussions. To aid in the discussion, several of the questions focus on particular categories of actors. The Office recognizes that individuals and entities at any given time might be acting as rightsholders, intermediaries, or users. Please provide an answer to at least one of these questions in your written statement of interest to participate in the consultations in order to assist in effectively organizing these consultations. For those who do not wish to participate in the consultations, the Office will also accept, by the date above, written comments for the record responding to at least one of the questions below.

1. *Rightsholders:* Please identify any technical measures currently used or in development by you, your organization, company, industry, or sector to identify or protect copyrighted works online. How do these technical measures affect your ability to protect your copyrighted works online?

2. Online service providers: Please identify any technical measures currently used or in development by your organization, company, industry, or sector to identify or protect copyrighted works online. How do these technical measures affect your ability to provide services to your users?

3. Users: How are you, or your organization, company, industry, or sector affected by technologies implemented by rightsholders and service providers to identify or protect copyrighted works online?

4. To what extent are any of these technical measures being adopted or discussed as part of any within-industry or cross-industry endeavors, initiatives, or agreement(s)?

5. Are there any other processes that are ongoing for identifying voluntary solutions or to identify and implement technical measures? Are there alternative processes, other than those that may currently be in place, that would better identify and implement technical measures? Please be specific, as different technical measures may have different solutions in different industry sectors.

6. To what extent would the adoption and broad implementation of existing or future technical measures by stakeholders, including online service providers and rightsholders, be likely to assist in addressing the problem of online copyright piracy? What are the obstacles to adopting and broadly implementing such existing or future technical measures? Would the adoption and broad implementation of such existing or future technical measures have negative effects? If so, what would be the effects, and who would be affected?

7. Is there a role for government to play in identifying, developing, cataloging, or communicating about existing or future technical measures for identifying or protecting copyrighted works online? Can the government facilitate the adoption or implementation of technical measures, and if so, how? Are there technical measures or other standards used to protect copyrighted works online of which the government should be aware when implementing statutory or regulatory provisions, such as requirements for procurement, grants, or required data inventories?

8. Please identify any other pertinent issues not referenced above that the Copyright Office should consider in these consultations.

For both comments and statements of interest, please indicate which question(s) above you are answering in your submission. For those who wish to participate in the consultations, please also indicate your organization's request to participate in the consultations in the written statement of interest and identify the individual (name, title, contact information) who will be participating in the plenary and industry-sector based sessions.

Dated: December 16, 2021.

Shira Perlmutter,

Register of Copyrights and Director of the U.S. Copyright Office.

[FR Doc. 2021–27705 Filed 12–21–21; 8:45 am]

BILLING CODE 1410–30–P

[16] Request Letter at 2.

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket Nos. 21–CRB–0014–AU (Audacy) and 21–CRB–0015–AU (Midwest Communications)]

Notice of Intent To Audit

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Public notice.

SUMMARY: The Copyright Royalty Judges announce receipt from SoundExchange, Inc., of notices of intent to audit the 2018, 2019, and 2020 statements of account submitted by commercial webcasters Audacy and Midwest Communications concerning the royalty payments they made pursuant to two statutory licenses.

ADDRESSES: *Docket:* For access to the dockets to read background documents, go to eCRB at *https://app.crb.gov* and perform a case search for docket 21–CRB–0014–AU (Audacy) or 21–CRB–0015–AU (Midwest Communications).

FOR FURTHER INFORMATION CONTACT: Anita Blaine, (202) 707–7658, *crb@loc.gov*.

SUPPLEMENTARY INFORMATION: The Copyright Act grants to sound recordings copyright owners the exclusive right to publicly perform sound recordings by means of certain digital audio transmissions, subject to limitations. Specifically, the right is limited by the statutory license in section 114, which allows nonexempt noninteractive digital subscription services, eligible nonsubscription services, and preexisting satellite digital audio radio services to perform publicly sound recordings by means of digital audio transmissions. 17 U.S.C. 114(f). In addition, a statutory license in section 112 allows a service to make necessary ephemeral reproductions to facilitate digital transmission of the sound recording. 17 U.S.C. 112(e).

Licensees may operate under these licenses provided they pay the royalty fees and comply with the terms set by the Copyright Royalty Judges. The rates and terms for the section 112 and 114 licenses are codified in 37 CFR parts 380 and 382–84.

As one of the terms for these licenses, the Judges designated SoundExchange, Inc., (SoundExchange) as the Collective, *i.e.,* the organization charged with collecting the royalty payments and statements of account submitted by eligible nonexempt noninteractive digital subscription services such as Commercial Webcasters and with distributing the royalties to the copyright owners and performers entitled to receive them under the section 112 and 114 licenses. *See* 37 CFR 380.4(d).

As the Collective, SoundExchange may, only once a year, conduct an audit of a licensee for any or all of the prior three calendar years to verify royalty payments. SoundExchange must first file with the Judges a notice of intent to audit a licensee and deliver the notice

to the licensee. *See* 37 CFR 380.6. On December 7, 2021, SoundExchange filed with the Judges notices of intent to audit Audacy and Midwest Communications for the years 2018, 2019, and 2020.

The Judges must publish notice in the **Federal Register** within 30 days of receipt of a notice announcing the Collective's intent to conduct an audit. *See* 37 CFR 380.6(c). This notice fulfills the Judges' publication obligation with respect to SoundExchange's December 7, 2021 notices of intent to audit Audacy and Midwest Communications.

Dated: December 16, 2021.

Suzanne M. Barnett,

Chief Copyright Royalty Judge.

[FR Doc. 2021–27670 Filed 12–21–21; 8:45 am]

BILLING CODE 1410–72–P

NATIONAL SCIENCE FOUNDATION

Notice of Intent To Seek Approval To Extend an Information Collection

AGENCY: National Science Foundation.

ACTION: Notice and request for comments.

SUMMARY: The National Science Foundation (NSF) is announcing plans to request clearance of this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting that OMB approve clearance of this collection for no longer than three years.

DATES: Written comments on this notice must be received by February 22, 2022 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

For Additional Information or Comments: Contact Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays). You also may obtain a copy of the data collection instrument and instructions from Ms. Plimpton.

SUPPLEMENTARY INFORMATION:

Title of Collection: Grantee Reporting Requirements for Science and Technology Centers (STC): Integrative Partnerships.

OMB Number: 3145–0194.

Expiration Date of Approval: February 28, 2022.

Type of Request: Intent to seek approval to extend an information collection.

Proposed Project: The Science and Technology Centers (STC): Integrative Partnerships Program supports innovation in the integrative conduct of research, education and knowledge transfer. Science and Technology Centers build intellectual and physical infrastructure within and between disciplines, weaving together knowledge creation, knowledge integration, and knowledge transfer. STCs conduct world-class research through partnerships of academic institutions, national laboratories, industrial organizations, and/or other public/private entities. New knowledge thus created is meaningfully linked to society.

STCs enable and foster excellent education, integrate research and education, and create bonds between learning and inquiry so that discovery and creativity more fully support the learning process. STCs capitalize on diversity through participation in center activities and demonstrate leadership in the involvement of groups underrepresented in science and engineering.

Centers selected will be required to submit annual reports on progress and plans, which will be used as a basis for performance review and determining the level of continued funding. To support this review and the management of a Center, STCs will be required to develop a set of management and performance indicators for submission annually to NSF via an NSF evaluation technical assistance contractor. These indicators are both quantitative and descriptive and may include, for example, the characteristics of center personnel and students; sources of financial support and in-kind support; expenditures by operational component; characteristics of industrial and/or other sector participation; research activities; education activities; knowledge transfer activities; patents, licenses; publications; degrees granted to students involved in Center activities; descriptions of significant advances and other outcomes of the STC effort. Part of this reporting will take the form of a database which will be owned by the institution and eventually made available to an evaluation contractor. This database will capture specific information to demonstrate progress towards achieving the goals of the program. Such reporting requirements will be included in the cooperative agreement which is binding between the academic institution and the NSF.

Each Center's annual report will address the following categories of activities: (1) Research, (2) education, (3) knowledge transfer, (4) partnerships, (5) diversity, (6) management and (7) budget issues.

For each of the categories the report will describe overall objectives for the year, problems the Center has encountered in making progress towards goals, anticipated problems in the following year, and specific outputs and outcomes.

Use of the Information: NSF will use the information to continue funding of the Centers, and to evaluate the progress of the program.

Estimate of Burden: 100 hours per center for twelve centers for a total of 1,200 hours.

Respondents: Non-profit institutions; federal government.

Estimated Number of Responses per Report: One from each of the twelve centers.

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: December 17, 2021.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2021–27712 Filed 12–21–21; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0252]

Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 6 to Regulatory Guide (RG), 1.26 ''Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants.'' Revision 6 to RG 1.26 incorporates additional information that provides guidance for alternative quality classification systems for components in light-water reactor (LWR) nuclear power plants and updates the staff position regarding classification of Quality Group C components to reflect the latest guidance on systems that contain radioactive material since Revision 5 (02/2017), of RG 1.26 was issued. The appendices to this revised RG provide guidance for alternative quality classification systems for components in LWR nuclear power plants.

DATES: Revision 6 to RG 1.26 is available on December 22, 2021.

ADDRESSES: Please refer to Docket ID NRC–2020–0252 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0252. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

Revision 6 to RG 1.26 and the regulatory analysis may be found in ADAMS under Accession Nos. ML21232A142 and ML20168A893, respectively.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT: Thomas Scarbrough, Office of Nuclear Reactor Regulation, telephone: 301–415–2794 email: *Thomas.Scarbrough@nrc.gov* or James Steckel, Office of Nuclear Regulatory Research, telephone: 301–415–1026 email: *James.Steckel@nrc.gov.* Both are staff members of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC is issuing a revision in the NRC's ''Regulatory Guide'' series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the NRC staff uses in evaluating specific issues or postulated events, and data that the NRC staff needs in its review of applications for permits and licenses.

Revision 6 of RG 1.26 was issued with a temporary identification of Draft Regulatory Guide, DG–1371.

II. Additional Information

The NRC published a notice of availability of DG–1371 in the **Federal Register** on May 7, 2021 (86 FR 24672) for a 60-day public comment period. The public comment period closed on July 6, 2021. Public comments on DG–1371 and the staff responses to the public comments are available in ADAMS under accession No. ML21235A011.

III. Congressional Review Act

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting, Forward Fitting, and Issue Finality

Revision 6 of RG 1.26 does not constitute backfitting as defined in section 50.109 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Backfitting,'' and as described in NRC Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; constitute forward fitting as that term is defined and described in MD 8.4; or affect the issue finality of any approval issued under 10 CFR part 52, ''Licenses, Certificates, and Approvals for Nuclear Power Plants.'' As explained in Revision 6 of RG 1.26, applicants and licensees are not required to comply with the positions set forth in this RG.

Dated: December 15, 2021.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Regulatory Guide and Programs Management Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2021–27688 Filed 12–21–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0141]

Evaluating the Habitability of a Nuclear Power Plant Control Room During a Postulated Hazardous Chemical Release

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 2 to Regulatory Guide (RG), 1.78, ''Evaluating the Habitability of a Nuclear Power Plant Control Room during a Postulated Hazardous Chemical Release.'' The revision of RG 1.78 describes an approach that is acceptable to the NRC staff to meet regulatory requirements for evaluating the habitability of a nuclear power plant control room during a postulated hazardous chemical release. Releases of hazardous chemicals, onsite and off-site, can result in the nearby control room becoming uninhabitable.

DATES: Revision 2 to RG 1.78 is available on December 22, 2021.

ADDRESSES: Please refer to Docket ID NRC–2021–0141 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0141. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

• *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

Revision 2 to RG 1.78 and the regulatory analysis may be found in ADAMS under Accession Nos. ML21253A071 and ML21119A159, respectively.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT: Casper Sun, telephone: 301–415–1646, email: *Casper.Sun@nrc.gov* and Michael Eudy, telephone: 301–415–3104, email: *Michael.Eudy@nrc.gov.* Both are staff members of the Office of Nuclear Regulatory Research at the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC is issuing a revision in the NRC's ''Regulatory Guide'' series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the NRC staff uses in evaluating specific issues or postulated events, and data that the NRC staff needs in its review of applications for permits and licenses.

Revision 2 of RG 1.78 was issued with a temporary identification of Draft Regulatory Guide, DG–1387.

II. Additional Information

The NRC published a notice of the availability of DG–1387 in the **Federal Register** on July 28, 2021 (86 FR 40661) for a 30-day public comment period. The public comment period closed on August 27, 2021. Public comments on DG–1387 and the staff responses to the public comments are available in ADAMS under Accession No. ML21253A074.

III. Congressional Review Act

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting, Forward Fitting, and Issue Finality

Revision 2 of RG 1.78 does not constitute backfitting as defined in section 50.109 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Backfitting,'' and as described in NRC Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; constitute forward fitting as that term is defined and described in MD 8.4; or affect the issue finality of any approval issued under 10 CFR part 52. As explained in Revision 2 of RG 1.78, applicants and licensees would not be required to comply with the positions set forth in the RG.

Dated: December 15, 2021.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Regulatory Guide and Programs Management Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2021–27667 Filed 12–21–21; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF SPECIAL COUNSEL

Privacy Act; System of Records

AGENCY: U.S. Office of Special Counsel.

ACTION: Notice of a new system of records.

SUMMARY: The U.S. Office of Special Counsel (OSC) seeks, in accordance with the Privacy Act of 1974, to establish a new system of records titled, ''Office of Special Counsel, OSC–4, Reasonable Accommodation Records.'' This system of records allows OSC to collect and maintain information from employees who request accommodations from OSC for medical or religious reasons.

DATES: Written comments should be received on or before January 21, 2022.

ADDRESSES: You may submit written comments by mail to the: U.S. Office of Special Counsel, Office of the Clerk, 1730 M St. NW, Washington, DC 20036; or by email via: *frliaison@osc.gov.*

FOR FURTHER INFORMATION CONTACT: Amy Beckett, Senior Litigation Counsel, by telephone at (202) 804–7000, or by email at *frliaison@osc.gov.*

SUPPLEMENTARY INFORMATION: OSC is a permanent independent federal investigative and prosecutorial agency. OSC's basic authorities come from four federal statutes: The Civil Service Reform Act, the Whistleblower Protection Act, the Hatch Act, and the Uniformed Services Employment & Reemployment Rights Act (USERRA). OSC's primary mission is to safeguard the merit system by protecting federal employees and applicants from prohibited personnel practices, especially reprisal for whistleblowing, and to serve as a safe channel for allegations of wrongdoing.

Title V of the Rehabilitation Act of 1973, as amended, prohibits discrimination in services and employment based on disability, and Title VII of the Civil Rights Act of 1974 prohibits discrimination, including based on religion. These prohibitions on discrimination require Federal agencies to provide reasonable accommodations to individuals with disabilities and those with sincerely held religious beliefs unless doing so would impose an undue hardship. In addition, some individuals may request modifications to their workspace, schedule, duties, or other requirements for reasons that may not qualify as a disability but may lead to an appropriate modification to workplace policies and practices.

In accordance with the Privacy Act of 1974, OSC proposes to establish a new system of records that allows OSC to collect and maintain information from employees who request reasonable accommodations from OSC for medical or religious reasons. Employees include applicants for employment and other individuals who participate in OSC programs and activities and who request reasonable accommodations and/or other appropriate modifications from OSC for medical or religious reasons.

SYSTEM NAME AND NUMBER:

Office of Special Counsel, OSC–4, Reasonable Accommodation Records.

SECURITY CLASSIFICATION:

OSC's work related to this system of records would not ordinarily involve records that contain classified information. In the event there is classified information, OSC would maintain such records using methods approved for handling classified material.

SYSTEM LOCATION:

Records are primarily maintained electronically by the Chief Human Capital Officer on OSC's Microsoft Enterprise System and/or in designated FedRAMP-authorized cloud service providers.

SYSTEM MANAGER(S):

Chief Information Officer and Chief Human Capital Officer, U.S. Office of Special Counsel, 1730 M St. NW, Suite 218, Washington, DC 20006, *itsupport@osc.gov* and *hco@osc.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Rehabilitation Act of 1973, 29 U.S.C. 701, 791, 794; Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e; 29 CFR 1605 (Guidelines on Discrimination Because of Religion); 29 CFR 1614 (Federal Sector Equal Employment Opportunity); 29 CFR 1614 (Regulations to Implement the Equal Employment Provisions of the Americans With Disabilities Act); 5 U.S.C. 302, 1103; Executive Order 13164, Requiring Federal Agencies to Establish Procedures to Facilitate the Provision of Reasonable Accommodation (July 26, 2000); and Executive Order 13548, Increasing Federal Employment of Individuals with Disabilities (July 26, 2010).

PURPOSE(S) OF THE SYSTEM:

The purpose of this system of records is to allow OSC to collect and maintain records on employees, applicants for employment, and other individuals who participate in OSC programs or activities, who request from OSC an accommodation or other modification for medical or religious reasons; to process, evaluate, and make decisions on individual requests; and to track and report the processing of such requests OSC-wide to comply with applicable requirements in law and policy.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicants for Federal employment, Federal employees, and visitors to Federal buildings who request a reasonable accommodation or other appropriate modifications from OSC for medical or religious reasons.

CATEGORIES OF RECORDS IN THE SYSTEM:

The principal types of records in the system are requests for reasonable accommodations that include the following:

- Requester's name;
- Requester's status (applicant or current employee);
- Date of request;
- Employee's position title, grade, series, step;
- Position title, grade, series, step of the position the requester is applying for;
- Requester's contact information (addresses, phone numbers, and email addresses);
- Description of the requester's medical condition or disability and any medical documentation provided in support of the request;
- Requester's statement of a sincerely held religious belief and any additional information provided concerning that religious belief and the need for an accommodation to exercise that belief;
- Description of the accommodation being requested;
- Description of previous requests for accommodation;
- Whether the request was made orally or in writing;
- Documentation by an OSC official concerning whether the disability is obvious, and the accommodation is obvious and uncomplicated, whether medical documentation is required to evaluate the request, whether research is necessary regarding possible accommodations, and any extenuating circumstances that prevent the OSC official from meeting the relevant timeframe;
- Whether the request for reasonable accommodation was granted or denied, and if denied the reason for the denial;
- The amount of time taken to process the request;
- The sources of technical assistance consulted in trying to identify a possible reasonable accommodation;
- Any reports or evaluations prepared in determining whether to grant or deny the request; and
- Any other information collected or developed in connection with the request for a reasonable accommodation.

RECORD SOURCE CATEGORIES:

Information is obtained from the individuals who request a reasonable accommodation or other appropriate modification from OSC; directly or indirectly from appropriate medical professionals; directly or indirectly from an individual's religious or spiritual advisors or institutions; and from management officials.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

The following routine uses permit OSC to:

a. Disclose information to appropriate federal entities with subject matter expertise to the extent necessary to obtain advice on any authorities, programs, or functions associated with records in this system;

b. Disclose information to the Office of Personnel Management (OPM) pursuant to Civil Service Rule 5.4 (5 CFR 5.4), or obtain an advisory opinion concerning the application or effect of civil service laws, rules, regulations, or OPM guidelines in particular situations;

c. Disclose to the Equal Employment Opportunity Commission or any other agency or office concerned with the enforcement of the anti-discrimination laws, information concerning the reasonable accommodation;

d. Disclose information to any source from which additional information is requested (to the extent necessary to identify the individual, inform the source of the purpose(s) of the request, and to identify the type of information requested), where necessary to obtain information relevant to an agency decision concerning: The grant or denial of a medical or religious accommodation or modification;

e. Provide information to a congressional office from the record of an individual in response to an inquiry from that congressional office (made at the written request of that individual);

f. Furnish information to the National Archives and Records Administration (NARA) in records management inspections conducted under authority of 44 U.S.C. 2904 and 2906, or other functions authorized by laws, regulations, and policies governing NARA operations and OSC records management responsibilities;

g. Disclose information when consulting with, or referring a record to, another Federal entity for the purpose of making a decision on a request for information under the FOIA or the Privacy Act; or to the Office of Government Information Services established at NARA by the Open Government Act of 2007, which amended the FOIA, for the purpose of conducting mediation and otherwise resolving disputes under FOIA;

h. Disclose records to the Department of Justice (DOJ) when: 1. Any of the following entities or individuals is a party to litigation or has an interest in litigation: A. The OSC; B. Any employee of OSC in their official capacity; C. Any employee of OSC in their individual capacity whom DOJ has been asked or agreed to represent; or D. The United States, where OSC determines that OSC will be affected by the litigation; and 2. OSC determines that use of the records by DOJ is relevant and necessary to the litigation;

i. Disclose records in a proceeding before a court or adjudicative body, before which OSC is authorized to appear, when: 1. Any of the following entities or individuals is a party to, or

has an interest in the proceedings: A. OSC; B. Any employee of OSC in their official capacity; C. Any employee of OSC in their individual capacity whom OSC has agreed to represent; or D. The United States, where OSC determines that OSC will be affected by the proceedings; and 2. OSC determines that use of the records is relevant and necessary to the proceedings;

j. Disclose information to first aid and safety personnel if the individual requires emergency treatment;

k. Disclose information to an Office of Inspector General (OIG) or comparable internal inspection, audit, or oversight office of an agency for the purpose of facilitating the coordination and conduct of investigations and review of allegations within the purview of both OSC and the agency OIG or comparable office; or in notifying an OIG (or comparable office) of the disposition of matters referred by the OIG (or comparable office) to OSC;

l. Disclose information to the news media and the public when (1) the matter under investigation has become public knowledge, (2) the Special Counsel determines that disclosure is necessary to preserve confidence in the integrity of the OSC investigative process or is necessary to demonstrate the accountability of OSC officers, employees, or individuals covered by this system, or (3) the Special Counsel determines that there exists a legitimate public interest (*e.g.,* to demonstrate that the law is being enforced, or to deter the commission of prohibited personnel practices, prohibited political activity, and other prohibited activity within OSC's jurisdiction), except to the extent that the Special Counsel determines in any of these situations that disclosure of specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy;

m. Disclose information to another Federal agency or oversight body charged with evaluating OSC's compliance with the laws, regulations, and policies governing reasonable accommodation requests;

n. Disclose information to another Federal agency pursuant to a written agreement with OSC to provide services (such as medical evaluations), when necessary, in support of reasonable accommodation decisions;

o. Disclose information to agency contractors, experts, consultants, detailees, or non-OSC employees performing or working on a contract, service, or other activity related to the system of records, when necessary to accomplish an agency function related to the system;

p. Make lists and reports available to the public pursuant to 5 U.S.C. 1219;

q. *Disclose information:* 1. To appropriate agencies, entities, and persons when: (1) OSC suspects or has confirmed that there has been a breach of the system of records; (2) OSC has determined that as a result of the suspected or confirmed compromise there is a risk of harm to individuals, OSC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with OSC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm; 2. To another Federal agency, or Federal entity when OSC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach;

r. Disclose pertinent information to the appropriate federal, state, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order where the record, either alone or in conjunction with other information, indicates a violation or potential violation of civil or criminal law or regulation; and

s. Disclose information to the Integrity Committee established under section 11(d) of the Inspector General Act of 1978, when needed because of receipt, review or referral to the Integrity Committee under section 7(b) of Public Law 110–409; or as needed for a matter referred to OSC by the Integrity Committee.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The records in this system of records are stored electronically on OSC's Microsoft Enterprise System and/or in designated FedRAMP-authorized cloud service providers segregated from non-government traffic and data. Access is limited to those agency personnel who have an official need for access to perform their duties and who have appropriate clearances or permissions. OSC requires new employees to read and acknowledge agency directives, including information technology user roles and responsibilities, records management, and privacy protection. OSC requires all employees to complete annual cybersecurity awareness training.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by name or other unique personal identifiers.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records in this system of records are maintained in accordance with GRS 2.3 and are destroyed three (3) years after separation from the agency or all appeals are concluded, whichever is later, but longer retention is authorized if requested for business use.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records in the system are protected from unauthorized access and misuse through various administrative, technical, and electronic security measures. OSC's security measures are in compliance with the Federal Information Security Modernization Act (Pub. L. 113–283), associated OSC's policies, and applicable standards and guidance from the National Institute of Standards and Technology. Controls are in place to minimize the risk of compromising the information that is electronically stored. Access to the paper and electronic records in this system of records is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RECORDS ACCESS PROCEDURES:

Individuals who wish to seek notification of and/or access to their records in the system of records should contact OSC's FOIA/Privacy Act Officer, U.S. Office of Special Counsel by mail at 1730 M Street NW, Suite 218, Washington, DC 20036; or by email at *foiarequest@osc.gov.* To assist in the process of locating and identifying records, individuals should furnish the following: Name and home address; business title and address; any other known identifying information such as an agency file number or identification number; a description of the circumstances under which the records were compiled; and any other information deemed necessary by OSC to properly process the request. Requesters should reasonably describe the records they seek. Rules about FOIA access are in 5 CFR 1820 and rules about Privacy Act access are in 5 CFR 1830.

CONTESTING RECORD PROCEDURES:

Individuals who wish to contest records about themselves should contact OSC's Privacy Act Officer, identify any information they believe should be corrected, and furnish a statement of the basis for the requested correction along with all available supporting documents and materials. See OSC Privacy Act regulations at 5 CFR part 1830.

NOTIFICATION PROCEDURES:

Individuals who wish to inquire whether this system contains information about them should follow the Record Access procedures noted above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Date: December 16, 2021.

Travis Millsaps,

Deputy Special Counsel for Public Policy.

[FR Doc. 2021–27726 Filed 12–21–21; 8:45 am]

BILLING CODE 7405–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93802; File No. SR–NYSE–2021–72]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change for Non-Substantive Conforming Changes to Rule 18

December 16, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on December 9, 2021, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes non-substantive conforming changes to Rule 18. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes non-substantive conforming changes to Rule 18 (Compensation in Relation to Exchange System Failure).

Earlier this year, the Exchange eliminated member and non-member employee Floor Officials and transited the duties and responsibilities of Floor Officials to newly created Trading Officials, who are Exchange employees appointed by the NYSE CEO or his or her designee.[4] As part of this change, the Exchange amended, among other rules, Rule 18, which sets forth the process for member organizations to seek reimbursement for losses resulting from system failures. Specifically, former Rule 18(d) established a Compensation Review Panel consisting of three Floor Governors and three Exchange employees to determine the eligibility of a claim for payment. Since elimination of Floor Governors left Exchange employees as the sole members of the Compensation Review Panel, the Exchange eliminated the Compensation Review Panel and amended Rule 18(d) to provide that the Exchange will review claims submitted pursuant to Rule 18 and determine eligibility of a claim for payment.[5]

As part of that filing, the Exchange inadvertently failed to amend subsections (e) and (f) of Rule 18, which describe the workings of the Compensation Review Panel, as well the deleting the references to the Compensation Review Panel in subsections (c) and (d) of Supplementary Material .10, which governs Rule 18 claims by the Exchange's affiliate NYSE American LLC. The Exchange accordingly proposes the following conforming changes to Rule 18.

Rule 18(e) provides that Compensation Review Panel determinations are by majority vote and that in the event of a deadlock the final determination will be made by the Chief Executive Officer of the Exchange (''CEO'') or his or her designee. Consistent with the previous filing, the Exchange proposes to delete subsection (e) as obsolete. Current subsection (f), which provides that all determinations made pursuant to Rule 18 by the Compensation Review Panel, the CEO or his or her designee are final, would become new subsection (e). The phrase ''the Compensation Review Panel, the CEO or his or her designee'' in subsection (f) would also be deleted. Proposed Rule 18(f) would accordingly provide that all determinations made pursuant to the Rule are final. Finally the references to Compensation Review Panel in subsections (c) and (d) of Supplementary Material .10 would be replaced with the Exchange.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Section 6(b)(5),[7] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

In particular, the Exchange believes that the proposed non-substantive conforming changes would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest because the proposed non-substantive changes would add clarity, transparency and consistency to the

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 92193 (June 16, 2021), 86 FR 33001 (June 23, 2021) (SR–NYSE–2020–105) (Order).

[5] *See id.,* 86 FR at 33002. As described in the previous filing, claims under Rule 18(d) would continue to be validated and reviewed by Exchange employees but retention of the Compensation Review Panel was unnecessary given that elimination of Floor Officials, which would leave the panels composed solely of Exchange employees.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

Exchange's rules. The Exchange believes that market participants would benefit from the increased clarity, thereby reducing potential confusion and ensuring that persons subject to the Exchange's jurisdiction, regulators, and the investing public can more easily navigate and understand the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but is rather concerned with making non-substantive conforming changes to the Exchange rules. Since the proposal does not substantively modify system functionality or processes on the Exchange, the proposed changes will not impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [8] and Rule 19b–4(f)(6) [9] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [10] of the Act to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2021–72 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2021–72. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2021–72 and should be submitted on or before January 12, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–27662 Filed 12–21–21; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[10] 15 U.S.C. 78s(b)(2)(B).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93803; File No. SR–NYSEAMER–2021–46]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt a New Historical Market Data Product To Be Known as the NYSE Options Open-Close Volume Summary

December 16, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on December 14, 2021, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt a new historical market data product to be known as the NYSE Options Open-Close Volume Summary. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries,

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt a new historical market data product to be known as the NYSE Options Open-Close Volume Summary, which will be available to all subscribers. The proposed NYSE Options Open-Close Volume Summary is based on market data products currently available on most other options exchanges.[4]

The Exchange proposes to offer the NYSE Options Open-Close Volume Summary, which will be a volume summary of trading activity on the Exchange at the option level by origin (Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker[5]), side of the market (buy or sell), contract volume, and transaction type (opening or closing). The Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker volume will be further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The NYSE Options Open-Close Volume Summary is proprietary Exchange trade data and does not include trade data from any other exchange. It is also a historical data product and not a real-time data feed.

Specifically, the NYSE Options Open-Close Volume Summary would include the following data: Aggregate number of buy and sell transactions in the affected series; aggregate volume traded electronically on the Exchange in the affected series; aggregate number of trades effected on the Exchange to open a position;[6] aggregate number of trades effected on the Exchange to close a position;[7] and origin of the orders and quotes involved in trades on the Exchange in the affected series during a particular trading session, specifically aggregated in the following categories of participants: Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker.

The Exchange anticipates a wide variety of market participants to purchase the NYSE Options Open-Close Volume Summary, including, but not limited to, individual customers, buy-side investors, and investment banks. The NYSE Options Open-Close Volume Summary would provide subscribers data that should enhance their ability to analyze options trade and volume data, and to create and test trading models and analytical strategies. The Exchange believes that NYSE Options Open-Close Volume Summary will be a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular options series. The NYSE Options Open-Close Volume Summary is a completely voluntary product, in that the Exchange is not required by any rule or regulation to make this data available and that potential subscribers may purchase it only if they voluntarily choose to do so.

The Exchange proposes to offer two versions of the NYSE Options Open-Close Volume Summary: End of Day Volume Summary and Intra-Day Volume Summary. The End of Day Volume Summary will contain historical data from the previous trading day and would be available after the end of each trading day, generally on a T+1 basis. The Intra-Day Volume Summary would include ''snapshots'' taken every 10 minutes throughout the trading day and would be available within five minutes of the conclusion of each 10-minute period. Each update would represent combined data captured from the current ''snapshot'' and all previous ''snapshots'' and thus would provide open-close data on an aggregate basis.

The Exchange will establish monthly subscriber fees for the NYSE Options Open-Close Volume Summary by way of a separate proposed rule change, which the Exchange will submit prior to the launch of the NYSE Options Open-Close Volume Summary. The Exchange plans to introduce the NYSE Options Open-Close Volume Summary in the first quarter of 2022. The Exchange will announce the exact date that the NYSE Options Open-Close Volume Summary will become available through a NYSE Trader Update.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)[8] of the Act, in general, and furthers the objectives of Section 6(b)(5)[9] of the Act, in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and it is not designed to permit unfair discrimination among customers, brokers, or dealers.

In adopting Regulation NMS, the Commission granted self-regulatory organizations and broker-dealers increased authority and flexibility to offer new and unique market data to consumers of such data. It was believed that this authority would expand the amount of data available to users and consumers of such data and also spur innovation and competition for the provision of market data. The Exchange believes that the NYSE Options Open-Close Volume Summary options data product proposed herein is precisely the sort of market data product evolutions that the Commission envisioned when it adopted Regulation NMS. The proposed rule change would benefit investors by providing access to the NYSE Options Open-Close Volume Summary, which contains information regarding opening and closing activity across different options series during the trading day that would provide investor sentiment and thereby allow market participants to make informed trading decisions throughout the day. Subscribers to the data may also be able to enhance their ability to analyze options trade and volume data and create and test trading models and analytical strategies. The Exchange believes the NYSE Options

[4] *See* Securities Exchange Act Release Nos. 89497 (August 6, 2020), 85 FR 48747 (August 12, 2020) (SR–CboeBZX–2020–059); 89498 (August 6, 2020), 85 FR 48735 (August 12, 2020) (SR–Cboe–EDGX–2020–36); 85817 (May 9, 2019), 84 FR 21863 (May 15, 2019) (SR–CBOE–2019–026); 89496 (August 6, 2020), 85 FR 48743 (August 12, 2020) (SR–C2–2020–010); 89586 (August 17, 2020), 85 FR 51833 (August 21, 2020) (SR–C2–2020–012); 62887 (September 10, 2010), 75 FR 57092 (September 17, 2010) (SR–Phlx–2010–121); 65587 (October 18, 2011), 76 FR 65765 (October 24, 2011) (SR–NASDAQ–2011–144); 61317 (January 8, 2010), 75 FR 2915 (January 19, 2010) (SR–ISE–2009–103); 81632 (September 15, 2017), 82 FR 44235 (September 21, 2017) (SR–GEMX–2017–42); 91963 (May 21, 2021), 86 FR 28662 (May 27, 2021) (SR–EMERALD–2021–18); 91964 (May 21, 2012), 86 FR 28667 (May 27, 2021) (SR–PEARL–2021–24); and 91965 (May 21, 2021), 86 FR 28665 (May 27, 2021) (SR–MIAX–2021–18). *See also* Securities Exchange Act Release No. 93132 (September 27, 2021), 86 FR 54499 (October 1, 2021) (SR–NYSEArca–2021–82) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt a New Historical Market Data Product To Be Known as the NYSE Options Open-Close Volume Summary). The Exchange notes that the NYSE Options Open-Close Volume Summary on NYSE Arca, Inc. (''NYSE Arca'') has not yet been made available for purchase by subscribers.

[5] *See* Exchange Rule 900.2.NY for the definitions of the terms Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker.

[6] An opening buy is a transaction that creates or increases a long position and an opening sell is a transaction that creates or increases a short position.

[7] A closing buy is a transaction made to close out an existing position and a closing sell is a transaction to reduce or eliminate a long position.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

Open-Close Volume Summary would provide a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series, but also emphasizes such data is not necessary for trading.

Moreover, other exchanges also offer a substantially identical data product.[10] Specifically, NASDAQ OMX PHLX (''PHLX'') and the NASDAQ Stock Market LLC (''NASDAQ'') offer the PHLX Options Trade Outline (''PHOTO'') and NASDAQ Options Trade Outline (''NOTO''), respectively. The Cboe Exchange, Inc. (''Cboe''), Cboe C2 Exchange, Inc. (''C2''), Cboe BZX Exchange, Inc. (''BZX''), Cboe EDGX Exchange, Inc. (''EDGX'') all offer the market data products called the End of Day and Intraday Open-Close Data. Additionally, Miami International Securities Exchange, LLC (''MIAX''), MIAX Emerald, LLC (''Emerald'') and MIAX PEARL, LLC (''PEARL'') all offer an End of Day Open-Close Report and an Intra-Day Open-Close Report. And as noted above, NYSE Arca has also established the NYSE Options Open-Close Volume Summary that it intends to introduce to the marketplace. The Phlx, Nasdaq, Cboe, C2, BZX, EDGX, MIAX, Emerald, PEARL and NYSE Arca products provide substantially the same information as that included in the proposed NYSE Options Open-Close Volume Summary. Like the proposed product, the data is provided to subscribers in the other exchange's market data products after the end of the trading day and cumulatively every 10 minutes and provided within five minutes of the conclusion of each 10-minute period.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[11] the Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposal will promote competition by permitting the Exchange to offer a data product similar to those offered by other competitor options exchanges.[12] The market for proprietary data products is currently competitive and inherently contestable because there is fierce competition for the inputs necessary to the creation of proprietary data. Numerous exchanges compete with each other for listings, trades, and market data itself, providing virtually limitless opportunities for entrepreneurs who wish to produce and distribute their own market data. The proposed introduction of the NYSE Options Open-Close Volume Summary is the Exchange's response to the many competing products available in the marketplace today. The Exchange believes the proposed rule change would contribute to the robust competition among national securities exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and Rule 19b–4(f)(6) thereunder.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2021–46 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2021–46. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2021–46 and should be submitted on or before January 12, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–27663 Filed 12–21–21; 8:45 am]

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[10] *See supra* note 4.

[11] 15 U.S.C. 78f(b)(8).

[12] *See supra* note 4.

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93800; File No. SR–IEX–2021–17]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Reintroduce a Market Maker Peg Order Type

December 16, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on December 14, 2021, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Act,[4] and Rule 19b–4 thereunder,[5] the Exchange is filing with the Commission a proposed rule change to reintroduce a new Market Maker Peg order type, designed to simplify market maker compliance with IEX Rule 11.151 (Market Maker Obligations), and make a conforming change regarding connectivity within the Exchange System.

The text of the proposed rule change is available at the Exchange's website at *www.iextrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statement [sic] may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78s(b)(1).

[5] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

IEX is filing this rule change proposal to reintroduce a Market Maker Peg order type. IEX previously had a Market Maker Peg order type,[6] which it retired in 2020 [7] because at the time there were no Exchange-registered market makers.[8] As described below, IEX's proposed new order type is almost identical to its original, Commission-approved, market maker peg order type, with the exception that the new Market Maker Peg order will have tighter quoting spreads than are required by IEX Rule 11.151.

Background

IEX Rule 11.151 (Market Maker Obligations) requires market makers for each stock in which they are registered to continuously maintain a two-sided quotation within a designated percentage of the National Best Bid (''NBB'') and National Best Offer (''NBO''),[9] as appropriate. In addition to the market maker quoting and pricing obligations set forth in the Exchange's rules, market makers must meet their obligations under Rule 15c3–5 under the Act (the ''Market Access Rule'') [10] and Regulation SHO.[11]

The Market Access Rule requires a broker-dealer with market access, or that provides a customer or any other person with access to an exchange or alternative trading system through use of its market participant identifier or otherwise, to establish, document, and maintain a system of risk management controls and supervisory procedures reasonably designed to manage the financial, regulatory, and other risks of this business activity. These controls must be reasonably designed to ensure compliance with all regulatory requirements, which are defined as ''all federal securities laws, rules and regulations, and rules of self-regulatory organizations, that are applicable in connection with market access.'' [12]

In addition to the obligations of the Market Access Rule, broker-dealers have independent obligations that arise under Regulation SHO. Regulation SHO obligations generally include properly marking sell orders, obtaining a ''locate'' for short sale orders, closing out fail to deliver positions, and, where applicable, complying with the short sale price test.[13] While there are certain exceptions to some of the requirements of Regulation SHO where a market maker is engaged in bona-fide market making activities,[14] the availability of those exceptions is distinct and independent from whether a market maker submits an order that is a Market Maker Peg order.

Proposed Rule

The Exchange is proposing to reintroduce an optional Market Maker Peg order type, which will be identical to the previously approved order type, with the exception of the tighter quoting obligations discussed below. The Market Maker Peg order type is designed to simplify market maker compliance with the continuous quoting and pricing obligations in IEX Rule 11.151(a) in a manner consistent with compliance with the Market Access Rule and Regulation SHO. The Market Maker Peg order, as proposed, is not only almost identical to IEX's previously approved Market Maker Peg order type,[15] it is also substantially similar to equivalent order types offered by other market centers, including Cboe

[6] *See* Securities Exchange Act Release No. 81482 (August 25, 2017), 82 FR 41452 (August 31, 2017) (SR–IEX–2017–22) (Approval Order).

[7] *See* Securities Exchange Act Release No. 89146 (June 24, 2020), 85 FR 39251 (June 24, 2020) (SR–IEX–2020–07).

[8] *See generally* IEX Rules 11.150 and 11.151.

[9] As defined by Regulation NMS Rule 600(b)(50). 17 CFR 242.600(50); *see also* IEX Rule 1.160(u).

[10] 17 CFR 240.15c3–5.

[11] 17 CFR 242.200 through 204.

[12] *See supra* note 10.

[13] *See supra* note 11.

[14] *See* 17 CFR 242.203(b)(1). The Commission adopted a narrow exception to Regulation SHO's ''locate'' requirement for market makers engaged in bona fide market making that may need to facilitate customer orders in a fast-moving market without being subject to the possible delays associated with complying with such requirement. *See* Exchange Act Release No. 50103 (July 28, 2004), 69 FR 48008, 48015 (August 6, 2004) (providing guidance as to what does not constitute bona-fide market making for purposes of claiming the exception to Regulation SHO's ''locate'' requirement). *See also* Exchange Act Release No. 58775 (October 14, 2008), 73 FR 61690, 61698–9 (October 17, 2008) (providing guidance regarding what is bona-fide market making for purposes of complying with the market maker exception to Regulation SHO's ''locate'' requirement including without limitation whether the market maker incurs any economic or market risk with respect to the securities, continuous quotations that are at or near the market on both sides and that are communicated and represented in a way that makes them widely accessible to investors and other broker-dealers and a pattern of trading that includes both purchases and sales in roughly comparable amounts to provide liquidity to customers or other broker-dealers). Thus, market makers would not be able to rely solely on quotations priced in accordance with the Designated Percentages under proposed Rule 11.190(b)(17) for eligibility for the bona-fide market making exception to the ''locate'' requirement based on the criteria set forth by the Commission. It should also be noted that a determination of bona-fide market making is relevant for the purposes of a broker-dealer's close-out obligations under Rule 204 of Regulation SHO. *See* 17 CFR 242.204(a)(3).

[15] *See supra* note 6.

BZX Exchange, Inc. (''Cboe BZX''), Nasdaq Stock Market LLC (''Nasdaq''), and Cboe EDGX Exchange, Inc. (''Cboe EDGX'').[16] Specifically, the Market Maker Peg order would be a one-sided limit order and, similar to other peg orders available to IEX Members,[17] priced in reference to or ''pegged'' to the NBB or NBO,[18] but is distinguishable in that like all other exchange market maker peg orders, it would always be displayed. In addition, a new timestamp is created for the order each time that it is automatically adjusted in accordance with the proposed rule. And Market Maker Peg orders may only be entered by a registered market maker, as defined in IEX Rule 11.150.

The Exchange believes that this order-based approach would provide an effective compliance tool to facilitate market makers' compliance with IEX Rule 11.151(a), while also enabling compliance with the requirements of the Market Access Rule and Regulation SHO. Specifically, market makers would have control of order origination, as required by the Market Access Rule, while also allowing market makers to make marking and locate determinations prior to order entry, as required by Regulation SHO. As such, market makers using Market Maker Peg orders would be able to comply with the requirements of the Market Access Rule and Regulation SHO, as they would when placing any order, while also facilitating compliance with their Exchange market making obligations. In this regard, the Market Maker Peg order does not ensure that the market maker is satisfying the requirements of the Market Access Rule, such as maintaining a system of risk management and supervisory controls reasonably designed to manage the risk of its market access business activity,[19] or of Regulation SHO, including the satisfaction of the locate requirements of Regulation SHO Rule 203(b)(1) or an exception thereto.[20] Market makers must continue to perform the necessary checks to comply with both the Market Access Rule and Regulation SHO, prior to entry of a Market Maker Peg order.

The Market Maker Peg order would be limited to registered market makers[21] and would have its price automatically set and adjusted by the System[22], both upon entry and any time thereafter, in order to comply with the Exchange's rules regarding market maker quoting and pricing obligations.[23] Specifically, upon entry or at the beginning of the Regular Market Session, as applicable, the entered bid or offer is automatically priced by the System at the Market Maker Peg Designated Percentage away from the then current NBB or NBO, as applicable, or if there is no NBB or NBO, at the Market Maker Peg Designated Percentage away from the last reported sale from the responsible single plan processor. Proposed IEX Rule 11.190(b)(17)(A) defines the ''Market Maker Peg Designated Percentage'' as eight (8) percentage points for all securities, except that between 9:30 a.m. and 9:45 a.m. and between 3:35 p.m. and the close of trading, the Market Maker Peg Designated Percentage shall be twenty (20) percentage points. For example, if the NBB of a security is $10 and the Market Maker Peg Designated Percentage for the security is 8%, the displayed price of a Market Marker Peg Order to buy would be $9.20. Market makers may submit Market Maker Peg orders to the Exchange starting at the beginning of the Pre-Market Session, but the order will not be executable or automatically priced until the beginning of the Regular Market Session and will expire at the end of the Regular Market Session.

IEX also proposes to define, in proposed IEX Rule 11.190(b)(17)(B), a new term, ''Market Maker Peg Defined Limit'', as nine and one half (9.5) percentage points for all securities, except that between 9:30 a.m. and 9:45 a.m. and between 3:35 p.m. and the close of trading, the Market Maker Peg Defined Limit shall be twenty-one and one half (21.5) percentage points.

Upon reaching the Market Maker Peg Defined Limit, the price of a Market Maker Peg order bid or offer will be adjusted by the System to the Market Maker Peg Designated Percentage away from the then current NBB or NBO, or, if there is no NBB or NBO, the order will, by default, be the Market Maker Peg Designated Percentage away from the last reported sale from the responsible single plan processor. In the foregoing example, if the Market Maker Peg Defined Limit is 9.5% and the NBB increased to $10.17, such that the displayed price of the Market Maker Peg order would be more than 9.5% away, the order would be repriced to $9.36, or 8% away from the NBB.

If a Market Maker Peg order bid or offer moves a specified number of percentage points away from the Market Maker Peg Designated Percentage towards the then current NBB or NBO, which number of percentage points will be determined and published in a circular distributed to Members from time to time, the price of such bid or offer will be adjusted by the System to the Market Maker Peg Designated Percentage away from the then current NBB or NBO, as applicable. If there is no NBB or NBO, as applicable, the order will be adjusted by the System to the Market Maker Peg Designated Percentage away from the last reported sale from the responsible single plan processor. In the event that pricing a Market Maker Peg order at the Market Maker Peg Designated Percentage away from the then current NBB and NBO, or, if no NBB or NBO, to the Market Maker Peg Designated Percentage away from the last reported sale from the responsible single plan processor, would result in the order exceeding its limit price, the order will be cancelled or rejected.

If, after entry, the Market Maker Peg order is priced based on the last reported sale from the single plan processor and such Market Maker Peg order is established as the NBB or NBO, the Market Maker Peg order will not be subsequently adjusted in accordance with this rule until either there is a new consolidated last sale, or a new NBB or NBO is established by a national securities exchange.

As noted above, this proposed reintroduction of the IEX Market Maker Peg order type is identical to the Market Maker Peg order type previously approved by the Commission, with the exception of the tighter quoting spreads that result from using the ''Market Maker Peg Designated Percentage'' and ''Market Maker Peg Defined Limit'' instead of the ''Designated Percentage''[24] and ''Defined Limit''[25] set forth in IEX's Market Maker Obligations rule. Specifically, the Market Maker Obligations rule sets the Designated Percentage at 28% below/above the NBB/NBO, and 30% below/above the NBB/NBO at the market open and close for stocks not included in the S&P 500® Index, Russell 1000® Index, and a pilot list of Exchange Traded Products. And the Market Maker Obligations rule sets the Defined Limit for those same stocks to be 29.5% below/above the NBB/NBO, and 31.5% below/above the NBB/NBO at the market open and close. For stocks that

[16] *See e.g.*, Cboe BZX Rule 11.9(c)(15), Nasdaq Rule 4702(b)(7), and Cboe EDGX Rule 11.8(e).

[17] *See* IEX Rule 1.160(s).

[18] *See* IEX Rule 11.190(a)(3).

[19] *See supra* note 10.

[20] 17 CFR 242.203(b)(1).

[21] *See* IEX Rule 11.150.

[22] *See* IEX Rule 1.160(nn).

[23] The Market Maker Peg order is one-sided, and thus a market maker seeking to use Market Maker Peg orders to comply with the Exchange's continuous two-sided quotation requirements would need to submit both a bid and an offer using the order type.

[24] *See* IEX Rule 11.151(a)(6).

[25] *See* IEX Rule 11.151(a)(7).

are included in the S&P 500® Index, Russell 1000® Index, and a pilot list of Exchange Traded Products; the Designated Percentage and Defined Limit would be the same as the Market Maker Peg Designated Percentage and Market Maker Peg Defined Limit, respectively. Thus, as proposed, market makers using the optional IEX Market Maker Peg order type will quote at narrower spreads than required by IEX Rule 11.151 for stocks not included in the S&P 500® Index, Russell 1000® Index, and a pilot list of Exchange Traded Products.

IEX proposes to incorporate a tighter quoting structure for the Market Maker Peg order type in order to simplify technical complexities in the design of the order type associated with treating all stocks equally. Moreover, IEX believes that tighter displayed quoting spreads could help to increase access to displayed liquidity being posted by IEX market makers.

The Exchange notes that notwithstanding the availability of the proposed Market Maker Peg order functionality, a market maker remains responsible for entering, monitoring, and resubmitting, as applicable, quotations that meet the requirements of IEX Rule 11.151. Furthermore, a market maker would not be required to use the Market Maker Peg order type and can instead submit its own quotes to satisfy its quoting and pricing obligations for any securities for which it is a registered market maker.[26]

Market Maker Peg orders, like all incoming orders, will be subject to 350 microseconds of inbound latency [27] from the IEX point-of-presence (''POP'') before reaching the System.[28] Each time a Market Maker Peg order is automatically adjusted by the System in accordance with this proposed rule change (in response to a change in the NBB or NBO), the modified order instruction will be subject to 350 microseconds of latency between the Market Maker Peg order repricing logic (*i.e.,* the process by which the System determines that the price of the Market Maker Peg order should be adjusted) and the Order Book [29] (to be equivalent to the 350 microseconds of inbound latency for all incoming orders) and all outbound communications to the market maker related to the modified order instruction will be subject to 37 microseconds of latency between the Market Maker Peg order repricing logic and the POP (to be equivalent to the 37 microseconds of outbound latency that a market maker would have to wait for order entry confirmation), pursuant to IEX Rule 11.510(c)(1).[30] In addition, a new timestamp is created for the order each time that it is automatically adjusted by the System in accordance with the proposed rule. This approach is designed so that a market maker using a Market Maker Peg order to facilitate compliance with the Exchange's continuous quoting and pricing obligations is in the same position as a market maker updating its own quote, whose orders and order modification instructions would be subjected to a 350-microsecond inbound latency and 37-microsecond outbound latency.

The Exchange also proposes to make a conforming change to IEX Rule 11.510(c)(1) regarding connectivity, to provide that, pursuant to IEX Rule 11.190(b)(17), each time a Market Maker Peg order is automatically adjusted by the System, all inbound communications related to the modified order instruction will be subject to a 350-microsecond latency and all outbound communications related to the modified order instruction will be subject to a 37-microsecond latency between the Market Maker Peg order repricing logic and the Order Book.

The Exchange plans to implement the proposed changes in December 2021 or January 2022, subject to the effectiveness of filing with the Commission. The Exchange will announce the implementation date of the proposed changes by Trader Alert at least 10 business days in advance of such implementation date and within 90 days of the effectiveness of this proposed rule change.

2. Statutory Basis

IEX believes that the proposed rule change is consistent with Section 6(b) of the Act in general, [31] and furthers the objectives of Section 6(b)(5) of the Act,[32] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. As noted above, the Exchange believes that the proposed rule is designed to simplify market maker compliance with the minimum continuous quoting and pricing obligations, as well as facilitate market maker compliance with the requirements of the Market Access Rule and Regulation SHO.

Specifically, the Exchange believes that simplifying compliance with this rule will remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest, because it will provide a simplified means by which market makers may offer liquidity, using a tighter quoting spread than the market maker obligations require, even in circumstances where they are not willing to quote at the inside market. As a result, in circumstances where liquidity available at displayed prices closer to the inside than the price of a Market Maker Peg order is exhausted during an aggressive market-wide sweep, the Market Maker Peg order may nevertheless be available to support executions at prices that are at least within the applicable Market Maker Peg Designated Percentage or Market Maker Peg Defined Limit. Moreover, the methodology for repricing Market Maker Peg orders is consistent with the requirements of the Act because it is designed to ensure that the displayed price of the order is at least within the applicable Market Maker Peg Designated Percentage or Market Maker Peg Defined Limit, as applicable.

The proposed rule change also is designed to support the principles of Section 11A(a)(1) of the Act [33] in that it seeks to assure fair competition among brokers and dealers and among exchange markets. The Exchange believes that offering the Market Maker Peg order to market makers exclusively is consistent with fair competition among brokers and dealers in that market makers have chosen to subject themselves to the obligations of IEX Rule 11.151, and the benefit conferred on such market participants by this order type is commensurate with such obligations. Furthermore, all Members are eligible to apply for registration as a market maker under Rule 11.150 on a fair and equal basis.

The Exchange also believes that it is fair and reasonable for all inbound communications related to the repricing of a Market Maker Peg order to be subject to 350 microseconds of latency and for all outbound communications related to the repricing of a Market Maker Peg order to be subject to 37 microseconds of latency, each between the Market Maker Peg repricing logic and the Order Book. As noted in the

[26] *See* IEX Rule 11.151(a)(1).

[27] *See* IEX Rule 11.510(b)(1).

[28] *See* IEX Rule 11.510(a).

[29] *See* IEX Rule 1.160(p).

[30] *See* proposed edits to IEX Rule 11.510(c)(1).

[31] 15 U.S.C. 78f.

[32] 15 U.S.C. 78f(b)(5).

[33] 15 U.S.C. 78k–1.

Purpose section, this approach is designed so that a market maker using a Market Maker Peg order to facilitate compliance with the Exchange's continuous quoting and pricing obligations is in the same position as a market maker updating its own quote, whose order instructions would be subject to 350 microseconds of inbound latency and 37 microseconds of outbound latency. Similarly, price adjustments to Market Maker Peg orders will experience the same latency as other displayed limit orders entered on the Exchange.

Accordingly, the Exchange believes that it is consistent with the public interest and the protection of investors to reprice Market Maker Peg orders subject to a 350-microsecond latency for all inbound communications related to the modified order instruction and a 37-microsecond latency for all outbound communications related to the modified order instruction in the interest of ensuring that market makers using the Market Maker Peg order type will not have any unfair advantage over market makers that update their own quotes, as well as with other market participants using displayed orders.

Furthermore, the Exchange believes that it is consistent with the public interest and the protection of investors to apply a new timestamp to a Market Maker Peg order each time it is repriced so that a Market Maker Peg order does not achieve execution priority superior to a displayed order entered at that price earlier in time. Accordingly, market makers will not have any unfair advantage over a market maker updating its own quote, or other market participants using displayed orders on the Exchange.

Additionally, the Exchange believes that the proposed conforming rule change to IEX Rule 11.510(c)(1) is consistent with the protection of investors and the public interest in that it is designed to provide clarity to market participants regarding Market Maker Peg order repricing methodology.

Finally, IEX notes that the Commission previously approved an almost identical market maker peg order type.[34] As described in the Purpose section, the one difference between this proposed Market Maker Peg order type and IEX's previous market maker peg order type is that this order type will apply the same Market Maker Peg Designated Percentage and Market Maker Peg Defined Limit to all stocks, irrespective of if they are included in the S&P 500® Index, Russell 1000® Index, and a pilot list of Exchange Traded Products. IEX believes this modification is consistent with the protection of investors and helps perfect the mechanism of a free and open market because this proposal will result in Market Maker Peg orders resting on the Order Book quoting at the tighter limit that is only required for certain securities. IEX believes these tighter quote spreads would be of particular benefit to investors during times of high market volatility by making it more likely that a security will avoid so-called ''stub quotes'' that are so far away from the NBB or NBO that the quote is unlikely to be executed. Additionally, IEX notes that the proposed application of the tighter quote spreads to all Market Maker Peg orders will simplify the technical complexities in the design and functioning of the order type. Furthermore, IEX notes that the proposed Market Maker Peg order is an optional order type that may be used by any registered market maker to facilitate its compliance with their obligations but that market makers are free to manage their own quotes subject to the applicable quoting and pricing requirements of IEX Rule 11.151.

B. Self-Regulatory Organization's Statement on Burden on Competition

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes that the proposal will enhance the Exchange's competitiveness by providing market makers on IEX with a tool designed to facilitate quoting and offering liquidity even in circumstances where they are not willing to quote at the inside market. Based on informal discussion with market participants that serve as market makers on other trading centers, the Exchange believes that this functionality will be appealing to potential market makers, and therefore will make it more likely that market participants will choose to become registered market makers on the Exchange. This may, in turn, increase the extent of liquidity available on IEX and increase its ability to compete with other execution venues to attract orders that are seeking liquidity. The Exchange further notes that the Market Maker Peg order, as proposed, is substantially similar to equivalent order types offered by other market centers, including Cboe BZX, Nasdaq, and Cboe EDGX, and therefore will not impair market participants or other market centers from competing, but would in fact allow the Exchange to compete with existing functionality offered by competing market centers.[35] Moreover, there is no barrier to other exchanges adopting the same repricing functionality subject to the Commission rule filing process pursuant to Section 19(b) of the Act.

With regard to intra-market competition, the Exchange does not believe that the method of repricing Market Maker Peg orders will result in any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, as described in the Statutory Basis section, the proposed Market Maker Peg order type is an optional order type that would be available to IEX market makers that is designed so that market makers using Market Maker Peg orders will not be subject to any competitive advantage compared to market makers updating their own quotes, or other market participants using displayed orders. Furthermore, as discussed in the Statutory Basis section, the Exchange believes that offering the Market Maker Peg order to market makers exclusively is consistent with fair competition among brokers and dealers in that market makers have chosen to subject themselves to the obligations of IEX Rule 11.151, and the benefit conferred on such market participants by this order type is commensurate with the obligations. Furthermore, all Members are eligible to apply for registration as a market maker under IEX Rule 11.150 on a fair and equal basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[36] and Rule 19b–4(f)(6) thereunder.[37]

[34] *See supra* note 6.

[35] *See supra* note 16.

[36] 15 U.S.C. 78s(b)(3)(A).

[37] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing

Continued

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[38] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[39] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. The proposed rule change provides for the reintroduction of a Market Maker Peg Order type on the Exchange. The Exchange believes that waiver of the operative delay is consistent with the protection of investors and the public interest because IEX is restoring an order type previously available on IEX, which is substantially similar to order types offered on several other exchanges (discussed above), with the only difference being that this version of the Market Maker Peg order will apply the tighter market maker quoting requirement to all securities and will not apply wider limits for stocks in the Russell 1000® Index and a pilot list of Exchange Traded Products. IEX believes that allowing market makers to begin using the Market Maker Peg order type immediately upon effectiveness of this rule change will potentially increase liquidity on IEX to the benefit all investors, which will serve the public interest. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed rule change does not raise any novel issues, adopts the narrower limits for all securities and thus will result in prices closer to the NBB or NBO (as applicable) compared to the prior version of this order type, and may help increase displayed liquidity on IEX during periods of volatility. Therefore, the Commission hereby waives the operative delay and designates the proposal as operative upon filing.[40]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purpose of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[41] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–IEX–2021–17 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–IEX–2021–17. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the IEX's principal office and on its internet website at *www.iextrading.com.* All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–IEX–2021–17 and should be submitted on or before January 12, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[42]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–27660 Filed 12–21–21; 8:45 am]

BILLING CODE 8011–01–P

of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[38] 17 CFR 240.19b–4(f)(6).

[39] 17 CFR 240.19b–4(f)(6)(iii).

[40] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[41] 15 U.S.C. 78s(b)(2)(B).

[42] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93799; File No. SR–CBOE–2021–074]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Make Juneteenth National Independence Day a Holiday of the Exchange

December 16, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 6, 2021, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend its rules to make Juneteenth National Independence Day a holiday of the Exchange. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 5.1 (Trading Days and Hours) to make Juneteenth National Independence Day a holiday of the Exchange. On June 17, 2021, Juneteenth National Independence Day was designated a legal public holiday.[5] Consistent with broad industry sentiment [6] and the approach recommended by the Securities Industry and Financial Markets Association (''SIFMA''),[7] the Exchange proposes to add ''Juneteenth National Independence Day'' to the existing list of holidays set forth in Rule 5.1(d). As a result, the Exchange will not be open for business on Juneteenth National Independence Day, which falls on June 19 of each year. In accordance with Rule 5.1(d), when a holiday falls on a Saturday, the Exchange will not be open for business on the preceding Friday, and when it falls on a Sunday, the Exchange will not be open for business on the succeeding Monday.[8]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[9] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [10] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(1) of the Act,[11] which provides that the Exchange be organized and have the capacity to be able to carry out the purposes of the Act and to enforce compliance by the Exchange's Trading Permit Holders and persons associated with its Trading Permit Holders with the Act, the rules and regulations thereunder, and the rules of the Exchange.

The Exchange believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest because the proposed amended rule would clearly state that the Exchange will not be open for business on Juneteenth National Independence Day, which is a federal holiday, and would address what day would be taken off if June 19 fell on a Saturday or Sunday. The change would thereby promote clarity and transparency in the Exchange rules by updating the list of holidays of the Exchange. The proposed rule change is also based on recent proposals by other exchanges.[12] Therefore, the proposed change does not raise any new or novel issues.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[13] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather to conform to industry practice with respect to holidays.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [14] and Rule 19b–4(f)(6) [15] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [16] of the Act to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule

[5] Public Law 117–17.

[6] *See e.g., https://www.bloomberg.com/news/articles/2021-06-18/bofa-makesjuneteenth-a-holiday-joining-jpmorgan-wells-fargo?sref=Hhue1scO.*

[7] SIFMA recommends a full market close in observance of Juneteenth National Independence Day. See *https://www.sifma.org/resources/general/holidayschedule/.* See also *https://www.sifma.org/resources/news/sifma-revises-2022-fixed-income-market-close-recommendations-in-the-u-s-to-include-full-close-for-juneteenth-national-independence-day/.*

[8] *See* Cboe Exchange Rule 5.1(d). There is an exception to the practice if unusual business conditions exist.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5)

[11] 15 U.S.C. 78f(b)(1).

[12] *See e.g.,* Securities Exchange Act Release No. 93186 (September 30, 2021), 86 FR 55068 (October 5, 2021) (SR–NYSE–2021–56). *See also* Securities Exchange Act Release No. 93461 (October 28, 2021), 86 FR 60670 (November 3, 2021) (SR–MIAX–2021–55).

[13] 15 U.S.C. 78f(b)(8).

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[16] 15 U.S.C. 78s(b)(2)(B).

change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov. Please include File Number SR–CBOE–2021–074 on the subject line.*

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2021–074. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2021–074 and should be submitted on or before January 12, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–27658 Filed 12–21–21; 8:45 am]

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[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93817; File No. 4–698]

Joint Industry Plan; Notice of Withdrawal of Amendment to the National Market System Plan Governing the Consolidated Audit Trail

December 17, 2021.

I. Introduction

On March 31, 2021, the Operating Committee for Consolidated Audit Trail, LLC, on behalf of the following parties to the National Market System Plan Governing the Consolidated Audit Trail (the ''CAT NMS Plan'' or ''Plan''): [1] BOX Exchange LLC, Cboe BYX Exchange, Inc., Cboe BZX Exchange, Inc., Cboe EDGA Exchange, Inc., Cboe EDGX Exchange, Inc., Cboe C2 Exchange, Inc., Cboe Exchange, Inc., Financial Industry Regulatory Authority, Inc., Investors Exchange LLC, Long-Term Stock Exchange, Inc., Miami International Securities Exchange LLC, MEMX, LLC, MIAX Emerald, LLC, MIAX PEARL, LLC, Nasdaq BX, Inc., Nasdaq GEMX, LLC, Nasdaq ISE, LLC, Nasdaq MRX, LLC, Nasdaq PHLX LLC, The NASDAQ Stock Market LLC, New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (the ''Participants'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 11A(a)(3) of the Securities Exchange Act of 1934 (''Exchange Act''),[2] and Rule 608 thereunder,[3] a proposed amendment (''Proposed Amendment'') to the CAT NMS Plan to implement a revised funding model (''Proposed Funding Model'') for the consolidated audit trail (''CAT'') and to establish a fee schedule for Participant CAT fees in accordance with the Proposed Funding Model. The Proposed Amendment was published for comment in the **Federal Register** on April 21, 2021.[4]

On July 20, 2021, the Commission instituted proceedings pursuant to Rule 608(b)(2)(i) of Regulation NMS,[5] to determine whether to disapprove the Proposed Amendment or to approve the Proposed Amendment with any changes or subject to any conditions the Commission deems necessary or appropriate after considering public comment.[6] On October 1, 2021, the Commission designated a longer period within which to conclude proceedings regarding the Proposed Amendment.[7]

The Commission is publishing this notice to reflect that on December 8, 2021, prior to the end of the 240-day period provided for in Exchange Act Rule 608(b)(2)(i),[8] the Participants withdrew the Proposed Amendment.[9]

By the Commission.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–27749 Filed 12–21–21; 8:45 am]

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[1] The CAT NMS Plan is a national market system plan approved by the Commission pursuant to Section 11A of the Exchange Act and the rules and regulations thereunder. *See* Securities Exchange Act Release No. 79318 (November 15, 2016), 81 FR 84696 (November 23, 2016) (''CAT NMS Plan Approval Order''). The CAT NMS Plan functions as the limited liability company agreement of the jointly owned limited liability company formed under Delaware state law through which the Participants conduct the activities of the CAT (''Company''). On August 29, 2019, the Participants replaced the CAT NMS Plan in its entirety with the limited liability company agreement of a new limited liability company named Consolidated Audit Trail, LLC, which became the Company. The latest version of the CAT NMS Plan is available at *https://catnmsplan.com/about-cat/cat-nms-plan.*

[2] 15 U.S.C. 78k–1(a)(3).

[3] 17 CFR 242.608.

[4] *See* Securities Exchange Act Release No. 91555 (April 14, 2021), 86 FR 21050 (''Notice'').

[5] 17 CFR 242.608(b)(2)(i).

[6] *See* Securities Exchange Act Release No. 92451, 86 FR 40114 (July 26, 2021) (''OIP''). Comments received in response to the OIP and the Notice can be found on the Commission's website at *https://www.sec.gov/comments/4-698/4-698-a.htm.*

[7] *See* Securities Exchange Act Release No. 93227 (October 1, 2021), 86 FR 55900 (October 7, 2021).

[8] 17 CFR 242.608(b)(2)(i).

[9] *See* Letter from Michael Simon, Chair, CAT NMS Plan Operating Committee, to Vanessa Countryman, Secretary, Commission, dated December 8, 2021.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93804]

Order Granting Applications by Nasdaq BX, Inc., The Nasdaq Stock Market LLC, and Nasdaq PHLX LLC for Exemption Pursuant to Section 36(a) of the Exchange Act From the Rule Filing Requirements of Section 19(b) of the Exchange Act With Respect to the Nasdaq ISE, LLC Options 4 Options Listing Rules Incorporated by Reference

December 16, 2021.

Nasdaq BX, Inc. (''BX''), The Nasdaq Stock Market LLC (''Nasdaq''), and Nasdaq PHLX LLC (''Phlx'') (collectively the ''Exchanges'') have filed with the Securities and Exchange Commission (the ''Commission'') an application for an exemption under Section 36(a)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] from the rule filing requirements of Section 19(b) of the

[1] 15 U.S.C. 78mm(a)(1).

Exchange Act [2] with respect to certain rules of Nasdaq ISE, LLC (''ISE'') that the Exchanges seek to incorporate by reference (''ISE Options 4 Rules'').[3] Section 36(a)(1) of the Exchange Act,[4] subject to certain limitations, authorizes the Commission to conditionally or unconditionally exempt any person, security, or transaction, or any class thereof, from any provision of the Exchange Act or rule thereunder, if necessary or appropriate in the public interest and consistent with the protection of investors.

The Exchanges each filed a proposed rule change [5] under Section 19(b) of the Exchange Act to replace its Options 4 Options Listing Rules (''Options Listing Rules''), as set forth in Options 4 of their respective rulebooks, with the Options 4 Rules of the ISE rulebook, as such rules may be in effect from time to time. Namely, in the proposed rule changes, the Exchanges each proposed to incorporate by reference the ISE Options 4 Rules such that ISE Options 4 Rules would be applicable to each of the Exchanges' respective members, member organizations, Participants, Options Participants, associated persons and personnel, and other persons subject to the Exchanges' jurisdiction as though such rules were fully set forth within each of the Exchanges' rulebooks.[6]

The Exchanges have requested, pursuant to Rule 0–12 under the Exchange Act,[7] that the Commission grant the Exchanges an exemption from the rule filing requirements of Section 19(b) of the Exchange Act for changes to each of the Exchanges' rules that are effected solely by virtue of a change to the ISE Options 4 Rules that are incorporated by reference. Specifically, the Exchanges request that they be permitted to incorporate by reference changes made to the ISE Options 4 Rules that are cross-referenced in each of the Exchanges' rules without the need for each of the Exchanges to file separately the same proposed rule change pursuant to Section 19(b) of the Exchange Act.[8]

The Exchanges represent that the ISE Options 4 Rules are not trading rules.[9] Moreover, the Exchanges state that in each instance, they propose to incorporate by reference a category of rules (rather than individual rules within a category).[10] The Exchanges also represent that, as a condition of this exemption, the Exchanges will provide written notice to their respective members, member organizations, Participants, Options Participants, associated persons and personnel, whenever ISE proposes a change to ISE Options 4 Rules.[11] Additionally, the Exchange will similarly inform their members, member organizations, Participants, associated persons and personnel, in writing when the Commission approves any such proposed changes.[12]

According to the Exchanges, this exemption is necessary and appropriate because it will result in the Exchanges' Options Listing Rules being consistent with the relevant cross-referenced ISE Options Listing Rules at all times.[13] The Exchanges states that harmonization of the Options Listing Rules between the Exchanges and ISE will ensure consistent regulation of joint members of the Phlx, Nasdaq, BX and ISE and increase internal efficiencies associated with administering the options listing rules of each exchange.[14]

The Commission has issued exemptions similar to the Exchanges' request.[15] The Commission has stated that it would consider exemption requests, provided that:

- A self-regulatory organization (''SRO'') wishing to incorporate rules of another SRO by reference has submitted a written request for an order exempting it from the requirement in Section 19(b) of the Exchange Act to file proposed rule changes relating to the rules incorporated by reference, has identified the applicable originating SRO(s), together with the rules it wants to incorporate by reference, and otherwise has complied with the procedural requirements set forth in the Commission's release governing procedures for requesting exemptive orders pursuant to Rule 0–12 under the Exchange Act; [16]
- The incorporating SRO has requested incorporation of categories of rules (rather than individual rules within a category) that are not trading rules (*e.g.,* the SRO has requested incorporation of rules such as margin, suitability, or arbitration); and
- The incorporating SRO has reasonable procedures in place to provide written notice to its members each time a change is proposed to the incorporated rules of another SRO.[17]

[2] 15 U.S.C. 78s(b).

[3] *See* letter from Angela S. Dunn, Principal Associate General Counsel, Nasdaq Inc., to J. Matthew DeLesDernier, Assistant Secretary, Commission, dated September 3, 2021 (''Exemptive Request'').

[4] 15 U.S.C. 78mm(a)(1).

[5] *See* Securities Exchange Act Release Nos. 92987 (September 15, 2021), 86 FR 52511 (September 21, 2021) (SR–BX–2021–038); 93003 (September 15, 2021), 86 FR 52534 (September 21, 2021) (SR–NASDAQ–2021–070); 92990 (September 15, 2021) 86 FR 52513 (September 21, 2021) (SR–PHLX–2021–53). Although the proposed rule changes were filed pursuant to Section 19(b)(3)(A)(iii) of the Exchange Act, and thereby became effective upon filing with the Commission, the Exchanges stipulated in their proposals that the incorporation by reference would not be operative until such time as the Commission grants this Exemptive Request.

[6] *See* note 5, *supra.*

[7] 17 CFR 240.0–12.

[8] *See* Exemptive Request, *supra* note 3.

[9] *Id. at 2.*

[10] *Id.* at 2, n.7.

[11] *Id.* at 3. The Exchanges state that they will provide such notice via a posting on the same website location where the Exchanges post their own rule filings pursuant to Rule 19b–4(l) within the timeframe required by such Rule. In addition, the Exchanges state that the website posting will include a link to the location on ISE's website where the applicable proposed rule change is posted. *Id.* at 3 n.8.

[12] *See id.* at 3.

[13] *See id.* at 2.

[14] *See id.*

[15] *See* Securities Exchange Act Release No. 70050 (July 26, 2013), 78 FR 46622 (August 1, 2013) (order granting approval of Topaz Exchange, LLC as a national securities exchange and incorporating by reference listing rules of Nasdaq ISE, LLC). *See also, e.g.,* Securities Exchange Act Release Nos. 92136 (June 9, 2021), 86 FR 31772 (June 15, 2021) (order granting exemptive request from Nasdaq GEMX, LLC and Nasdaq MRX, LLC relating to rules of The Nasdaq Stock Market LLC incorporation by reference); 91202 (February 24, 2021), 86 FR 12250 (March 2, 2021) (order granting application by Nasdaq ISE, LLC for exemption pursuant to Section 36(a) of the Exchange Act from the rule filing requirements of section 19(b) of the Exchange Act with respect to the Nasdaq Rule 1000 Series incorporated by reference); 89902 (September 17, 2020), 85 FR 59843 (September 23, 2020) (order granting exemptive request from Nasdaq BX, Inc., Nasdaq GEMX, LLC, Nasdaq ISE, LLC, Nasdaq MRX, LLC, and Nasdaq PHLX LLC relating to investigatory, disciplinary, and adjudication rules of The Nasdaq Stock Market LLC incorporation by reference); 86896 (September 6, 2019), 84 FR 48186 (September 12, 2019) (order granting exemptive request from Nasdaq BX, Inc. relating to rules of The Nasdaq Stock Market LLC incorporation by reference); 80338 (March 29, 2017), 82 FR 16464 (April 4, 2017) (order granting exemptive request from MIAX PEARL, LLC relating to rules of Miami International Securities Exchange, LLC incorporated by reference); 72650 (July 22, 2014), 79 FR 44075 (July 29, 2014) (order granting exemptive requests from NASDAQ OMX BX, Inc. and the NASDAQ Stock Market LLC relating to rules of NASDAQ OMX PHLX LLC incorporated by reference); 67256 (June 26, 2012), 77 FR 39277, 39286 (July 2, 2012) (order approving SR–BX–2012–030 and granting exemptive request relating to rules incorporated by reference by the BX Options rules); 61534 (February 18, 2010), 75 FR 8760 (February 25, 2010) (order granting BATS Exchange, Inc.'s exemptive request relating to rules incorporated by reference by the BATS Exchange Options Market rules) (''BATS Options Market Order''); and 57478 (March 12, 2008), 73 FR 14521, 14539–40 (March 18, 2008) (order approving SR–NASDAQ–2007–004 and SR–NASDAQ–2007–080, and granting exemptive request relating to rules incorporated by reference by The NASDAQ Options Market).

[16] *See* 17 CFR 240.0–12 and Securities Exchange Act Release No. 39624 (February 5, 1998), 63 FR 8101 (February 18, 1998) (''Commission Procedures for Filing Applications for Orders for Exemptive Relief Pursuant to Section 36 of the Exchange Act; Final Rule'').

[17] *See* BATS Options Market Order, *supra* note 15 (citing Securities Exchange Act Release No. 49260 (February 17, 2004), 69 FR 8500 (February 24, 2004)

Continued

The Commission believes that the Exchanges have satisfied each of these conditions. Further, the Commission also believes that granting the Exchanges an exemption from the rule filing requirements under Section 19(b) of the Exchange Act will promote efficient use of the Commission's and the Exchanges' resources by avoiding duplicative rule filings based on simultaneous changes to identical rule text sought by more than one SRO.[18] The Commission therefore finds it appropriate in the public interest and consistent with the protection of investors to exempt the Exchanges from the rule filing requirements under Section 19(b) of the Exchange Act with respect to the above-described rules it incorporates by reference. This exemption is conditioned upon the Exchanges promptly providing written notice to their respective members, member organizations, Participants, *Options Participants,* associated persons and personnel whenever ISE proposes to change a rule that the Exchanges incorporate by reference and whenever the Commission approves any such proposed rule change.

Accordingly, *it is ordered*, pursuant to Section 36 of the Exchange Act,[19] that the Exchanges are exempt from the rule filing requirements of Section 19(b) of the Exchange Act solely with respect to changes to the rules identified in the Exemptive Request, provided that the Exchanges promptly provide written notice to their applicants and members whenever ISE proposes to change a rule that the Exchanges have incorporated by reference.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–27664 Filed 12–21–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34443; File No. 812–15124]

Neuberger Berman BDC LLC, et al.

December 16, 2021.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application for an order under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain business development companies (''BDCs'') and closed-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment funds and accounts.

APPLICANTS: Neuberger Berman BDC LLC (''NBBDC''); NB Private Markets Fund II (Master) LLC (''NB Private Markets II''); NB Private Markets Fund III (Master) LLC (''NB Private Markets III''); NB Crossroads Private Markets Fund IV Holdings LLC (''NB Private Markets IV''); NB Crossroads Private Markets Fund V Holdings LP (''NB Private Markets V''); NB Crossroads Private Markets Fund VI Holdings LP (''NB Private Markets VI''); NB Crossroads Private Markets Fund VII Holdings LP (''NB Private Markets VII''); NB Crossroads Private Markets Access Fund LLC (''NB Private Markets Access'' and, together with NB Private Markets II, NB Private Markets III, NB Private Markets IV, NB Private Markets V, NB Private Markets VI, and NB Private Markets VII, the ''Existing Regulated Funds''); NB Alternatives Advisers LLC (''NBAA''); Neuberger Berman Investment Advisers LLC (''NBIA''); Columbia NB Crossroads Fund II LP; Golden Road Capital Pooling L.P.; MEP Opportunities Fund Holdings LP; NB—Iowa's Public Universities LP; NB 1 PE Investment Holdings LP; NB 1911 LP; NB AGI PE Portfolio II Fund LP; NB ASGA Fund Holdings LP; NB AYAME Holdings LP; NB Blue Ensign Fund LP; NB Caspian Holdings LP; NB CPEG Fund Holdings LP; NB Credit Opportunities Co-Invest Affordable Care I LP; NB Credit Opportunities Co-Invest I LP; NB Credit Opportunities Fund II LP; NB Credit Opportunities II Cayman LP; NB Credit Opportunities II Co-Investment Fund (Cayman) LP; NB Credit Opportunities II Co-Investment (Whistler) LP; NB Crossroads 23 LC Holdings LP; NB Crossroads 23 MC Holdings LP; NB Crossroads 23 SS Holdings LP; NB Crossroads 23 VC Holdings LP; NB Crossroads 24 LC Holdings LP; NB Crossroads 24 MC Holdings LP; NB Crossroads 24 SS Holdings LP; NB Crossroads 24 VC Holdings LP; NB Crossroads XXII—MC Holdings LP; NB Crossroads XXII—VC Holdings LP; NB Crystal PE Holdings LP; NB Enhanced Income Holdings LP; NB Enstar PE Opportunities Fund, LP; NB Euro Crossroads 2018 Holdings SCSP; NB Euro Crossroads 2021 Holdings SCSP; NB Flamingo Private Debt LP; NB Flat Corner PE Holdings LP; NB Gemini Fund LP; NB Granite Private Debt LP; NB Greencastle LP; NB Initium Infrastructure (Eur) Holdings LP; NB Initium Infrastructure (USD) Holdings LP; NB Initium PE (Eur) Holdings LP; NB Initium PE (USD) Holdings LP; NB K–P Loan Partners LP; NB Oak LP; NB PA Co-Investment Fund LP; NB PD III Holdings (LO) LP; NB PD III Holdings (LS) LP; NB PD III Holdings (UO) LP; NB PD III Holdings (US) LP; NB PD IV Equity LP; NB PD IV Holdings (LO–A) LP; NB PD IV Holdings (LS–A) LP; NB PD IV Holdings (US–A) (Levered) LP; NB PD IV Holdings (US–B) (Unlevered) LP; NB PD IV Holdings (UO–A) LP; NB PEP Holdings Limited; NB Pinnacol Assurance Fund LP; NB Private Debt Fund LP; NB Private Debt II Holdings LP; NB Private Equity Credit Opportunities Holdings LP; NB Private Package LP; NB Rembrandt Holdings 2018 LP; NB Rembrandt Holdings 2020 LP; NB Rembrandt Holdings 2022 LP; NB Renaissance Partners Holdings S.A R.L.; NB RESOF Holdings LP; NB RESOF II Cayman Holdings LP; NB RESOF II Holdings LP; NB Resof SP1 LP; NB RP Co-Investment & Secondary Fund LLC; NB RPPE Partners LP; NB SBS US 3 Fund LP; NB Select Opps III MHF LP; NB Select Opps IV MHF LP; NB Select Opps V MHF LP; NB SHP Fund Holdings LP; NB Si-Apollo Sengai Fund Holdings LP; NB SOF III Holdings LP; NB SOF IV Cayman Holdings LP; NB SOF IV Holdings LP; NB SOF V Cayman Holdings LP; NB SOF V Holdings LP; NB Sonoran Fund Limited Partnership; NB Star Buyout Strategy 2020 Holdings Ltd; NB Star Buyout Strategy 2021 Holdings Ltd; NB Strategic Capital LP; NB Strategic Co-Investment Partners IV Holdings LP; NB TCC Strategic Holdings LP; NB Wildcats Fund LP; NB ZCF LP; NBAL Holdings LP; NBFOF Impact—Holdings LP; NBPD III Equity Co-Invest Holdings A LP; NB-Sompo RA Holdings LP; Neub Holdings LP; Neub Infrastructure Holdings LP; Neuberger Berman/New Jersey Custom Investment Fund III LP; NYC-Northbound Emerging Managers Program LP; NYSCRF NB Co-Investment Fund LLC; NYSCRF NB Co-Investment Fund II LLC; Olive Cayman Holdings Ltd; PECO–PD III Borrower LP; SJFED Private Equity Strategic Partnership, L.P.; SJPF Private Equity Strategic Partnership, L.P.; Soleil 2020 Cayman

(order granting exemptive request relating to rules incorporated by reference by several SROs) (''2004 Order'')).

[18] *See* BATS Options Market Order, *supra* note 15, 75 FR at 8761; *see also* 2004 Order, *supra* note 17, 69 FR at 8502.

[19] 15 U.S.C. 78mm.

[20] 17 CFR 200.30–3(a)(76).

Holdings Ltd; Sunberg PE Opportunities Fund LLC; Sunbern Alternative Opportunities Fund LLC; and Toranomon Private Equity 1, L.P.

DATES: The application was filed on April 17, 2020, and amended on September 11, 2020, January 22, 2021, August 6, 2021, and November 18, 2021.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving applicants with a copy of the request, by email. Hearing requests should be received by the Commission by 5:30 p.m. on January 10, 2022, and should be accompanied by proof of service on the applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov*.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov*. Applicants: *corey.issing@nb.com*.

FOR FURTHER INFORMATION CONTACT: Kieran G. Brown, Senior Counsel, at (202) 551–6773 or Terri G. Jordan, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Introduction

1. The applicants request an order of the Commission under sections 17(d) and 57(i) and rule 17d–1 thereunder (the ''Order'') to permit, subject to the terms and conditions set forth in the application (the ''Conditions''), a Regulated Fund [1] and one or more other Regulated Funds and/or one or more Affiliated Funds [2] to enter into Co-Investment Transactions with each other. ''Co-Investment Transaction'' means any transaction in which a Regulated Fund (or its Wholly-Owned Investment Sub) participated together with one or more Regulated Funds and/or one or more Affiliated Funds in reliance on the Order. ''Potential Co-Investment Transaction'' means any investment opportunity in which a Regulated Fund (or its Wholly-Owned Investment Sub) could not participate together with one or more other Regulated Funds and/or one or more Affiliated Funds without obtaining and relying on the Order.[3]

Applicants

2. NBBDC was organized as a Maryland limited liability company and prior to relying on the relief requested in the application will file an election to be regulated as a BDC under the Act.[4] Following the election to be regulated as a BDC, NBBDC will be a closed-end management investment company. NBBDC intends to have a Board,[5] a majority of which will be Independent Directors.[6] The Board will approve NBAA to serve as investment adviser to NBBDC prior to the commencement of NBBDC's operations and the reliance by NBBDC on the relief requested in the application.

3. NB Private Markets II was organized as a Delaware limited liability company and is a closed-end management investment company registered under the Act. The Board of NB Private Markets II has six members, each of whom is an Independent Director.

4. NB Private Markets III was organized as a Delaware limited liability company and is a closed-end management investment company registered under the Act. The Board of NB Private Markets III has six members, each of whom is an Independent Director.

5. NB Private Markets IV was organized as a Delaware limited liability company and is a closed-end management investment company registered under the Act. The Board of NB Private Markets IV has six members, each of whom is an Independent Director.

6. NB Private Markets V was organized as a Delaware limited partnership and is a closed-end management investment company registered under the Act. The Board of NB Private Markets V has six members, each of whom is an Independent Director.

7. NB Private Markets VI was organized as a Delaware limited partnership and is a closed-end management investment company registered under the Act. The Board of NB Private Markets VI has six members, each of whom is an Independent Director.

[1] ''Regulated Funds'' means NBBDC, any Existing Regulated Fund and any Future Regulated Fund. ''Future Regulated Fund'' means a closed-end management investment company formed in the future (a) that is registered under the Act or has elected to be regulated as a BDC, (b) whose investment adviser (and sub-adviser, if any) is an Adviser, and (c) that intends to participate in the Co-investment Program. ''Adviser'' means NBAA and NBIA, together with any future investment adviser that (i) controls, is controlled by or is under common control with NBAA or NBIA, as applicable, (ii) is registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''), and (iii) is not a Regulated Fund or a subsidiary of a Regulated Fund.

[2] ''Affiliated Fund'' means the Existing Affiliated Funds (identified in Appendix A to the application), the Existing NB Proprietary Accounts (as defined below), any Future NB Proprietary Account, and any entity formed in the future (a) whose investment adviser (and sub-adviser, if any) is an Adviser, (b) that either (i) would be an investment company but for section 3(c)(1), 3(c)(5)(C) or 3(c)(7) of the Act or (ii) relies on rule 3a–7 under the Act, and (c) that intends to participate in the Co-Investment Program. ''Future NB Proprietary Account'' means any direct or indirect, wholly- or majority-owned subsidiary of NBAA, or any other Adviser, formed in the future that, from time to time, may hold various financial assets in a principal capacity. Affiliated Funds may include funds that are ultimately structured as collateralized loan obligation funds (''CLOs''). Such CLOs would be investment companies but for the exception provided in section 3(c)(7) of the Act or their ability to rely on rule 3a–7 of the Act. During the investment period of a CLO, the CLO may engage in certain transactions customary in CLO formations with another Affiliated Fund on a secondary basis at fair market value. For purposes of the Order, any securities that were acquired by an Affiliated Fund in a particular Co-Investment Transaction (as defined below) that are then transferred in such customary transactions to an Affiliated Fund that is or will become a CLO (an ''Affiliated Fund CLO'') will be treated as if the Affiliated Fund CLO acquired such securities in the Co-Investment Transaction. For the avoidance of doubt, any such transfer from an Affiliated Fund to an Affiliated Fund CLO will be treated as a Disposition and completed pursuant to terms and conditions of the Application, though Applicants note that the Regulated Funds would be prohibited from participating in such Disposition by Section 17(a)(2) or Section 57(a)(2) of the Act, as applicable. The participation by any Affiliated Fund CLO in any such Co-Investment Transaction will remain subject to the Order.

[3] All existing entities that currently intend to rely on the Order have been named as applicants and any existing or future entities that may rely on the Order in the future will comply with the terms and Conditions set forth in the application.

[4] Section 2(a)(48) defines a BDC to be any closed-end investment company that operates for the purpose of making investments in securities described in section 55(a)(1) through 55(a)(3) and makes available significant managerial assistance with respect to the issuers of such securities.

[5] ''Board'' means with respect to a Regulated Fund, the board of directors (or the equivalent) of the Regulated Fund.

[6] ''Independent Director'' means a member of the Board of any relevant entity who is not an ''interested person'' as defined in section 2(a)(19) of the Act. No Independent Director of a Regulated Fund will have a financial interest in any Co-Investment Transaction, other than indirectly through share ownership in one of the Regulated Funds.

8. NB Private Markets VII was organized as a Delaware limited partnership and is a closed-end management investment company registered under the Act. The Board of NB Private Markets VII has six members, each of whom is an Independent Director.

9. NB Private Markets Access was organized as a Delaware limited liability company and is a closed-end management investment company registered under the Act. The Board of NB Private Markets Access has six members, each of whom is an Independent Director.

10. NBAA, a Delaware limited liability company that is registered under the Advisers Act: (i) Is investment adviser to the Existing Affiliated Funds; (ii) will serve as investment adviser to NBBDC at the time NBBDC relies on the order requested in the application; and (iii) is sub-investment adviser to the Existing Regulated Funds. NBIA, a Delaware limited liability company that is registered as an investment adviser under the Advisers Act, serves as investment adviser to the Existing Regulated Funds and may serve as investment adviser to Future Regulated Funds. NBAA, and its direct and indirect wholly-owned subsidiaries, from time to time may hold various financial assets in a principal capacity (the ''Existing NB Proprietary Accounts'' and together with any Future NB Proprietary Account, the ''NB Proprietary Accounts'').

11. The Existing Affiliated Funds are the investment funds identified in Appendix A to the application. Applicants represent that each Existing Affiliated Fund is a separate and distinct legal entity and each would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act.

12. Each of the applicants may be deemed to be controlled by Neuberger Berman Group LLC (''NBG''). NBG owns controlling interests in the Advisers and, thus, may be deemed to control the Regulated Funds and the Affiliated Funds. Applicants state that NBG does not currently offer investment advisory services to any person and is not expected to do so in the future. Applicants state that as a result, NBG has not been included as an applicant. NBG's voting equity is owned by NBSH Acquisition, LLC (''NBSH''). NBSH is owned by current and former NBG employees, directors, consultants and, in certain instances, their permitted transferees.

13. Applicants state that a Regulated Fund may, from time to time, form one or more Wholly-Owned Investment Subs.[7] Such a subsidiary may be prohibited from investing in a Co-Investment Transaction with a Regulated Fund (other than its parent) or any Affiliated Fund because it would be a company controlled by its parent Regulated Fund for purposes of section 57(a)(4) and rule 17d–1. Applicants request that each Wholly-Owned Investment Sub be permitted to participate in Co-Investment Transactions in lieu of the Regulated Fund that owns it and that the Wholly-Owned Investment Sub's participation in any such transaction be treated, for purposes of the Order, as though the parent Regulated Fund were participating directly. Applicants represent that this treatment is justified because a Wholly-Owned Investment Sub would have no purpose other than serving as a holding vehicle for the Regulated Fund's investments and, therefore, no conflicts of interest could arise between the parent Regulated Fund and the Wholly-Owned Investment Sub. The Board of the parent Regulated Fund would make all relevant determinations under the Conditions with regard to a Wholly-Owned Investment Sub's participation in a Co-Investment Transaction, and the Board would be informed of, and take into consideration, any proposed use of a Wholly-Owned Investment Sub in the Regulated Fund's place. If the parent Regulated Fund proposes to participate in the same Co-Investment Transaction with any of its Wholly-Owned Investment Subs, the Board of the parent Regulated Fund will also be informed of, and take into consideration, the relative participation of the Regulated Fund and the Wholly-Owned Investment Sub.

Applicants' Representations

A. Allocation Process

14. Applicants state that NBAA maintains relationships with more than 540 private equity firms across a diverse range of geographies, enterprise value sizes, industries and transaction types, and this broad coverage of the private equity space generates a significant volume of investment opportunities. Applicants state that, as a result, the Advisers must determine how to allocate those opportunities in a manner that is, over time, fair and equitable to all of their clients. Such investment opportunities may be Potential Co-Investment Transactions.

15. Applicants represent that the Advisers have established, and any future Advisers will establish, processes for allocating initial investment opportunities, opportunities for subsequent investments in an issuer and dispositions of securities holdings reasonably designed to treat all clients fairly and equitably over time. Further, applicants represent that these processes will be extended and modified in a manner reasonably designed to ensure that the additional transactions permitted under the Order will both (i) be fair and equitable to the Regulated Funds and the Affiliated Funds and (ii) comply with the Conditions.

16. Specifically, applicants state that the Advisers are organized and managed such that investment committees (''Investment Committees'') responsible for evaluating investment opportunities and making investment decisions on behalf of Regulated Funds and other clients employing similar strategies are promptly notified of the opportunities. If the requested Order is granted, the Advisers will establish, maintain and implement policies and procedures reasonably designed to ensure that, when such opportunities arise, the Advisers to the relevant Regulated Funds are promptly notified and receive the same information about the opportunity as any other Advisers considering the opportunity for their clients. In particular, consistent with Condition 1, if a Potential Co-Investment Transaction falls within the then-current Objectives and Strategies[8] and any Board-Established Criteria[9] of a

[7] ''Wholly-Owned Investment Sub'' means an entity (i) that is wholly-owned by NBBDC, an Existing Regulated Fund or a Future Regulated Fund (with such Regulated Fund at all times holding, beneficially and of record, 100% of the voting and economic interests); (ii) whose sole business purpose is to hold one or more investments on behalf of such Regulated Fund; (iii) with respect to which such Regulated Fund's Board has the sole authority to make all determinations with respect to the entity's participation under the Conditions; and (iv) that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act.

[8] ''Objectives and Strategies'' means with respect to any Regulated Fund, its investment objectives and strategies, as described in its most current registration statement on Form N–2, other current filings with the Commission under the Securities Act of 1933 (the ''Securities Act'') or under the Securities Exchange Act of 1934, as amended, and its most current report to stockholders.

[9] ''Board-Established Criteria'' means criteria that the Board of a Regulated Fund may establish from time to time to describe the characteristics of Potential Co-Investment Transactions regarding which the Adviser to the Regulated Fund should be notified under Condition 1. The Board-Established Criteria will be consistent with the Regulated Fund's Objectives and Strategies. If no Board-Established Criteria are in effect, then the Regulated Fund's Adviser will be notified of all Potential Co-Investment Transactions that fall within the Regulated Fund's then-current Objectives and Strategies. Board-Established Criteria will be objective and testable, meaning that they will be based on observable information, such as industry/sector of the issuer, minimum EBITDA of the issuer,

Regulated Fund, the policies and procedures will require that the Adviser to such Regulated Fund receives sufficient information to allow such Adviser's Investment Committee to make its independent determination and recommendations under the Conditions.

17. The Adviser to each applicable Regulated Fund will then make an independent determination of the appropriateness of the investment for the Regulated Fund in light of the Regulated Fund's then-current circumstances. If the Adviser to a Regulated Fund deems the Regulated Fund's participation in such Potential Co-Investment Transaction to be appropriate, then it will formulate a recommendation regarding the proposed order amount for the Regulated Fund.

18. Applicants state that, for each Regulated Fund and Affiliated Fund whose Adviser recommends participating in a Potential Co-Investment Transaction, the applicable Investment Committee will approve the investment and the investment amount. Prior to the External Submission (as defined below), each proposed order or investment amount may be reviewed and adjusted, in accordance with the applicable Advisers' written allocation policies and procedures, by the Advisers' Investment Committee.[10] The order of a Regulated Fund or Affiliated Fund resulting from this process is referred to as its ''Internal Order.'' The Internal Order will be submitted for approval by the Required Majority of any participating Regulated Funds in accordance with the Conditions.[11]

19. Applicants acknowledge that some of the Affiliated Funds may not be funds advised by Advisers to Affiliated Funds [12] because they are NB Proprietary Accounts. Applicants do not believe participation by these NB Proprietary Accounts should raise issues under the Conditions because the allocation policies and procedures of the Advisers provide that investment opportunities are offered to client accounts before they are offered to NB Proprietary Accounts.

20. If the aggregate Internal Orders for a Potential Co-Investment Transaction do not exceed the size of the investment opportunity immediately prior to the submission of the orders to the underwriter, broker, dealer or issuer, as applicable (the ''External Submission''), then each Internal Order will be fulfilled as placed and to the extent there is excess amount available to invest, the NB Proprietary Accounts will be permitted to invest. If, on the other hand, the aggregate Internal Orders for a Potential Co-Investment Transaction exceed the size of the investment opportunity immediately prior to the External Submission, then the allocation of the opportunity will be made pro rata on the basis of the size of the Internal Orders and the NB Proprietary Accounts will not be permitted to invest.[13] If, subsequent to such External Submission, the size of the opportunity is increased or decreased, or if the terms of such opportunity, or the facts and circumstances applicable to the Regulated Funds' or the Affiliated Funds' consideration of the opportunity, change, the participants will be permitted to submit revised Internal Orders in accordance with written allocation policies and procedures that the Advisers will establish, implement and maintain.[14]

B. Follow-On Investments

21. Applicants state that from time to time the Regulated Funds and Affiliated Funds may have opportunities to make Follow-On Investments [15] in an issuer in which a Regulated Fund and one or more other Regulated Funds and/or Affiliated Funds previously have invested.

22. Applicants propose that Follow-On Investments would be divided into two categories depending on whether the prior investment was a Co-Investment Transaction or a Pre-Boarding Investment.[16] If the Regulated Funds and Affiliated Funds had previously participated in a Co-Investment Transaction with respect to the issuer, then the terms and approval of the Follow-On Investment would be subject to the Standard Review Follow-Ons described in Condition 8. If the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer but hold a Pre-Boarding Investment, then the terms and approval of the Follow-On Investment would be subject to the Enhanced-Review Follow-Ons described in Condition 9. All Enhanced Review Follow-Ons require the approval of the Required Majority. For a given issuer, the participating Regulated Funds and Affiliated Funds must comply with the requirements of Enhanced-Review Follow-Ons only for the first Co-Investment Transaction. Subsequent Co-Investment Transactions with respect to the issuer would be governed by the requirements of Standard Review Follow-Ons.

23. A Regulated Fund would be permitted to invest in a Standard Review Follow-On either with the approval of the Required Majority under Condition 8(c) or without obtaining the prior approval of the Required Majority if the Standard Review Follow-On is (i) a Pro Rata Follow-On Investment [17] and

asset class of the investment opportunity or required commitment size, and not on characteristics that involve a discretionary assessment. The Adviser to the Regulated Fund may from time to time recommend criteria for the Board's consideration, but Board-Established Criteria will only become effective if approved by a majority of the Independent Directors. The Independent Directors of a Regulated Fund may at any time rescind, suspend or qualify their approval of any Board-Established Criteria, although applicants anticipate that, under normal circumstances, a Board would not modify these criteria more often than quarterly.

[10] The reason for any such adjustment to a proposed order will be documented in writing and preserved in the records of each Adviser.

[11] ''Required Majority'' means a ''required majority'' as defined in section 57(o) of the Act. In the case of a Regulated Fund that is a registered closed-end fund, the Board members that make up the Required Majority will be determined as if the Regulated Fund were a BDC subject to section 57(o).

[12] ''Advisers to Affiliated Funds'' means NBAA, NBIA and any other Adviser that, in the future, serves as investment adviser (or sub-adviser, if any) to one or more Affiliated Funds.

[13] The Advisers will maintain records of all proposed order amounts, Internal Orders and External Submissions in conjunction with Potential Co-Investment Transactions. Each applicable Adviser will provide the Eligible Directors with information concerning the Affiliated Funds' and Regulated Funds' order sizes to assist the Eligible Directors with their review of the applicable Regulated Fund's investments for compliance with the Conditions. ''Eligible Directors'' means, with respect to a Regulated Fund and a Potential Co-Investment Transaction, the members of the Regulated Fund's Board eligible to vote on that Potential Co-Investment Transaction under section 57(o) of the Act.

[14] However, if the size of the opportunity is decreased such that the aggregate of the original Internal Orders would exceed the amount of the remaining investment opportunity, then upon submitting any revised order amount to the Board of a Regulated Fund for approval, the Adviser to the Regulated Fund will also notify the Board promptly of the amount that the Regulated Fund would receive if the remaining investment opportunity were allocated pro rata on the basis of the size of the original Internal Orders. The Board of the Regulated Fund will then either approve or disapprove of the investment opportunity in accordance with Condition 2, 6, 7, 8 or 9, as applicable.

[15] ''Follow-On Investment'' means an additional investment in the same issuer, including, but not limited to, through the exercise of warrants, conversion privileges or other rights to purchase securities of the issuer.

[16] ''Pre-Boarding Investments'' are investments in an issuer held by a Regulated Fund as well as one or more other Regulated Funds and/or one or more Affiliated Funds that were acquired prior to participating in any Co-Investment Transaction in: (i) Transactions in which the only term negotiated by or on behalf of such funds was price in reliance on one of the JT No-Action Letters (defined below); or (ii) transactions occurring at least 90 days apart and without coordination between the Regulated Fund and any Affiliated Fund or other Regulated Fund.

[17] A ''Pro Rata Follow-On Investment'' is a Follow-On Investment in which (i) the participation of each Regulated Fund and each Affiliated Fund is proportionate to its outstanding investments in

Continued

meets the other requirements of Condition 8(b)(i) or (ii) a Non-Negotiated Follow-On Investment.[18] Applicants believe that these Pro Rata Follow-On Investments and Non-Negotiated Follow-On Investments do not present a significant opportunity for overreaching on the part of any Adviser and thus do not warrant the time or attention of the Board. Pro Rata Follow-On Investments and Non-Negotiated Follow-On Investments remain subject to the Board's periodic review in accordance with Condition 10.

C. Dispositions

24. Applicants propose that Dispositions[19] would be divided into two categories. If the Regulated Funds and Affiliated Funds holding investments in an issuer had previously participated in a Co-Investment Transaction with respect to the issuer, then the terms and approval of the Disposition would be subject to the Standard Review Dispositions described in Condition 6. If the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer but hold a Pre-Boarding Investment, then the terms and approval of the Disposition would be subject to the Enhanced Review Dispositions described in Condition 7. Subsequent Dispositions with respect to the same issuer would be governed by Condition 6 under the Standard Review Dispositions.[20]

25. A Regulated Fund may participate in a Standard Review Disposition either with the approval of the Required Majority under Condition 6(d) or without obtaining the prior approval of the Required Majority if (i) the Disposition is a Pro Rata Disposition[21] and meets the other requirements of Condition 6(c)(i); or (ii) the securities are Tradable Securities[22] and the Disposition meets the other requirements of Condition 6(c)(ii). Pro Rata Dispositions and Dispositions of a Tradable Security remain subject to the Board's periodic review in accordance with Condition 10.

D. Delayed Settlement

26. Applicants represent that under the terms and Conditions of the application, all Regulated Funds and Affiliated Funds participating in a Co-Investment Transaction will invest at the same time, for the same price and with the same terms, conditions, class, registration rights and any other rights, so that no such fund receives terms more favorable than any other. However, the settlement date for an Affiliated Fund in a Co-Investment Transaction may occur up to ten business days after the settlement date for the Regulated Fund, and vice versa.[23] Nevertheless, in all cases, (i) the date on which the commitment of the Regulated Funds and Affiliated Funds is made will be the same even where the settlement date is not and (ii) the earliest settlement date and the latest settlement date of any Regulated Fund and Affiliated Fund participating in the transaction will occur within ten business days of each other.

E. Holders

27. Under Condition 15, if an Adviser, its principals, or any person controlling, controlled by, or under common control with the Adviser or its principals, and the Affiliated Funds (collectively, the ''Holders'') own in the aggregate more than 25 percent of the outstanding voting shares of a Regulated Fund (the ''Shares''), then the Holders will vote such Shares in the same percentages as the Regulated Fund's other shareholders (not including the Holders).

Applicants' Legal Analysis

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit participation by a registered investment company and an affiliated person in any ''joint enterprise or other joint arrangement or profit-sharing plan,'' as defined in the rule, without prior approval by the Commission by order upon application. Section 17(d) of the Act and rule 17d–1 under the Act are applicable to Regulated Funds that are registered closed-end investment companies.

2. Similarly, with regard to BDCs, section 57(a)(4) of the Act generally prohibits certain persons specified in section 57(b) from participating in joint transactions with the BDC or a company controlled by the BDC in contravention of rules as prescribed by the Commission. Section 57(i) of the Act provides that, until the Commission prescribes rules under section 57(a)(4), the Commission's rules under section 17(d) of the Act applicable to registered closed-end investment companies will be deemed to apply to transactions subject to section 57(a)(4). Because the Commission has not adopted any rules under section 57(a)(4), rule 17d–1 also

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the issuer or security, as appropriate, immediately preceding the Follow-On Investment, and (ii), in the case of a Regulated Fund, a majority of such fund's Board has approved the Regulated Fund's participation in the pro rata Follow-On Investment as being in the best interests of the Regulated Fund. The Regulated Fund's Board may refuse to approve, or at any time rescind, suspend or qualify, its approval of Pro Rata Follow-On Investments, in which case all subsequent Follow-On Investments will be submitted to the Regulated Fund's Eligible Directors in accordance with Condition 8(c).

[18] A ''Non-Negotiated Follow-On Investment'' is a Follow-On Investment in which a Regulated Fund participates together with one or more other Regulated Funds and/or one or more Affiliated Funds (i) in which the only term negotiated by or on behalf of the funds is price and (ii) with respect to which, if the transaction were considered on its own, the funds would be entitled to rely on one of the JT No-Action Letters. ''JT No-Action Letters'' means SMC Capital, Inc., SEC No-Action Letter (pub. avail. Sept. 5, 1995) and Massachusetts Mutual Life Insurance Company, SEC No-Action Letter (pub. avail. June 7, 2000).

[19] ''Disposition'' means the sale, exchange or other disposition of an interest in a security of an issuer.

[20] However, with respect to an issuer, if a Regulated Fund's first Co-Investment Transaction is an Enhanced Review Disposition and the Regulated Fund does not dispose of its entire position in the Enhanced Review Disposition, then before such Regulated Fund may complete its first Standard Review Follow-On in such issuer, the Eligible Directors must review the proposed Follow-On Investment not only on a stand-alone basis but also in relation to the total economic exposure in such issuer (*i.e.,* in combination with the portion of the Pre-Boarding Investment not disposed of in the Enhanced Review Disposition) and the other terms of the investments. This additional review would be required because such findings would not have been required in connection with the prior Enhanced Review Disposition, but would have been required had the first Co-Investment Transaction been an Enhanced Review Follow-On.

[21] A ''Pro Rata Disposition'' is a Disposition in which (i) the participation of each Regulated Fund and each Affiliated Fund is proportionate to its outstanding investment in the security subject to Disposition immediately preceding the Disposition; and (ii) in the case of a Regulated Fund, a majority of the Board has approved the Regulated Fund's participation in pro rata Dispositions as being in the best interests of the Regulated Fund. The Regulated Fund's Board may refuse to approve, or at any time rescind, suspend or qualify, its approval of Pro Rata Dispositions, in which case all subsequent Dispositions will be submitted to the Regulated Fund's Eligible Directors.

[22] ''Tradable Security'' means a security that at the time of Disposition: (i) Trades on a national securities exchange or designated offshore securities market as defined in rule 902(b) under the Securities Act; (ii) is not subject to restrictive agreements with the issuer or other security holders; and (iii) trades with sufficient volume and liquidity (findings as to which are documented by the Advisers to any Regulated Funds holding investments in the issuer and retained for the life of the Regulated Fund) to allow each Regulated Fund to dispose of its entire position remaining after the proposed Disposition within a short period of time not exceeding 30 days at approximately the value (as defined by section 2(a)(41) of the Act) at which the Regulated Fund has valued the investment.

[23] Applicants state this may occur for two reasons. First, when the Regulated Fund or Affiliated Fund is not yet fully funded because, when the Regulated Fund or Affiliated Fund desires to make an investment, it must call capital from its investors to obtain the financing to make the investment, and in these instances, the notice requirement to call capital could be as much as ten business days. Second, where, for tax or regulatory reasons, a Regulated Fund or an Affiliated Fund does not purchase new issuances immediately upon issuance but only after a short seasoning period of up to ten business days.

applies to joint transactions with Regulated Funds that are BDCs.

3. Co-Investment Transactions are prohibited by either or both of rule 17d–1 and section 57(a)(4) without a prior exemptive order of the Commission to the extent that the Regulated Funds and Affiliated Funds participating in such transactions fall within the category of persons described by rule 17d–1 and/or section 57(b), as applicable, vis-à-vis each participating Regulated Fund. Each of the participating Regulated Funds and Affiliated Funds may be deemed to be ''affiliated persons'' vis-à-vis a Regulated Fund within the meaning of section 2(a)(3) of the Act by reason of common control because (i) the NBAA manages, and may be deemed to control, each of the Existing Affiliated Funds and any other Affiliated Fund will be managed by, and may be deemed to be controlled by, an Adviser to Affiliated Funds; (ii) at the time that NBBDC relies on the order requested in the application, NBAA will serve as investment adviser to NBBDC and may be deemed to control NBBDC; (iii) NBIA and NBAA currently serve as investment adviser and sub-adviser, respectively, to and may be deemed to control the Existing Regulated Funds, and an Adviser to Regulated Funds [24] will be the investment adviser (and sub-adviser, if any) to, and may be deemed to control, any Future Regulated Fund; and (iv) the Advisers to Regulated Funds and the Advisers to Affiliated Funds will be under common control. Thus, each of the Affiliated Funds could be deemed to be a person related to the Regulated Funds in a manner described by section 57(b) and related to the other Regulated Funds in a manner described by rule 17d–1; and therefore, the prohibitions of rule 17d–1 and section 57(a)(4) would apply respectively to prohibit the Affiliated Funds from participating in Co-Investment Transactions with the Regulated Funds. In addition, because the NB Proprietary Accounts are controlled by NBAA and, therefore, under common control with NBBDC, the Existing Regulated Funds, any future Advisers, and any Future Regulated Funds, the NB Proprietary Accounts could be deemed to be persons related to the Regulated Funds (or a company controlled by the Regulated Funds) in a manner described by section 57(b) and also prohibited from participating in the Co-Investment Program.

4. In passing upon applications under rule 17d–1, the Commission considers whether the company's participation in the joint transaction is consistent with the provisions, policies, and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of other participants.

5. Applicants state that in the absence of the requested relief, in many circumstances the Regulated Funds would be limited in their ability to participate in attractive and appropriate investment opportunities. Applicants state that, as required by rule 17d–1(b), the Conditions ensure that the terms on which Co-Investment Transactions may be made will be consistent with the participation of the Regulated Funds and on a basis that it is neither different from nor less advantageous than other participants, thus protecting the equity holders of any participant from being disadvantaged. Applicants further state that the Conditions ensure that all Co-Investment Transactions are reasonable and fair to the Regulated Funds and their stockholders and do not involve overreaching by any person concerned, including the Advisers. Applicants state that the Regulated Funds' participation in the Co-Investment Transactions in accordance with the Conditions will be consistent with the provisions, policies, and purposes of the Act and would be done in a manner such that each Regulated Fund's participation is not different from, or less advantageous than, that of the other participants.

Applicants' Conditions

Applicants agree that the Order will be subject to the following Conditions:

1. *Identification and Referral of Potential Co-Investment Transactions.*

(a) The Advisers will establish, maintain and implement policies and procedures reasonably designed to ensure that each Adviser is promptly notified of all Potential Co-Investment Transactions that fall within the then-current Objectives and Strategies and Board-Established Criteria of any Regulated Fund the Adviser manages.

(b) When an Adviser to a Regulated Fund is notified of a Potential Co-Investment Transaction under Condition 1(a), the Adviser will make an independent determination of the appropriateness of the investment for the Regulated Fund in light of the Regulated Fund's then-current circumstances.

2. *Board Approvals of Co-Investment Transactions.*

(a) If the Adviser deems a Regulated Fund's participation in any Potential Co-Investment Transaction to be appropriate for the Regulated Fund, it will then determine an appropriate level of investment for the Regulated Fund.

(b) If the aggregate amount recommended by the Advisers to be invested in the Potential Co-Investment Transaction by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, the investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.1.a.ii. of the application. Each Adviser to a participating Regulated Fund will promptly notify and provide the Eligible Directors with information concerning the Affiliated Funds' and Regulated Funds' order sizes to assist the Eligible Directors with their review of the applicable Regulated Fund's investments for compliance with these Conditions.

(c) After making the determinations required in Condition 1(b), each Adviser to a participating Regulated Fund will distribute written information concerning the Potential Co-Investment Transaction (including the amount proposed to be invested by each participating Regulated Fund and each participating Affiliated Fund) to the Eligible Directors of its participating Regulated Fund(s) for their consideration. A Regulated Fund will enter into a Co-Investment Transaction with one or more other Regulated Funds or Affiliated Funds only if, prior to the Regulated Fund's participation in the Potential Co-Investment Transaction, a Required Majority concludes that:

(i) The terms of the transaction, including the consideration to be paid, are reasonable and fair to the Regulated Fund and its equity holders and do not involve overreaching in respect of the Regulated Fund or its equity holders on the part of any person concerned;

(ii) The transaction is consistent with:

(A) The interests of the Regulated Fund's equity holders; and

(B) the Regulated Fund's then-current Objectives and Strategies;

(iii) the investment by any other Regulated Fund(s) or Affiliated Fund(s) would not disadvantage the Regulated Fund, and participation by the Regulated Fund would not be on a basis different from, or less advantageous than, that of any other Regulated Fund(s) or Affiliated Fund(s) participating in the transaction; provided, that the Required Majority shall not be prohibited from reaching

[24] ''Advisers to Regulated Funds'' means NBAA and NBIA, with respect to their management of NBBDC and the Existing Regulated Funds, and any other Adviser that, in the future, serves as investment adviser (or sub-adviser, if any) to one or more Regulated Funds.

the conclusions required by this Condition 2(c)(iii) if:

(A) The settlement date for another Regulated Fund or an Affiliated Fund in a Co-Investment Transaction is later than the settlement date for the Regulated Fund by no more than ten business days or earlier than the settlement date for the Regulated Fund by no more than ten business days, in either case, so long as: (x) The date on which the commitment of the Regulated Funds and Affiliated Funds is made is the same and (y) the earliest settlement date and the latest settlement date of any Regulated Fund or Affiliated Fund participating in the transaction will occur within ten business days of each other; or

(B) any other Regulated Fund or Affiliated Fund, but not the Regulated Fund itself, gains the right to nominate a director for election to a portfolio company's board of directors, the right to have a board observer or any similar right to participate in the governance or management of the portfolio company so long as: (x) The Eligible Directors will have the right to ratify the selection of such director or board observer, if any; (y) the Adviser agrees to, and does, provide periodic reports to the Regulated Fund's Board with respect to the actions of such director or the information received by such board observer or obtained through the exercise of any similar right to participate in the governance or management of the portfolio company; and (z) any fees or other compensation that any other Regulated Fund or Affiliated Fund, or any affiliated person of any other Regulated Fund or Affiliated Fund, receives in connection with the right of one or more Regulated Funds or Affiliated Funds to nominate a director or appoint a board observer or otherwise to participate in the governance or management of the portfolio company will be shared proportionately among any participating Affiliated Funds (who may, in turn, share their portion with their affiliated persons) and any participating Regulated Fund(s) in accordance with the amount of each such party's investment; and

(iv) the proposed investment by the Regulated Fund will not involve compensation, remuneration or a direct or indirect [25] financial benefit to the Advisers, any other Regulated Fund, the Affiliated Funds or any affiliated person of any of them (other than the parties to the Co-Investment Transaction), except (A) to the extent permitted by Condition 14, (B) to the extent permitted by section 17(e) or 57(k), as applicable, (C) indirectly, as a result of an interest in the securities issued by one of the parties to the Co-Investment Transaction or (D) in the case of fees or other compensation described in Condition 2(c)(iii)(B).

3. *Right to Decline.* Each Regulated Fund has the right to decline to participate in any Potential Co-Investment Transaction or to invest less than the amount proposed.

4. *General Limitation.* Except for Follow-On Investments made in accordance with Conditions 8 and 9,[26] a Regulated Fund will not invest in reliance on the Order in any issuer in which a Related Party has an investment.[27]

5. *Same Terms and Conditions.* A Regulated Fund will not participate in any Potential Co-Investment Transaction unless (i) the terms, conditions, price, class of securities to be purchased, date on which the commitment is entered into and registration rights (if any) will be the same for each participating Regulated Fund and Affiliated Fund and (ii) the earliest settlement date and the latest settlement date of any participating Regulated Fund or Affiliated Fund will occur as close in time as practicable and in no event more than ten business days apart. The grant to one or more Regulated Funds or Affiliated Funds, but not the respective Regulated Fund, of the right to nominate a director for election to a portfolio company's board of directors, the right to have an observer on the board of directors or similar rights to participate in the governance or management of the portfolio company will not be interpreted so as to violate this Condition 5, if Condition 2(c)(iii)(B) is met.

6. *Standard Review Dispositions.*

(a) *General.* If any Regulated Fund or Affiliated Fund elects to sell, exchange or otherwise dispose of an interest in a security and one or more Regulated Funds and Affiliated Funds have previously participated in a Co-Investment Transaction with respect to the issuer, then:

(i) The Adviser to such Regulated Fund or Affiliated Fund [28] will notify each Regulated Fund that holds an investment in the issuer of the proposed Disposition at the earliest practical time; and

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the Disposition.

(b) *Same Terms and Conditions.* Each Regulated Fund will have the right to participate in such Disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to any other Regulated Fund and the Affiliated Funds.

(c) *No Board Approval Required.* A Regulated Fund may participate in such a Disposition without obtaining prior approval of the Required Majority if:

(i) (A) The participation of each Regulated Fund and Affiliated Fund in such Disposition is proportionate to its then-current holding of the security (or securities) of the issuer that is (or are) the subject of the Disposition; [29] (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in such Dispositions on a pro rata basis (as described in greater detail in the application); and (C) the Board of the Regulated Fund is provided on a quarterly basis with a list of all Dispositions made in accordance with this Condition 6; or

(ii) each security is a Tradable Security and (A) the Disposition is not to the issuer or any affiliated person of the issuer; and (B) the security is sold for cash in a transaction in which the only term negotiated by or on behalf of the participating Regulated Funds and Affiliated Funds is price.

(d) *Standard Board Approval.* In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the

[25] For example, procuring the Regulated Fund's investment in a Potential Co-Investment Transaction to permit an affiliate to complete or obtain better terms in a separate transaction would constitute an indirect financial benefit.

[26] This exception applies only to Follow-On Investments by a Regulated Fund in issuers in which such Regulated Fund already holds investments.

[27] ''Related Party'' means (i) any Close Affiliate and (ii) in respect of matters as to which any Adviser has knowledge, any Remote Affiliate. ''Close Affiliate'' means the Advisers, the Regulated Funds, the Affiliated Funds and any other person described in section 57(b) (after giving effect to rule 57b–1) in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose), except for limited partners included solely by reason of the reference in section 57(b) to section 2(a)(3)(D). ''Remote Affiliate'' means any person described in section 57(e) in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose) and any limited partner holding 5% or more of the relevant limited partner interests that would be a Close Affiliate but for the exclusion in the definition of such term.

[28] Any NB Proprietary Account that is not advised by an Adviser is itself deemed to be an Adviser for purposes of Conditions 6(a)(i), 7(a)(i), 8(a)(i) and 9(a)(i).

[29] In the case of any Disposition, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the security in question immediately preceding the Disposition.

Eligible Directors, and the Regulated Fund will participate in such Disposition solely to the extent that a Required Majority determines that it is in the Regulated Fund's best interests.

7. *Enhanced Review Dispositions.*

(a) *General.* If any Regulated Fund or Affiliated Fund elects to sell, exchange or otherwise dispose of a Pre-Boarding Investment in a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds an investment in the issuer of the proposed Disposition at the earliest practical time;

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the Disposition; and

(iii) the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Funds, including the terms of such investments and how they were made, that is necessary for the Required Majority to make the findings required by this Condition 7.

(b) *Enhanced Board Approval.* The Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Disposition solely to the extent that a Required Majority determines that:

(i) The Disposition complies with Conditions 2(c)(i), (ii), (iii)(A) and (iv); and

(ii) the making and holding of the Pre-Boarding Investments were not prohibited by section 57 or rule 17d–1, as applicable, and records the basis for the finding in the Board minutes.

(c) *Additional Requirements.* The Disposition may only be completed in reliance on the Order if:

(i) *Same Terms and Conditions.* Each Regulated Fund has the right to participate in such Disposition on a proportionate basis, at the same price and on the same terms and Conditions as those applicable to any other Regulated Fund and the Affiliated Funds;

(ii) *Original Investments.* All of the Affiliated Funds' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(iii) *Advice of Counsel.* Independent counsel to the Board advises that the making and holding of the investments in the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b–1) or rule 17d–1, as applicable;

(iv) *Multiple Classes of Securities.* All Regulated Funds and Affiliated Funds that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Funds hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the Order, the Required Majority is presented with all information necessary to make a finding, and finds, that: (x) Any Regulated Fund's or Affiliated Fund's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial [30] in amount, including immaterial relative to the size of the issuer; and (y) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date, currency or denominations may be treated as the same security; and

(v) *No Control.* The Affiliated Funds, the other Regulated Funds and their ''affiliated persons'' (within the meaning of section 2(a)(3)(C) of the Act), individually or in the aggregate, do not ''control'' the issuer of the securities (within the meaning of section 2(a)(9) of the Act).

8. *Standard Review Follow-Ons.*

(a) *General.* If any Regulated Fund or Affiliated Fund desires to make a Follow-On Investment in an issuer and the Regulated Funds and Affiliated Funds holding investments in the issuer previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to each such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time; and

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund.

(b) *No Board Approval Required.* A Regulated Fund may participate in the Follow-On Investment without obtaining prior approval of the Required Majority if:

(i) (A) The proposed participation of each Regulated Fund and each Affiliated Fund in such investment is proportionate to its outstanding investments in the issuer or the security at issue, as appropriate,[31] immediately preceding the Follow-On Investment; and (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in Follow-On Investments on a pro rata basis (as described in greater detail in the application); or

(ii) it is a Non-Negotiated Follow-On Investment.

(c) *Standard Board Approval.* In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority makes the determinations set forth in Condition 2(c). If the only previous Co-Investment Transaction with respect to the issuer was an Enhanced Review Disposition, the Eligible Directors must complete this review of the proposed Follow-On Investment both on a stand-alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms of the investment.

(d) *Allocation.* If, with respect to any such Follow-On Investment:

(i) The amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Funds' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and

(ii) the aggregate amount recommended by the Advisers to be invested in the Follow-On Investment

[30] In determining whether a holding is ''immaterial'' for purposes of the Order, the Required Majority will consider whether the nature and extent of the interest in the transaction or arrangement is sufficiently small that a reasonable person would not believe that the interest affected the determination of whether to enter into the transaction or arrangement or the terms of the transaction or arrangement.

[31] To the extent that a Follow-On Investment opportunity is in a security or arises in respect of a security held by the participating Regulated Funds and Affiliated Funds, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the security in question immediately preceding the Follow-On Investment using the most recent available valuation thereof. To the extent that a Follow-On Investment opportunity relates to an opportunity to invest in a security that is not in respect of any security held by any of the participating Regulated Funds or Affiliated Funds, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the issuer immediately preceding the Follow-On Investment using the most recent available valuation thereof.

by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, then the Follow-On Investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.1.a.ii of the application.

(e) *Other Conditions.* The acquisition of Follow-On Investments as permitted by this Condition 8 will be considered a Co-Investment Transaction for all purposes and subject to the other Conditions set forth in the application.

9. *Enhanced Review Follow-Ons.*

(a) *General.* If any Regulated Fund or Affiliated Fund desires to make a Follow-On Investment in an issuer that is a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Funds holding investments in the issuer have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to each such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time;

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund; and

(iii) the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Funds, including the terms of such investments and how they were made, that is necessary for the Required Majority to make the findings required by this Condition 9.

(b) *Enhanced Board Approval.* The Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority reviews the proposed Follow-On Investment both on a stand–alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms and makes the determinations set forth in Condition 2(c). In addition, the Follow-On Investment may only be completed in reliance on the Order if the Required Majority of each participating Regulated Fund determines that the making and holding of the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b–1) or rule 17d–1, as applicable. The basis for the Board's findings will be recorded in its minutes.

(c) *Additional Requirements.* The Follow-On Investment may only be completed in reliance on the Order if:

(i) *Original Investments.* All of the Affiliated Funds' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(ii) *Advice of Counsel.* Independent counsel to the Board advises that the making and holding of the investments in the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b–1) or rule 17d–1, as applicable;

(iii) *Multiple Classes of Securities.* All Regulated Funds and Affiliated Funds that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Funds hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the Order, the Required Majority is presented with all information necessary to make a finding, and finds, that: (x) Any Regulated Fund's or Affiliated Fund's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial in amount, including immaterial relative to the size of the issuer; and (y) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date, currency or denominations may be treated as the same security; and

(iv) *No Control.* The Affiliated Funds, the other Regulated Funds and their ''affiliated persons'' (within the meaning of section 2(a)(3)(C) of the Act), individually or in the aggregate, do not ''control'' the issuer of the securities (within the meaning of section 2(a)(9) of the Act).

(d) *Allocation.* If, with respect to any such Follow-On Investment:

(i) The amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Funds' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and

(ii) the aggregate amount recommended by the Advisers to be invested in the Follow-On Investment by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, then the Follow-On Investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.1.a.ii of the application.

(e) *Other Conditions.* The acquisition of Follow-On Investments as permitted by this Condition will be considered a Co-Investment Transaction for all purposes and subject to the other Conditions set forth in the application.

10. *Board Reporting, Compliance and Annual Re-Approval.*

(a) Each Adviser to a Regulated Fund will present to the Board of each Regulated Fund, on a quarterly basis, and at such other times as the Board may request, (i) a record of all investments in Potential Co-Investment Transactions made by any of the other Regulated Funds or any of the Affiliated Funds during the preceding quarter that fell within the Regulated Fund's then-current Objectives and Strategies and Board-Established Criteria that were not made available to the Regulated Fund and an explanation of why such investment opportunities were not made available to the Regulated Fund; (ii) a record of all Follow-On Investments in and Dispositions of investments in any issuer in which the Regulated Fund holds any investments by any Affiliated Fund or other Regulated Fund during the prior quarter; and (iii) all information concerning Potential Co-Investment Transactions and Co-Investment Transactions, including investments made by other Regulated Funds or Affiliated Funds that the Regulated Fund considered but declined to participate in, so that the Independent Directors may determine whether all Potential Co-Investment Transactions and Co-Investment Transactions during the preceding quarter, including those investments that the Regulated Fund considered but declined to participate in, comply with the Conditions.

(b) All information presented to the Regulated Fund's Board pursuant to this Condition 10 will be kept for the life of the Regulated Fund and at least two years thereafter and will be subject to examination by the Commission and its staff.

(c) Each Regulated Fund's chief compliance officer, as defined in rule 38a–1(a)(4), will prepare an annual report for its Board each year that evaluates (and documents the basis of that evaluation) the Regulated Fund's compliance with the terms and Conditions of the application and the procedures established to achieve such compliance.

(d) The Independent Directors will consider at least annually whether continued participation in new and existing Co-Investment Transactions is in the Regulated Fund's best interests.

11. *Record Keeping.* Each Regulated Fund will maintain the records required by section 57(f)(3) of the Act as if each of the Regulated Funds were a BDC and each of the investments permitted under these Conditions were approved by the Required Majority under section 57(f).

12. *Director Independence.* No Independent Director of a Regulated Fund will also be a director, general partner, managing member or principal, or otherwise be an ''affiliated person'' (as defined in section 2(a)(3) of the Act) of any Affiliated Fund.

13. *Expenses.* The expenses, if any, associated with acquiring, holding or disposing of any securities acquired in a Co-Investment Transaction (including, without limitation, the expenses of the distribution of any such securities registered for sale under the Securities Act) will, to the extent not payable by the Advisers under their respective advisory agreements with the Regulated Funds and the Affiliated Funds, be shared by the Regulated Funds and the participating Affiliated Funds in proportion to the relative amounts of the securities held or being acquired or disposed of, as the case may be.

14. *Transaction Fees.*[32] Any transaction fee (including break-up, structuring, monitoring or commitment fees but excluding brokerage or underwriting compensation permitted by section 17(e) or 57(k)) received in connection with any Co-Investment Transaction will be distributed to the participants on a pro rata basis based on the amounts they invested or committed, as the case may be, in such Co-Investment Transaction. If any transaction fee is to be held by an Adviser pending consummation of the transaction, the fee will be deposited into an account maintained by the Adviser at a bank or banks having the qualifications prescribed in section 26(a)(1), and the account will earn a competitive rate of interest that will also be divided pro rata among the participants. None of the Advisers, the Affiliated Funds, the other Regulated Funds or any affiliated person of the Affiliated Funds or the Regulated Funds will receive any additional compensation or remuneration of any kind as a result of or in connection with a Co-Investment Transaction other than (i), in the case of the Regulated Funds and the Affiliated Funds, the pro rata transaction fees described above and fees or other compensation described in Condition 2(c)(iii)(B), (ii) brokerage or underwriting compensation permitted by section 17(e) or 57(k) or (iii), in the case of the Advisers, investment advisory compensation paid in accordance with investment advisory agreements between the applicable Regulated Fund(s) or Affiliated Fund(s) and its Adviser.

15. *Independence.* If the Holders own in the aggregate more than 25 percent of the Shares of a Regulated Fund, then the Holders will vote such Shares in the same percentages as the Regulated Fund's other shareholders (not including the Holders) when voting on (1) the election of directors; (2) the removal of one or more directors or (3) any other matter under either the Act or applicable state law affecting the Board's composition, size or manner of election.

16. *Proprietary Accounts.* The NB Proprietary Accounts will not be permitted to invest in a Potential Co-Investment Transaction except to the extent the aggregate demand from the Regulated Funds and the other Affiliated Funds is less than the total investment opportunity.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–27697 Filed 12–21–21; 8:45 am]

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[32] Applicants are not requesting, and the Commission is not providing, any relief for transaction fees received in connection with any Co-Investment Transaction.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93798; File No. SR–C2–2021–017]

Self-Regulatory Organizations; Cboe C2 Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Rules To Make Juneteenth National Independence Day a Holiday of the Exchange

December 16, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 6, 2021, Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2 Options'') proposes to amend its rules to make Juneteenth National Independence Day a holiday of the Exchange. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/ctwo/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 5.1 (Days and Hours of Business) to make Juneteenth National Independence Day a holiday of the Exchange. On June 17, 2021, Juneteenth National Independence Day was designated a legal public holiday.[5] Consistent with broad industry sentiment[6] and the approach recommended by the Securities Industry and Financial Markets Association

[5] Public Law 117–17.

[6] *See e.g., https://www.bloomberg.com/news/articles/2021-06-18/bofa-makesjuneteenth-a-holiday-joining-jpmorgan-wells-fargo?sref=Hhue1scO.*

(''SIFMA''),[7] the Exchange proposes to add ''Juneteenth National Independence Day'' to the existing list of holidays set forth in Rule 5.1(d). As a result, the Exchange will not be open for business on Juneteenth National Independence Day, which falls on June 19 of each year. In accordance with Rule 5.1(d), when a holiday falls on a Saturday, the Exchange will not be open for business on the preceding Friday, and when it falls on a Sunday, the Exchange will not be open for business on the succeeding Monday.[8]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[9] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [10] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(1) of the Act,[11] which provides that the Exchange be organized and have the capacity to be able to carry out the purposes of the Act and to enforce compliance by the Exchange's Trading Permit Holders and persons associated with its Trading Permit Holders with the Act, the rules and regulations thereunder, and the rules of the Exchange.

The Exchange believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest because the proposed amended rule would clearly state that the Exchange will not be open for business on Juneteenth National Independence Day, which is a federal holiday, and would address what day would be taken off if June 19 fell on a Saturday or Sunday. The change would thereby promote clarity and transparency in the Exchange rules by updating the list of holidays of the Exchange. The proposed rule change is also based on recent proposals by other exchanges.[12] Therefore, the proposed change does not raise any new or novel issues.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[13] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather to conform to industry practice with respect to holidays.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [14] and Rule 19b–4(f)(6) thereunder.[15] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [16] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–C2–2021–017 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–C2–2021–017. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the

[7] SIFMA recommends a full market close in observance of Juneteenth National Independence Day. See *https://www.sifma.org/resources/general/holidayschedule/.* See also *https://www.sifma.org/resources/news/sifma-revises-2022-fixed-income-market-close-recommendations-in-the-u-s-to-include-full-close-for-juneteenth-national-independence-day/.*

[8] *See* Cboe C2 Exchange Rule 5.1(d). There is an exception to the practice if unusual business conditions exist.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5)

[11] 15 U.S.C. 78f(b)(1).

[12] *See e.g.,* Securities Exchange Act Release No. 93186 (September 30, 2021), 86 FR 55068 (October 5, 2021) (SR–NYSE–2021–56). *See also* Securities Exchange Act Release No. 93461 (October 28, 2021), 86 FR 60670 (November 3, 2021) (SR–MIAX–2021–55).

[13] 15 U.S.C. 78f(b)(8).

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6).

[16] 15 U.S.C. 78s(b)(2)(B).

provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–C2–2021–017 and should be submitted on or before January 12, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–27657 Filed 12–21–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93801; File No. SR–MIAX–2021–61]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Increase Position Limits for Options on Two Exchange-Traded Funds

December 16, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 3, 2021, Miami International Securities Exchange, LLC (''MIAX Options'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Exchange Rule 307 (Position Limits) and Exchange Rule 309 (Exercise Limits).

The text of the proposed rule change is available on the Exchange's website, at *http://www.miaxoptions.com/rule-filings/* at MIAX Options' principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 307 (Position Limits) and Exchange Rule 309 (Exercise Limits) to increase the position and exercise limits for options on certain exchange-traded funds (''ETFs''). These proposed rule changes are based on the similar proposal by Cboe Exchange, Inc. (''Cboe'') and approved by the Commission.[3]

Position limits are designed to address potential manipulative schemes and adverse market impacts surrounding the use of options, such as disrupting the market in the security underlying the options. While position limits should address and discourage the potential for manipulative schemes and adverse market impact, if such limits are set too low, participation in the options market may be discouraged. The Exchange believes that position limits must therefore be balanced between mitigating concerns of any potential manipulation and the cost of inhibiting potential hedging activity that could be used for legitimate economic purposes.

The Exchange has observed an ongoing increase in demand, for both trading and hedging purposes in options on iShares® iBoxx $ Investment Grade Corporate Bond ETF (''LQD'') and VanEck Vectors Gold Miners ETF (''GDX,'' and collectively, with the aforementioned ETF, the ''Underlying ETFs''). Though the demand for these options appears to have increased, position limits for options on the Underlying ETFs have remained the same. The Exchange believes these unchanged position limits may have impeded, and may continue to impede, trading activity and strategies of investors, such as use of effective hedging vehicles or income generating strategies (*e.g.,* buy-write or put-write), and the ability of Market Makers[4] to make liquid markets with tighter spreads in these options resulting in the transfer of volume to over-the-counter (''OTC'') markets. OTC transactions occur through bilateral agreements, the terms of which are not publicly disclosed to the marketplace. As such, OTC transactions do not contribute to the price discovery process on a public exchange or other lit markets. Therefore, the Exchange believes that the proposed increases in position limits (and exercise limits) for options on the Underlying ETFs may enable liquidity providers to provide additional liquidity to the Exchange and other market participants to transfer their liquidity demands from OTC markets to the Exchange. As described in further detail below, the Exchange believes that the continuously increasing market capitalization of the Underlying ETFs, ETF components, as well as the highly liquid markets for each, reduces the concerns for potential market manipulation and/or disruption in the underlying markets upon increasing position limits, while the rising demand for trading options on the Underlying ETFs for legitimate economic purposes compels an increase in position limits.

Proposed Position Limits for Options on the Underlying ETFs

Position limits for options on ETFs are determined pursuant to Exchange Rule 307 and vary according to the number of outstanding shares and the trading volumes of the underlying equity security (which includes ETFs) over the past six months. Pursuant to Rule 307, the largest in capitalization and the most frequently traded stocks and ETFs have an option position limit of 250,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market; and smaller

[17] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 93525 (November 4, 2021), 86 FR 62584 (November 10, 2021) (SR–Cboe–2021–029) (Notice of Filing of Amendment Nos. 2 and 3 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1, 2, and 3, To Increase Position Limits for Options on Two-Exchange-Traded Funds).

[4] ''Market Makers'' means ''Lead Market Makers,'' ''Primary Lead Market Makers'' and ''Registered Market Makers'' collectively. *See* Exchange Rule 100. A Market Maker has the rights and responsibilities set forth in Chapter VI of the Exchange's Rulebook.

capitalization stocks and ETFs have position limits of 200,000, 75,000, 50,000, or 25,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market. Options on LQD and GDX are currently subject to the standard position limit of 250,000 contracts as set forth in Exchange Rule 307, Policy .01 of Exchange Rule 307 sets forth separate, higher position limits for specific equity options (including options on specific ETFs).[5]

The Exchange proposes to amend Policy .01 of Exchange Rule 307 to increase the position limits for options on each of LQD and GDX. The Exchange also proposes to amend Policy .01 of Exchange Rule 309 to increase the exercise limits for options on each of LQD and GDX. The table below represents the current, and proposed, position and exercise limits for options on the Underlying ETFs subject to this proposal:

Product	Current position/ exercise limit	Proposed position/ exercise limit
LQD	250,000	500,000
GDX	250,000	500,000

The Exchange notes that the proposed position limit for options on LQD and GDX are consistent with current position limits for options on the iShares® MSCI Brazil ETF (''EWZ''), iShares® 20+ Year Treasury Bond Fund ETF (''TLT''), iShares® MSCI Japan ETF (''EWJ''), and iShares® iBoxx $ High Yield Corporate Bond Fund (''HYG'').[6] The Exchange represents that the Underlying ETFs qualify for either (1) the initial listing criteria set forth in Rule 402(i)(5)(ii) for ETFs holding non-U.S. component securities, (2) the generic listing standards for series of portfolio depository receipts and index fund shares based on international or global indexes under which a comprehensive surveillance agreement (''CSA'') is not required, or (3) the continued listing criteria in Exchange Rule 403 (for ETFs).[7] In compliance with its listing rules, the Exchange also represents that non-U.S. component securities that are not subject to a CSA do not, in the aggregate, represent more than 50% of the weight of any of the Underlying ETFs.[8]

Composition and Growth Analysis for Underlying ETFs

As stated above, position (and exercise) limits are intended to prevent the establishment of options positions that can be used to, or potentially create incentives to, manipulate the underlying market so as to benefit options positions. The Commission has recognized that these limits are designed to minimize the potential for mini-manipulations and for corners or squeezes of the underlying market, as well as serve to reduce the possibility for disruption of the options market itself, especially in illiquid classes.[9] The Underlying ETFs, as well as the ETF components, are highly liquid and are based on a broad set of highly liquid securities and other reference assets, as demonstrated through the trading statistics presented in this proposal. To support the proposed position limit increases (and corresponding exercise limit increases), the Exchange considered the liquidity of the Underlying ETFs, the Value of the underlying ETFs, their components and the relevant marketplace, the share and option volume for the Underlying ETFs, and, where applicable, the availability or comparison of economically equivalent products to options on the Underlying ETFs.

Cboe demonstrated the below trading statistics regarding shares of and options on the Underlying ETFs and the values of the Underlying ETFs and their components: [10]

Product	ADV [11] (ETF shares millions)	ADV (options contracts)	Shares outstanding (millions) [12]	Fund market cap (USD millions) [13]	Share value [14] (USD)
LQD	14.1	30,300	308.1	54,113.7	130.13 (NAV)
GDX	39.4	166,000	419.8	16,170.5	33.80 (NAV)

Cboe collected the same trading statistics as above regarding a sample of other ETFs, as well as the current position limits for options on such ETFs pursuant to its Rule 13.07, to draw comparisons in support of the proposed position limit increases for options on the Underlying ETFs (see further discussion below).[15]

[5] Adjusted option series, in which one option contract in the series represents the delivery of other than 100 shares of the underlying security as a result of a corporate action by the issuer of the security underlying such option series, do not impact the notional value of the underlying security represented by those options. When an underlying security undergoes a corporate action resulting in adjusted series, the Exchange lists new standard option series across all appropriate expiration months the day after the existing series are adjusted. The adjusted series are generally actively traded for a short period of time following adjustment, but orders to open options positions in the underlying security are almost exclusively placed in the new standard option series contracts.

[6] *See* Exchange Rule 307, Interpretation and Policy .01.

[7] The Exchange notes that the initial listing criteria for options on ETFs that hold non-U.S. component securities are more stringent than the maintenance listing criteria for those same ETF options. *See* Exchange Rule 402(i)(5)(ii) and Exchange Rule 403(g).

[8] *See* Exchange Rule 402(i)(5)(ii).

[9] *See* Securities Exchange Act Release No. 67672 (August 15, 2012), 77 FR 50750 (August 22, 2012) (SR–NYSEAmex–2012–29).

[10] *See supra* note 3.

[11] Average daily volume (ADV) data for ETF shares and option contracts, as well as for ETF shares and options on the comparative ETFs presented below, are for all of 2020. Additionally, reference to ADV in ETF shares and ETF options, and indexes herein this proposal are for all of calendar year 2020, unless otherwise indicated.

[12] Shares Outstanding and Net Asset Values (''NAV''), as well as for the comparative ETFs presented below, are as of April 5, 2021 for all ETFs.

[13] Fund Market Capitalization data, as well as for the comparative ETFs presented below, are as of January 14, 2021.

[14] *See supra* note 12.

[15] *See supra* note 3.

Product	ADV (ETF shares millions)	ADV (options contract)	Shares outstanding (millions)	Fund market cap (USD millions)	Share value (USD)	Current position limits
EWZ	29.2	139,400	173.8	6,506.8	33.71 (NAV) ...	500,000
TLT	11.5	111,800	103.7	17,121.3	136.85 (NAV)	500,000
EWJ	8.2	15,500	185.3	13,860.7	69.72 (NAV) ...	500,000
HYG	30.5	261,600	254.5	24,067.5	86.86 (NAV) ...	500,000

The Exchange believes that, overall, the liquidity in the shares of the Underlying ETFs and in their overlying options, the larger market capitalizations for each of the Underlying ETFs, and the overall market landscape relevant to each of the Underlying ETFs support the proposal to increase the position limits for each option class. Given the robust liquidity in, and value of, the Underlying ETFs and their components, the Exchange does not anticipate that the proposed increase in position limits would create significant price movements as the relevant markets are large enough to adequately absorb potential price movements that may be caused by larger trades.

LQD tracks the performance of the Markit iBoxx USD Liquid Investment Grade (''IBOXIG'') Index, which is an index designed as a subset of the broader U.S. dollar-denominated corporate bond market which can be used as a basis for tradable products, such as ETFs, and is comprised of over 8,000 bonds.[16] Cboe noted that from 2019 through 2020, ADV has grown significantly in shares of LQD and in options on LQD, from approximately 9.7 million shares in 2019 to 14.1 million through 2020, and from approximately 8,200 option contracts in 2019 to 30,300 option contracts through 2020. LQD also continued to experience significant growth in ADV in the first quarter of 2021 with an ADV of approximately 140,200 options contracts. Further, LQD generally experiences higher ADV in shares than both TLT (11.5 million shares) and EWJ (8.2 million share) and almost double the ADV in option contracts than EWJ (15,500 option contracts). Options on each of EWZ, TLT, and EWJ are currently subject to a position limit of 500,000 contracts—the proposed limit for options on LQD. The NAV of LQD is also higher than, or comparable to, that of the NAV of the ETFs underlying the options that are currently subject to a position limit of 500,000 option contracts (as presented in the table above), which is indicative that the total value of its underlying components is generally higher or comparable. Per the tables above, LQD's total market capitalization of approximately $54.1 billion is also higher than or comparable to the total market capitalization of the ETFs underlying the options currently subject to a position limit of 500,000 contracts. In addition to this, Cboe noted that, although there are currently no options listed for trading on the IBOXIG Index, the components [17] of the IBOXIG Index, which can be used in creating a basket of securities that equate to the LQD ETF, are made up of over 8,000 bonds for which the outstanding face value of each must be greater than or equal to $2 billion.[18] The Exchange believes that the total value of the bonds in the IBOXIG Index, coupled with LQD's share and option volume, total market capitalization, and NAV price indicates that the market is large enough to absorb potential price movements caused by a large trade in LQD. Also, as evidenced above, trading volume in LQD shares has increased over the past few years, and the Exchange understands that market participants' need for options has continued to grow alongside the ETF. Particularly, the Exchange notes that in the last year, market participants have sought more cost-effective hedging strategies through the use of LQD options as a result of the borrow on other fixed income ETFs, such as HYG. Therefore, the Exchange believes that because LQD options are being increasingly utilized as an alternative to similar products, such as HYG options, then it is appropriate that options on LQD be subject to the same 500,000 contract position limit that currently exists for options on HYG.

GDX seeks to replicate as closely as possible the price and yield performance of the NYSE Arca Gold Miners (''GDMNTR'') Index, which is intended to track the overall performance of companies involved in the gold mining industry.[19] Cboe noted ADV in GDX options has increased from 2019 through 2020, with an ADV of approximately 117,400 option contracts in 2019 to an ADV of approximately 166,000 option contracts in 2020. Cboe noted that ADV in GDX shares did not increase from 2019 to 2020. GDX options also experienced an ADV of approximately 287,800 option contracts in the first quarter of 2021. Cboe noted that the ADV in GDX shares (39.4 million) and options on GDX (166,000 option contracts) are greater than the ADV in EWZ (29.2 million shares and 139,300 option contracts), TLT (11.5 million shares and 111,800 option contracts), EWJ (8.2 million shares and 15,500 option contracts), and HYG (30.5 million shares and 261,600 option contracts), each of which is currently subject to a position limit of 500,000 option contracts—the proposed limit for options on GDX. GDX also experiences a comparable, or higher, market capitalization (approximately $16.2 billion) than EWZ, TLT and EWJ. Cboe noted that many of the Brazil-based gold mining constituents included in GDX are also included in EWZ, which tracks the investment results of an index composed of Brazilian equities, and that Cboe had not identified any issues with the continued listing and trading of EWZ options or any adverse market impact on EWZ in connection with the current 500,000 position limit in place for EWZ options. Additionally, like that of LDQ [sic] above, there is currently no index option analogue for the GDX ETF on the GDMNTR Index approved for options trading; however, the components of the GDMNTR Index, which can be used to create the GDX ETF, currently must each have a market capitalization greater than $750 million, an ADV of at least 50,000 shares, and an average daily value traded of at least $1 million in order to be eligible for inclusion in the GDMNTR Index. The Exchange believes that the GDMNTR Index component inclusion requirements, as well as GDX's share and option volume and total market capitalization, indicate that the GDX

[16] *See* Markit iBoxx USD Liquid Investment Grade Index, available at *https://cdn.ihs.com/www/pdf/MKT-iBoxx-USD-Liquid-Investment-Grade-Index-factsheet.pdf.* (March 31, 2021).

[17] Investment grade corporate bonds.

[18] *See supra* note 16.

[19] *See* VanEck Vectors Gold Miners ETF, available at *https://www.vaneck.com/library/vaneck-vectors-etfs/gdx-fact-sheet-pdf/.* (October 31, 2021).

market is sufficiently large and liquid enough to absorb price movements as a result of potentially oversized trades.

Creation and Redemption for ETFs

The Exchange believes that the creation and redemption process for the ETFs subject to this proposal will lessen the potential for manipulative activity with options on the Underlying ETFs. When an ETF provider wants to create more shares, it looks to an Authorized Participant (''AP'') (generally a Market-Maker or other large financial institution) to acquire the securities the ETF is to hold. For instance, when an ETF is designed to track the performance of an index, the AP can purchase all the constituent securities in the exact same weight as the index, then deliver those shares to the ETF provider. In exchange, the ETF provider gives the AP a block of equally valued ETF shares, on a one-for-one fair value basis. The price is based on the NAV, not the market value at which the ETF is trading. The creation of new ETF units can be conducted during an entire trading day and is not subject to position limits. This process works in reverse where the ETF provider seeks to decrease the number of shares that are available to trade. The creation and redemption processes for the Underlying ETFs creates a direct link to the underlying components of the ETF and serves to mitigate potential price impact of the ETF shares that might otherwise result from increased position limits for the options on the Underlying ETFs.

The Exchange understands that the ETF creation and redemption processes seek to keep an ETF's share price trading in line with the product's underlying net asset value. Because an ETF trades like a stock, its share price will fluctuate during the trading day, due to simple supply and demand. If demand to buy an ETF is high, for instance, an ETF's share price might rise above the value of its underlying components. When this happens, the AP or issuer believes the ETF may now be overpriced, so it may buy shares of the component securities or assets and then sell ETF shares in the open market. This may drive the ETF's share price back toward the underlying net asset value. Likewise, if an ETF share price starts trading at a discount to the component securities or assets it holds, the AP or issuer can buy shares of the ETF and redeem them for the underlying components. Buying undervalued ETF shares may drive the share price of an ETF back toward fair value. This arbitrage process helps to keep an ETF's share price in line with the value of its underlying portfolio.

Surveillance and Reporting Requirements

The Exchange believes that increasing the position limits (and exercise limits) for the options on the Underlying ETFs would lead to a more liquid and competitive market environment for these options, which will benefit customers interested in trading these products. The reporting requirement for the options on the Underlying ETFs would remain unchanged. Thus, the Exchange would still require that each Member [20] maintains that positions in the options on the same side of the market, for its own account or for the account of a customer, report certain information to the Exchange. This information would include, but would not be limited to, the options positions, whether such positions are hedged and, if so, a description of the hedge(s). Market-Makers (including Primary Lead Market-Makers) [21] would continue to be exempt from this reporting requirement; however, the Exchange may access Market-Maker position information.[22] Moreover, the Exchange's requirement that Members file reports with the Exchange for any customer who held aggregate large long or short positions on the same side of the market of 200 or more option contracts of any single class for the previous day will remain at this level for the options subject to this proposal and will continue to serve as an important part of the Exchange's surveillance efforts.[23]

The Exchange believes that the existing surveillance procedures and reporting requirements at the Exchange and other SROs are capable of properly identifying disruptive and/or manipulative trading activity. The Exchange also represents that it has adequate surveillances in place to detect potential manipulation, as well as reviews in place to identify potential changes in composition of the Underlying ETFs and continued compliance with the Exchange's listing standards. These procedures utilize daily monitoring of market activity via automated surveillance techniques to identify unusual activity in both options and the Underlying ETFs, as applicable.[24] The Exchange also notes that large stock holdings must be disclosed to the Commission by way of Schedules 13D or 13G,[25] which are used to report ownership of stock that exceeds 5% of a company's total stock issue and may assist in providing information in monitoring for any potential manipulative schemes.

The Exchange believes that the current financial requirements imposed by the Exchange and by the Commission adequately address concerns regarding potentially large, unhedged positions in the options on the Underlying ETFs. Current margin and risk-based haircut methodologies serve to limit the size of positions maintained by any one account by increasing the margin and/or capital that a Member must maintain for a large position held by itself or by its customer.[26] In addition, Rule 15c3–1 [27] imposes a capital charge on Members to the extent of any margin deficiency resulting from the higher margin requirement.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[28] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [29] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and

[20] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[21] ''Primary Lead Market Maker'' means a Lead Market Maker appointed by the Exchange to act as the Primary Lead Market Maker for the purpose of making markets in securities traded on the Exchange. The Primary Lead Market Maker is vested with certain rights and responsibility specified Chapter VI of the Rulebook. *See* Exchange Rule 100.

[22] The Options Clearing Corporation (''OCC'') through the Large Option Position Reporting (''LOPR'') system acts as a centralized service provider for Member compliance with position reporting requirements by collecting data from each Member, consolidating the information, and ultimately providing detailed listings of each Member's report to the Exchange, as well as Financial Industry Regulatory Authority, Inc. (''FINRA''), acting as its agent pursuant to a regulatory services agreement (''RSA'') with the Exchange.

[23] *See* Rule 310(a).

[24] The Exchange believes these procedures have been effective for the surveillance of trading the options subject to this proposal and will continue to employ them.

[25] 17 CFR 240.13d–1.

[26] *See* Exchange Rule 1502 for a description of margin requirements.

[27] 17 CFR 240.15c3–1.

[28] 15 U.S.C. 78f(b).

[29] 15 U.S.C. 78f(b)(5).

open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [30] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed increase in position limits for options on the Underlying ETFs will remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, because it will provide market participants with the ability to more effectively execute their trading and hedging activities. The proposed increases will allow market participants to more fully implement hedging strategies in related derivative products and to further use options to achieve investment strategies (*e.g.,* there are other exchange-traded products (''ETPs'') that use options on the ETFs subject to this proposal as part of their investment strategy, and the applicable position limits as they stand today may inhibit these other ETPs in achieving their investment objectives to the detriment of investors). Also, increasing the applicable position limits may allow Market-Makers to provide the markets for these options with more liquidity in amounts commensurate with increased consumer demand in such markets. The proposed position limit increases may also encourage other liquidity providers to shift liquidity, as well as encourage consumers to shift demand, from over the counter markets onto the Exchange, which will enhance the process of price discovery conducted on the Exchange through increased order flow.

In addition, the Exchange believes that the structure of the Underlying ETFs, the considerable market capitalization of the funds and underlying components, and the liquidity of the markets for the applicable options and underlying component securities will mitigate concerns regarding potential manipulation of the products and/or disruption of the underlying markets upon increasing the relevant position limits. As a general principle, increases in market capitalizations, active trading volume, and deep liquidity of the underlying components do not lead to manipulation and/or disruption. This general principle applies to the recently observed increased levels of market capitalization and trading volume and liquidity in shares of and options on the Underlying ETFs (as described above), and, as a result, the Exchange does not believe that the options markets or underlying markets would become susceptible to manipulation and/or disruption as a result of the proposed position limit increases. Indeed, the Commission has previously expressed the belief that not just increasing, but removing, position and exercise limits may bring additional depth and liquidity to the options markets without increasing concerns regarding intermarket manipulation or disruption of the options or the underlying securities.[31]

The proposed increase to the position and exercise limits on the Underlying ETFs has recently been approved by the Commission.[32] Further, the Exchange notes that the proposed rule change to increase position limits for select actively traded options is not novel and the Commission has approved similar proposed rule changes by Cboe to increase position limits for options on similar, highly liquid and actively traded ETPs.[33] Furthermore, the Exchange again notes that the proposed position limits for options on LQD and GDX are consistent with existing position limits for options on other ETFs in Rule 307, Policy .01.[34]

The Exchange's surveillance and reporting safeguards continue to be designed to deter and detect possible manipulative behavior that might arise from increasing or eliminating position and exercise limits in certain classes. The Exchange believes that the current financial requirements imposed by the Exchange and by the Commission adequately address concerns regarding potentially large, unhedged position in the options on the Underlying ETFs, further promoting just and equitable principles of trading, the maintenance of a fair and orderly market, and the protection of investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the increased position limits (and exercise limits) will be available to all market participants and apply to each in the same manner. The Exchange believes that the proposed rule change will provide additional opportunities for market participants to more efficiently achieve their investment and trading objectives of market participants.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the Act. On the contrary, the Exchange believes the proposal promotes competition because it may attract additional order flow from the OTC market to exchanges, which would in turn compete amongst each other for those orders.[35] The Exchange believes market participants would benefit from being able to trade options with increased position limits in an exchange environment in several ways, including but not limited to the following: (1) Enhanced efficiency in initiating and closing out positions; (2) increased market transparency; and (3) heightened contra-party creditworthiness due to the role of OCC as issuer and guarantor. Additionally, BOX Exchange LLC (''BOX''), Nasdaq ISE, LLC (''ISE''), and Nasdaq PHLX LLC (''PHLX'') have recently filed similar proposed rule changes to increase position limits and exercise limits on options on the Underlying ETFs.[36]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant

[30] *Id.*

[31] *See* Securities Exchange Act Release No. 62147 (October 28, 2005) (SR–CBOE–2005–41), at 62149.

[32] *See supra* note 3.

[33] *See* Securities Exchange Act Release Nos. 88768 (April 29, 2020), 85 FR 26736 (May 5, 2020) (SR–CBOE–2021–015); 83415 (June 12, 2018), 83 FR 28274 (June 18, 2018) (SR–CBOE–2018–042); *and* 68086 (October 23, 2012), 77 FR 65600 (October 29, 2012) (SR–CBOE–2012–066).

[34] *See supra* note 6.

[35] Additionally, several other options exchanges have the same position limits as the Exchange, as they incorporate by reference to the position limits established by Cboe, and as a result, the position limits for options on the Underlying ETFs will increase at those exchanges. For example, The Nasdaq Options Markets LLC (''NOM'') and Nasdaq BX, Inc. (''BX'') position limits are determined by the position limits established by Cboe. *See* NOM and BX Rules, Options 9, Sec. 13 (Position Limits).

[36] *See* Securities Exchange Act Release No. 93659 (November 23, 2021) (SR–BOX–2021–27); Securities Exchange Act Release No. 93658 (November 23, 2021) (SR–ISE–2021–25); Securities Exchange Act Release No. 93661 (November 23, 2021) (SR–Phlx–2021–70).

burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [37] and Rule 19b–4(f)(6) thereunder.[38]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [39] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [40] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange states that waiver of the operative delay would be consistent with the protection of investors and the public interest because it will ensure fair competition among exchanges by allowing the Exchange to amend the position and exercise limits and immediately benefit a greater number of participants who are MIAX Members and members of Cboe by ensuring consistency and uniformity among competing options exchanges as to the position and exercise limits for these multiply-listed options classes. For this reason, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal as operative upon filing.[41]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2021–61 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2021–61. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2021–61, and should be submitted on or before January 12, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[42]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–27661 Filed 12–21–21; 8:45 am]

BILLING CODE 8011–01–P

[37] 15 U.S.C. 78s(b)(3)(A).

[38] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[39] 17 CFR 240.19b–4(f)(6).

[40] 17 CFR 240.19b–4(f)(6)(iii).

[41] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[42] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93797; File No. SR–NYSEArca–2021–47]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 1, To Adopt New Rules 6.1P–O, 6.37AP–O, 6.40P–O, 6.41P–O, 6.62P–O, 6.64P–O, 6.76P–O, and 6.76AP–O and Amendments to Rules 1.1, 6.1–O, 6.1A–O, 6.37–O, 6.65A–O and 6.96–O

December 16, 2021.

On June 21, 2021, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt new Rules 6.1P–O (Applicability), 6.37AP–O (Market Maker Quotations), 6.40P–O (Pre-Trade and Activity-Based Risk Controls), 6.41P–O (Price Reasonability Checks—Orders and Quotes), 6.62P–O (Orders and Modifiers), 6.64P–O (Auction Process), 6.76P–O (Order Ranking and Display), and 6.76AP–O (Order Execution and Routing) and proposed amendments to Rules 1.1 (Definitions), 6.1–O (Applicability, Definitions and References), 6.1A–O (Definitions and References—OX), 6.37–O (Obligations of Market Makers), 6.65A–O (Limit-Up and Limit-Down During Extraordinary Market Volatility), and 6.96–O (Operation of Routing Broker) to reflect the implementation of the Exchange's Pillar trading technology on its options market. The proposed rule change was published for comment in the **Federal Register** on July 9, 2021.[3]

On August 18, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 92304 (June 30, 2021), 86 FR 36440 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change.[5] On September 28, 2021, the Exchange filed Amendment No. 1 to the proposed rule change, which superseded the proposed rule change as originally filed in its entirety.[6] On September 29, 2021, the Commission published the proposed rule change, as modified by Amendment No. 1, for notice and comment and instituted proceedings to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.[7] The Commission has received no comments on the proposed rule change.

Section 19(b)(2) of the Act[8] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for notice and comment in the **Federal Register** on July 9, 2021.[9] January 5, 2022 is 180 days from that date, and March 6, 2022 is 240 days from that date. The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[10] designates March 6, 2022 as the date by which the Commission shall either approve or disapprove the proposed rule change, as modified by Amendment No. 1 (File No. SR–NYSEArca–2021–47).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–27656 Filed 12–21–21; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17153 and #17154; Louisiana Disaster Number LA–00116]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Louisiana

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Louisiana (FEMA–4611–DR), dated 09/07/2021.

Incident: Hurricane Ida.

Incident Period: 08/26/2021 through 09/03/2021.

DATES: Issued on 12/14/2021.

Physical Loan Application Deadline Date: Filing Period for the parishes listed below ends on 01/13/2022. Filing Period for the previously declared parishes ends on 12/28/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 06/07/2022.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Louisiana, dated 09/07/2021, is hereby amended to include the parishes listed below. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 to request an application. Applications for physical damages for previously declared parishes may be filed until 12/28/2021. Applications for physical damages for the parishes listed below may be filed until 01/13/2022. Applications for economic injury may be filed until 06/07/2022.

Primary Parishes: Ascension, Assumption, East Baton Rouge, East Feliciana, Iberville, Livingston, Pointe Coupee, Saint Helena, Saint Martin, Saint Mary, West Feliciana.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Barbara Carson,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2021–27693 Filed 12–21–21; 8:45 am]

BILLING CODE 8026–03–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 290 (Sub-No. 5) (2022–1)]

Quarterly Rail Cost Adjustment Factor

AGENCY: Surface Transportation Board.

ACTION: Approval of rail cost adjustment factor.

SUMMARY: The Board has approved the first quarter 2022 Rail Cost Adjustment Factor (RCAF) and cost index filed by the Association of American Railroads. The first quarter 2022 RCAF (Unadjusted) is 1.154. The first quarter 2022 RCAF (Adjusted) is 0.478. The first quarter 2021 RCAF–5 is 0.451.

DATES: *Applicability Date:* January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Pedro Ramirez at (202) 245–0333. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision, which is available at *www.stb.gov.*

Decided: December 17, 2021.

By the Board, Board Members Begeman, Fuchs, Oberman, Primus, and Schultz.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2021–27753 Filed 12–21–21; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2021–0018]

Petition for Exemption; Summary of Petition Received; Southern California Edison

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief

[5] *See* Securities Exchange Act Release No. 92696, 86 FR 47350 (August 24, 2021). The Commission designated October 7, 2021, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to approve or disapprove, the proposed rule change.

[6] Amendment No. 1 is available on the Commission's website at *https://www.sec.gov/comments/sr-nysearca-2021-47/srnysearca202147-9304467-259869.pdf.*

[7] *See* Securities Exchange Act Release No. 93193, 86 FR 55926 (October 7, 2021).

[8] 15 U.S.C. 78s(b)(2).

[9] *See* Notice, *supra* note 3.

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(57).

from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before January 11, 2022.

ADDRESSES: Send comments identified by docket number FAA–2021–0644 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Michael McGuire, AIR–621, Federal Aviation Administration, 10101 Hillwood Pkwy, Fort Worth, TX 76177; (817) 222–5107; email: *Michael.P.McGuire@faa.gov.*

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on December 17, 2021.

Daniel J. Commins,

Manager, Technical Writing Section.

PETITION FOR EXEMPTION

Docket No.: FAA–2021–0644.

Petitioner: Southern California Edison.

Section(s) of 14 CFR Affected: 14 CFR 27.1.

Description of Relief Sought: Southern California Edison (SCE) is seeking relief from § 27.1(a), which mandates a maximum gross weight (MGW) of 7000 lbs. Specifically, SCE is requesting an exemption from § 27.1(a) to operate the Bell 429 Helicopter up to an MGW of 7,500 lbs. for power grid operations. The 500 lbs. increase would allow SCE extra capacity for carrying additional fuel, personnel, and equipment.

[FR Doc. 2021–27743 Filed 12–21–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Request To Release Property at Bowman Field, Louisville, KY (LOU)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration is requesting public comment on a request by Louisville Regional Airport Authority (LRAA), to retroactively release land (8.1 acres) at Bowman Field from federal obligations.

DATES: Comments must be received on or before January 21, 2022.

ADDRESSES: Comments on this notice may be emailed to the FAA at the following email address: FAA/Memphis Airports District Office, Attn: Jamal R. Stovall, Community Planner, *Jamal.Stovall@faa.gov.*

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Adam Thomas, Director of Properties, Louisville Regional Airport Authority at the following address: 700 Administration Drive, Louisville, KY 40209.

FOR FURTHER INFORMATION CONTACT: Jamal R. Stovall, Community Planner, Federal Aviation Administration, Memphis Airports District Office, 2600, Thousand Oaks Boulevard, Suite 2250, Memphis, TN 38118–2482, Phone (901) 322–8185, *Jamal.Stovall@faa.gov.* The application may be reviewed in person at this same location, by appointment.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the request to release property for disposal at Bowman Field, 700 Administration Drive, Louisville, KY 28208, under the provisions of 49 U.S.C. 47107(h)(2). The FAA determined that the request to release property at Bowman Field (LOU) submitted by the Sponsor meets the procedural requirements of the Federal Aviation Administration and the release of these properties does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this notice.

The request consists of the following:

The Property consists of approximately 8.1 acres and is located in the northeastern portion of the Airport and is labeled on the current Exhibit A as Parcel 74. The Property is physically located north of Runway 6/24 and west of Cannons Ln. and includes a portion of the Interstate 64 Exit Ramp which was constructed in 1967.

This request will release this property from federal obligations. This action is taken under the provisions of 49 U.S.C. 47107(h)(2).

Any person may inspect the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT.**

In addition, any person may, upon request, inspect the request, notice and other documents germane to the request in person at Bowman Field (LOU).

Issued in Memphis, Tennessee on December 14, 2021.

Duane Leland Johnson,

Assistant Manager, Memphis Airports District Office, Southern Region.

[FR Doc. 2021–27698 Filed 12–21–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Public Workshop on Corporate Average Fuel Economy Reporting Templates

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notification of public workshop.

SUMMARY: This notice announces that the National Highway Traffic Safety Administration (NHTSA) will hold a workshop to present three new compliance reporting templates for the

Corporate Average Fuel Economy (CAFE) Program. The workshop will provide a demonstration of the use of the templates which automobile manufacturers will use to provide NHTSA required compliance data. Vehicle manufacturers and other interested parties who wish to attend the workshops are asked to pre-register (the workshop will be held virtually) and are invited to submit reporting questions and credit related technical issues to be considered for discussion during the workshops. Attendance requires electronic registration and confirmation in advance and is free.

DATES: NHTSA will hold the public workshop on Jan 27th, 2022, from 8:30 a.m. to 4 p.m., Eastern Standard Time. Log-in on the day of the workshop will begin at 8:30 a.m.

ADDRESSES: The public workshop will be held virtually. Attendees should register online at *https://register.gotowebinar.com/register/9085063788931066894,* by January 13, 2022. Registration is necessary for all attendees. Please provide your name, email address, and affiliation. Interested parties wishing to submit comments or questions should submit their questions when they register. NHTSA will attempt to address those submissions as a part of the workshop. The Agency may also attempt to answer any questions that come up after January 13th, to the extent possible during the workshop. NHTSA also intends to publish FAQs on the templates following the workshop, which may also incorporate questions received during registration.

FOR FURTHER INFORMATION CONTACT: If you have questions about registering or connecting to the public workshop, please contact NHTSA staff at *NHTSA.Communication@dot.gov* or Chris LaMance at (202) 366–9525. For any legal questions, contact Michael Kuppersmith at *michael.kuppersmith@dot.gov* or (202) 366–9957. For questions concerning the workshop discussions contact Maurice Hicks at *Maurice.Hicks@dot.gov* or (202) 366–5289.

SUPPLEMENTARY INFORMATION: 49 CFR part 537, ''Automotive Fuel Economy Report,'' requires manufacturers to provide early model year projections on automobiles demonstrating how they intend to comply with CAFE standards. The regulation requires manufacturers to submit a pre-model year report by December 31st before the model year and a mid-model year report by July 31st of the model year. When NHTSA received and reviewed manufacturers' projection reports for MYs 2013 through 2015, the agency observed that most did not conform to the requirements specified in Part 537. In a 2015 notice of proposed rulemaking, NHTSA proposed to amend Part 537 to require a new data format for manufacturers' CAFE projection reporting template.[1] However, NHTSA did not adopt the proposed data format from the 2015 proposed rule after receiving adverse comments from manufacturers.[2]

After identifying the sources of manufacturers' concerns, in the April 2020 CAFE final rule, NHTSA established a new standardized template for reporting PMY and MMY information, as specified in 49 CFR 537.7(b) and (c), as well as for the supplementary information required by 49 CFR 537.8. The new template allows manufacturers to build out the required confidential versions of CAFE reports specified in 49 CFR part 537 and to produce automatically the required non-confidential versions by clicking a button within the template. The standardized template assists manufacturers in providing the agency with all necessary data, thereby helping manufacturers to ensure they are complying with CAFE regulations. The template organizes the required data in a manner consistent with NHTSA and EPA regulations and simplifies the reporting process by incorporating standardized responses consistent with those provided to EPA. The template collects the relevant data, calculates intermediate and final values in accordance with EPA and NHTSA methodologies, and aggregates all the final values required by NHTSA regulations in a single summary worksheet. Thus, NHTSA believes that the standardized template will benefit both the agency and manufacturers by helping to avoid reporting errors, such as data omissions and miscalculations, and will ultimately simplify and streamline reporting. NHTSA requires that manufacturers use the standardized Projection Reporting Template for all PMY, MMY, and supplementary CAFE reports beginning in MY 2023. NHTSA also modified its existing compliance database to accept and import the standardized template and automatically aggregate manufacturers' data. This allows NHTSA to execute its regulatory obligations to the public more efficiently and effectively. Overall, the template helps to ensure compliance with data requirements under EPCA/EISA and drastically reduce the industry and government's burden for reporting in accordance with the Paperwork Reduction Act.[3] The reporting template is available for download through the PIC located at: *https://one.nhtsa.gov/cafe_pic/home*—see ''Light Duty Templates: NHTSA CAFE Projections Reporting Template''.

To reduce the burden on all parties, encourage compliance, and facilitate quicker NHTSA credit transaction approval, in April 2020 final rule, NHTSA added a new template to standardize the information parties submit to the agency to request a credit transaction. Often manufacturers inconsistently submit the information required by 49 CFR 536.8, making it difficult for NHTSA to process transactions. The credit transaction template is a simple spreadsheet that credit holders and trading parties fill out. When completed, parties are able to click a button on the spreadsheet to generate a credit transaction summary, and if applicable, credit trade confirmation, the latter of which needs to be signed by both trading entities. The credit trade confirmation serves as an acknowledgement that the parties have agreed to trade credits. The completed credit trade summary, and a PDF copy of the signed trade confirmation must be submitted to NHTSA. Using the Credit Transaction Template simplifies the credit trading process for OVSC and manufacturers, and helps to ensure that trading parties follow the requirements for a credit transaction found in 49 CFR 536.8(a).[4] Additionally, the credit trade confirmation includes an acknowledgement of the ''error or fraud'' provisions in 49 CFR 536.8(f)–(g), and the finality provision of 49 CFR 536.8(g). The credit transaction template is available for download through the PIC located at: *https://one.nhtsa.gov/cafe_pic/home*—see ''Light Duty Templates: NHTSA CAFE Credit Transaction Template''.

Finally, NHTSA adopted requirements in the 2020 final rule requiring manufacturers to submit the costs of all credit trade contracts to the agency starting September 1, 2022. NHTSA intends to use this information to determine the true cost of compliance for all manufacturers. This information would allow NHTSA to better assess the impact of its regulations on the industry and provide more insightful information in developing future rulemakings. NHTSA also adopted requirements allowing manufacturers to submit the information confidentially, in

[1] 80 FR 40540 (Jul. 13, 2015).

[2] 81 FR 73958 (Oct. 25, 2016).

[3] 44 U.S.C. 3501 *et seq.*

[4] Submitting a properly completed template and accompanying transaction letter will satisfy the trading requirements in 49 CFR part 536.

accordance with 49 CFR part 512.[5] This confidential information would be held by secure electronic means in NHTSA's database systems. As for public information, NHTSA intends to use the information to provide more credit reports on the PIC such as aggregated credit transactions or data comparable to the credit information which EPA makes available to the public.

In response to NHTSA new templates, manufacturers have identified errors and offered suggestions for improvements. As a result, in the August 2021 CAFE NPRM,[6] NHTSA proposed changes to its new reporting and credit templates as well as established a new standardized template to collect information on the monetary and non-monetary costs of credit trades. NHTSA has identified a series of monetary and non-monetary factors which it believes to be important to the costs associated with credit trading in the CAFE program which predicated the development of its new credit value template.[7] The agency believes this information will allow for a better assessment of the true costs of compliance. NHTSA further notes that greater government oversight is needed over the CAFE credit market and it needs to understand the full range of complexity in transactions, monetary and non-monetary, in addition to the range of partnerships and cooperative agreements between credit account holders—which may impact the price of credit trades.[8] NHTSA proposed that manufacturers should start using both credit templates starting September 1, 2022. Note, the credit value template is available for download through the PIC located at: *https://one.nhtsa.gov/cafe_pic/home*—see ''Light Duty Templates: NHTSA CAFE Credit Value Reporting Template''.

In the August 2021 rulemaking, NHTSA also committed to demonstrate its templates through a workshop designed to give manufacturers an open forum for communicating directly with the agency. This notice satisfies that obligation and announces the details of the workshop.

Public Workshop Agenda

8:30–9 a.m.—Welcome and Introductory Remarks
9–10a.m.—PMY/MMY Reporting Template (Part 1)
10–11 a.m.—PMY/MMY Reporting Template (Part 2-Examples)
11–11:30 a.m.—Credit Transaction Template
11:30 a.m.–12 p.m. Public Information Center Overview
12–1 p.m.—Lunch Break
1–2 p.m.—Credit Value Reporting Template
2–3 p.m.—FAQ Session
3–4 p.m.—CAFE 101—CAFE Compliance Process Overview

Participation in Virtual Public Hearing

Please note that NHTSA is deviating from its typical approach for public hearings. Because of current CDC recommendations, as well as state and local orders for social distancing to limit the spread of COVID–19, NHTSA is not holding in-person public meetings at this time.

If you do not receive your confirmation email(s), or have further questions about this hearing, please email *NHTSA.Communication@dot.gov*. NHTSA is committed to providing equal access to this event for all participants. People with disabilities who need additional accommodations should send a request to *NHTSA.Communication@dot.gov* no later than January 13th, 2022.

Issued in Washington, DC, under authority delegated in 49 CFR 1.95.

Anne L. Collins,

Associate Administrator for Enforcement.

[FR Doc. 2021–27722 Filed 12–21–21; 8:45 am]

BILLING CODE 4910–59–P

[5] *See also* 49 U.S.C. 32910(c).

[6] *https://www.regulations.gov/document/NHTSA-2021-0053-0012/comment.*

[7] UCS, Detailed Comments, NHTSA–2018–0067–12039; Jason Schwartz, Detailed Comments, NHTSA–2018–0067–12162.

[8] Honda, Detailed Comments, NHTSA–2018–0067–11819.

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing updates to the identifying information of one or more persons currently included on the Specially Designated Nationals and Blocked Persons List (SDN List). All property and interests in property subject to U.S. jurisdiction of these persons remain blocked, and U.S. persons are generally prohibited from engaging in transactions with them. In addition, OFAC is publishing updates to the identifying information of one or more persons currently included in the Non-SDN Chinese Military-Industrial Complex Companies List. OFAC is also publishing updates to the identifying information of one person currently included in the Sectoral Sanctions Identifications List.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2480; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Actions

A. On December 1, 2021, OFAC updated the entry on the SDN List for the following person, whose property and interests in property subject to U.S. jurisdiction continue to be blocked pursuant to Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism'' and Executive Order 13582 of August 17, 2011, ''Blocking Property of the Government of Syria and Prohibiting Certain Transactions with Respect to Syria.''

Individual

1. SHUKR, Fu'ad (a.k.a. CHAKAR, Fouad Ali; a.k.a. CHAKAR, Fu'ad; a.k.a. ''CHAKAR, Al-Hajj Mohsin''), Harat Hurayk, Lebanon; Ozai, Lebanon; Al-Firdaws Building, Al-'Arid Street, Haret Hreik, Lebanon; Damascus, Syria; DOB 15 Apr 1961; alt. DOB 1962; POB An Nabi Shit, Ba'labakk, Biqa' Valley, Lebanon; alt. POB Beirut, Lebanon; nationality Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Gender Male; Passport RL2418369 (Lebanon) (individual) [SDGT] [SYRIA] (Linked To: HIZBALLAH).

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SHUKR, Fu'ad (a.k.a. CHAKAR, Fouad Ali; a.k.a. CHAKAR, Fu'ad; a.k.a. ''CHAKAR, Al-Hajj Mohsin''), Harat Hurayk, Lebanon; Ozai, Lebanon; Al-Firdaws Building, Al-'Arid Street, Haret Hreik, Lebanon; Damascus, Syria; DOB 15 Apr 1961; alt. DOB 1962; POB An Nabi Shit, Ba'labakk, Biqa' Valley, Lebanon; alt. POB Beirut, Lebanon; nationality Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Gender Male; Passport RL2418369 (Lebanon) (individual) [SDGT] [SYRIA] (Linked To: HIZBALLAH).

B. On December 16, 2021, OFAC updated the entries on the SDN List for the following persons, whose property and interests in property subject to U.S. jurisdiction continue to be blocked under the relevant sanctions authorities listed below.

Individuals

1. AHMED, Abubaker Shariff (a.k.a. AHMED, Abubakar; a.k.a. AHMED, Abubaker Shariff; a.k.a. AHMED, Sheikh Abubakar; a.k.a. MAKABURI; a.k.a. SHARIFF, Abu Makaburi; a.k.a. SHARIFF, Abubaker), Majengo Area, Mombasa, Kenya; DOB 1962; alt. DOB 1967; POB Kenya; citizen Kenya (individual) [SOMALIA].

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AHMED, Abubaker Shariff (a.k.a. AHMED, Abubakar; a.k.a. AHMED, Sheikh Abubakar; a.k.a. MAKABURI; a.k.a. SHARIFF, Abu Makaburi; a.k.a. SHARIFF, Abubaker), Majengo Area, Mombasa, Kenya; DOB 1962; alt. DOB 1967; POB Kenya; citizen Kenya (individual) [SOMALIA].

Blocked pursuant to one or more of the criteria set forth in Executive Order 13536 of April 12, 2010, ''Blocking Property of Certain Persons Contributing to the Conflict in Somalia.''

2. AL–HUMAYQANI, 'Abd al-Wahhab Muhammad 'Abd al-Rahman (a.k.a. AL–HAMAYQANI, 'Abd al-Wahab; a.k.a. AL–HAMAYQANI, 'Abd al-Wahab Muhammad 'Abd al-Rahman; a.k.a. AL–HAMIQANI, 'Abd al-Wahab; a.k.a. AL–HAMIQANI, 'Abd al-Wahab al-Qawi; a.k.a. AL–HAMIQANI, 'Abd al-Wahab Muhammad 'Abd al-Rahman; a.k.a. AL–HAMIQANI, 'Abdul-Wahab Mohammed Abdul-Rahman; a.k.a. AL–HUMAIKANI, Abdul-Wahab Mohammed Abdul Rahman; a.k.a. AL–HUMAIKANI, Abdulwahhab Mohammed Abdulrahman; a.k.a. AL–HUMAIQANI, 'Abdul-Wahab Mohammed Abdul-Rahman; a.k.a. AL–HUMAIQANI, 'Abdul-Wahab Mohammed Abdul-Rahman; a.k.a. AL–HUMAYQANI, Abd al-Wahab; a.k.a. AL–HUMAYQANI, 'Abd al-Wahab al-Qawi; a.k.a. AL–HUMAYQANI, 'Abd al-Wahab Muhammad 'Abd al-Rahman; a.k.a. AL–HUMAYQANI, 'Abd al-Wahhab Muhammad 'Abd al-Rahim; a.k.a. AL–HUMAYQANI, Abdul Wahab; a.k.a. AL–HUMAYQANI, 'Abdul-Wahab Mohammed Abdul-Rahman; a.k.a. AL–HUMIQANI, 'Abd al-Wahab; a.k.a. ''ABU AYED''; a.k.a. ''ABU AYID''), Yemen; DOB 04 Aug 1972; POB al-Zahir, al-Bayda', Yemen; Passport 03902409 (Yemen) issued 13 Jun 2010 expires 13 Jun 2016; alt. Passport 01772281 (Yemen); Personal ID Card 1987853 (Yemen) (individual) [SDGT].

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AL–HUMAYQANI, 'Abd al-Wahhab Muhammad 'Abd al-Rahman (a.k.a. AL–HAMAYQANI, 'Abd al-Wahab; a.k.a. AL–HAMAYQANI, 'Abd al-Wahab Muhammad 'Abd al-Rahman; a.k.a. AL–HAMIQANI, 'Abd al-Wahab; a.k.a. AL–HAMIQANI, 'Abd al-Wahab al-Qawi; a.k.a. AL–HAMIQANI, 'Abd al-Wahab Muhammad 'Abd al-Rahman; a.k.a. AL–HAMIQANI, 'Abdul-Wahab Mohammed Abdul-Rahman; a.k.a. AL–HUMAIKANI, Abdul-Wahab Mohammed Abdul Rahman; a.k.a. AL–HUMAIKANI, Abdulwahhab Mohammed Abdulrahman; a.k.a. AL–HUMAIQANI, 'Abdul-Wahab Mohammed Abdul-Rahman; a.k.a. AL–HUMAIQANI, 'Abdul-Wahab Mohammed Abdul-Rahman; a.k.a. AL–HUMAYQANI, Abd al-Wahab; a.k.a. AL–HUMAYQANI, 'Abd al-Wahab al-Qawi; a.k.a. AL–HUMAYQANI, 'Abd al-Wahab Muhammad 'Abd al-Rahman; a.k.a. AL–HUMAYQANI, 'Abd al-Wahhab Muhammad 'Abd al-Rahim; a.k.a. AL–HUMAYQANI, Abdul Wahab; a.k.a. AL–HUMAYQANI, 'Abdul-Wahab Mohammed Abdul-Rahman; a.k.a. AL–HUMIQANI, 'Abd al-Wahab; a.k.a. ''ABU AYED''; a.k.a. ''ABU AYID''), Yemen; DOB 04 Aug 1972; POB al-Zahir, al-Bayda', Yemen; Passport 03902409 (Yemen) issued 13 Jun 2010 expires 13 Jun 2016; alt. Passport 01772281 (Yemen); Personal ID Card 1987853 (Yemen) (individual) [SDGT].

Blocked pursuant to one or more of the criteria set forth in Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism.''

3. BEHZAD, Ahmad Abdulla Mohammad Abdulla (a.k.a. BAHZAD, Ahmad Abdullah Mohamed Abdullah; a.k.a. BEHZAD BSTAKI, Ahmad Abdullah Mohammed Abdullah; a.k.a. BEHZAD, Abdulla Mohd Abdulla; a.k.a. BEHZAD, Ahmad Abdulla Mohammad A; a.k.a. BEHZAD, Ahmad Abdulla Mohammad Abdulla; a.k.a. BEHZAD, Ahmad Abdulla Mohd Abdulla; a.k.a. BEHZAD, Ahmed Abdullah; a.k.a. ''ABDULLA MOHAMAD ABDULLA MOHAMAD BEHZAD''; a.k.a. ''ABDULLAH AHMAD ABDULLAH MOHAMAD BAHZAD''; a.k.a. ''ABDULLAH MOHAMMED ABDULLAH BAHZAD''; a.k.a. ''AHMED BEHZA''; a.k.a. ''AHMED MOHAMMED ABDULLAH''; a.k.a. ''MOHAMMED ABDULLAH MOHAMMED BAHZAD''), c/o SHAHBAZ KHAN GENERAL TRADING LLC, Dubai, United Arab Emirates; c/o FMF GENERAL TRADING LLC, Dubai, United Arab Emirates; Dubai, United Arab Emirates; Sharjah, United Arab Emirates; DOB 02 Nov 1971; POB Dubai, United Arab Emirates; citizen United Arab Emirates; Passport A1042768 (United Arab Emirates); alt. Passport A0269124 (United Arab Emirates) (individual) [SDNTK].

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BEHZAD, Ahmad Abdulla Mohammad Abdulla (a.k.a. BAHZAD, Ahmad Abdullah Mohamed Abdullah; a.k.a. BEHZAD BSTAKI, Ahmad Abdullah Mohammed Abdullah; a.k.a. BEHZAD, Abdulla Mohd Abdulla; a.k.a. BEHZAD, Ahmad Abdulla Mohammad A; a.k.a. BEHZAD, Ahmad Abdulla Mohd Abdulla; a.k.a. BEHZAD, Ahmed Abdullah; a.k.a. ''ABDULLA MOHAMAD ABDULLA MOHAMAD BEHZAD''; a.k.a. ''ABDULLAH AHMAD ABDULLAH MOHAMAD BAHZAD''; a.k.a. ''ABDULLAH MOHAMMED ABDULLAH BAHZAD''; a.k.a. ''AHMED BEHZA''; a.k.a. ''AHMED MOHAMMED ABDULLAH''; a.k.a. ''MOHAMMED ABDULLAH MOHAMMED BAHZAD''), c/o SHAHBAZ KHAN GENERAL TRADING LLC, Dubai, United Arab Emirates; c/o FMF GENERAL TRADING LLC, Dubai, United Arab Emirates; Dubai, United Arab Emirates; Sharjah, United Arab Emirates; DOB 02 Nov 1971; POB Dubai, United Arab Emirates; citizen United Arab Emirates; Passport A1042768 (United Arab Emirates); alt. Passport A0269124 (United Arab Emirates) (individual) [SDNTK].

Blocked pursuant to one or more of the criteria under the Foreign Narcotics Kingpin Designation Act, 21 U.S.C. 1904(b).

4. GADDAFI, Mutassim (a.k.a. AL–GADDAFI, Mutassim; a.k.a. AL–QADHAFI, Mutassim; a.k.a. ELKADDAFI, Mutassim; a.k.a. EL–QADDAFI, Mutassim; a.k.a. GADDAFI, Mutassim; a.k.a. GADHAFI, Mutassim Billah; a.k.a. GHADAFFI, Mutassim; a.k.a. GHATHAFI, Mutassim; a.k.a. QADDAFI, Mutassim; a.k.a. QADHAFI, Mutassim); DOB 1975 (individual) [LIBYA2].

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GADDAFI, Mutassim (a.k.a. AL–GADDAFI, Mutassim; a.k.a. AL–QADHAFI, Mutassim; a.k.a. ELKADDAFI, Mutassim; a.k.a. EL–QADDAFI, Mutassim; a.k.a. GADHAFI, Mutassim Billah; a.k.a. GHADAFFI, Mutassim; a.k.a. GHATHAFI, Mutassim; a.k.a. QADDAFI, Mutassim; a.k.a. QADHAFI, Mutassim); DOB 1975 (individual) [LIBYA2].

Blocked pursuant to one or more of the criteria set forth in Executive Order 13566 of February 25, 2011, ''Blocking Property and Prohibiting Certain Transactions Related to Libya.''

5. KIM, Kyong Ok (a.k.a. KIM, Kyong Ok), Korea, North; DOB 01 Jan 1937 to 31 Dec 1938; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214; First Vice Director of the Organization and Guidance Department (individual) [DPRK2].

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KIM, Kyong Ok, Korea, North; DOB 01 Jan 1937 to 31 Dec 1938; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214; First Vice Director of the Organization and Guidance Department (individual) [DPRK2].

Blocked pursuant to one or more of the criteria set forth in Executive Order 13687 of January 2, 2015, ''Imposing Additional Sanctions With Respect to North Korea.''

Entity

1. TARIQ ABU SHANAB EST. FOR TRADE & COMMERCE (a.k.a. ABU SHANAB METALS ESTABLISHMENT; a.k.a. AMIN ABU SHANAB & SONS CO.; a.k.a. AMIN ABU SHANAB AND SONS CO.; a.k.a. AMIN ABU SHANAB AND SONS CO.; a.k.a. SHANAB METALS ESTABLISHMENT; a.k.a. TARIQ ABU SHANAB EST.; a.k.a. TARIQ ABU SHANAB EST. FOR TRADE AND COMMERCE; a.k.a. TARIQ ABU SHANAB METALS ESTABLISHMENT), Musherfeh, P.O. Box 766, Zarka, Jordan [IRAQ2].

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TARIQ ABU SHANAB EST. FOR TRADE & COMMERCE (a.k.a. ABU SHANAB METALS ESTABLISHMENT; a.k.a. AMIN ABU SHANAB & SONS CO.; a.k.a. AMIN ABU SHANAB AND SONS CO.; a.k.a. SHANAB METALS ESTABLISHMENT; a.k.a. TARIQ ABU SHANAB EST.; a.k.a. TARIQ ABU

SHANAB EST. FOR TRADE AND COMMERCE; a.k.a. TARIQ ABU SHANAB METALS ESTABLISHMENT), Musherfeh, P.O. Box 766, Zarka, Jordan [IRAQ2].

Blocked pursuant to one or more of the criteria set forth in Executive Order 13315 of August 28, 2003, ''Blocking Property of the Former Iraqi Regime, Its Senior Officials and Their Family Members, and Taking Certain Other Actions'' and Executive Order 13350 of July 29, 2004, ''Termination of Emergency Declared in Executive Order 12722 With Respect to Iraq and Modification of Executive Order 13290, Executive Order 13303, and Executive Order 13315.''

C. On December 16, 2021, OFAC updated the entries on the Non-SDN Chinese Military-Industrial Complex Companies List for the following persons, who remain subject to the prohibitions in Executive Order 13959 of November 12, 2020, ''Addressing the Threat From Securities Investments That Finance Communist Chinese Military Companies,'' as amended by Executive Order 14032 of June 3, 2021, ''Addressing the Threat from Securities Investments that Finance Certain Companies of the People's Republic of China.''

Entities

1. CHINA SOUTH INDUSTRIES GROUP CORPORATION (a.k.a. CHINA SOUTH INDUSTRIES GROUP CO., LTD.; a.k.a. CHINA SOUTH INDUSTRIES GROUP CORPORATION; a.k.a. ''CSGC''; a.k.a. ''CSIGC''), No. 46, Sanlihe Road, Xicheng District, Beijing 100032, China; No. 10 Yard, Chedaogou, Haidian District, Beijing 100089, China; Issuer Name China South Industries Group Co., Ltd.; alt. Issuer Name China South Industries Group Corporation; ISIN CND10000KTG5; alt. ISIN CND10000K5V9; alt. ISIN CND10000KTF7; alt. ISIN CND10000GGC9; alt. ISIN CND10000K0B2; alt. ISIN CND10000GGD7; alt. ISIN CND10000KTD2; alt. ISIN CND10000K5W7; alt. ISIN CND10001TRP9; alt. ISIN CND10001TRQ7; Target Type Private Company; Effective Date (CMIC) 02 Aug 2021; Purchase/Sales For Divestment Date (CMIC) 03 Jun 2022; Listing Date (CMIC) 03 Jun 2021; Unified Social Credit Code (USCC) 91110000710924929L (China) [CMIC–EO13959].

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CHINA SOUTH INDUSTRIES GROUP CORPORATION (a.k.a. CHINA SOUTH INDUSTRIES GROUP CO., LTD.; a.k.a. ''CSGC''; a.k.a. ''CSIGC''), No. 46, Sanlihe Road, Xicheng District, Beijing 100032, China; No. 10 Yard, Chedaogou, Haidian District, Beijing 100089, China; Issuer Name China South Industries Group Co., Ltd.; alt. Issuer Name China South Industries Group Corporation; ISIN CND10000KTG5; alt. ISIN CND10000K5V9; alt. ISIN CND10000KTF7; alt. ISIN CND10000GGC9; alt. ISIN CND10000K0B2; alt. ISIN CND10000GGD7; alt. ISIN CND10000KTD2; alt. ISIN CND10000K5W7; alt. ISIN CND10001TRP9; alt. ISIN CND10001TRQ7; Target Type Private Company; Effective Date (CMIC) 02 Aug 2021; Purchase/Sales For Divestment Date (CMIC) 03 Jun 2022; Listing Date (CMIC) 03 Jun 2021; Unified Social Credit Code (USCC) 91110000710924929L (China) [CMIC–EO13959].

2. CHINA NUCLEAR ENGINEERING CORPORATION LIMITED (a.k.a. CHINA NATIONAL ENGINEERING & CONSTRUCTION CORPORATION LIMITED; a.k.a. CHINA NUCLEAR ENGINEERING & CONSTRUCTION CORP LTD; a.k.a. CHINA NUCLEAR ENGINEERING CORPORATION LIMITED; a.k.a. ''CNEC''; a.k.a. ''CNECC''), No. 12 Chegongzhuang Avenue, Xicheng District, Beijing 100037, China; Equity Ticker 601611 CN; Issuer Name China Nuclear Engineering Corporation Limited; ISIN CNE100002896; alt. ISIN CND10003XJ14; Target Type Public Company; Effective Date (CMIC) 02 Aug 2021; Purchase/Sales For Divestment Date (CMIC) 03 Jun 2022; Listing Date (CMIC) 03 Jun 2021; Unified Social Credit Code (USCC) 91110000717828569P (China) [CMIC–EO13959].

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CHINA NUCLEAR ENGINEERING CORPORATION LIMITED (a.k.a. CHINA NATIONAL ENGINEERING & CONSTRUCTION CORPORATION LIMITED; a.k.a. CHINA NUCLEAR ENGINEERING & CONSTRUCTION CORP LTD; a.k.a. ''CNEC''; a.k.a. ''CNECC''), No. 12 Chegongzhuang Avenue, Xicheng District, Beijing 100037, China; Equity Ticker 601611 CN; Issuer Name China Nuclear Engineering Corporation Limited; ISIN CNE100002896; alt. ISIN CND10003XJ14; Target Type Public Company; Effective Date (CMIC) 02 Aug 2021; Purchase/Sales For Divestment Date (CMIC) 03 Jun 2022; Listing Date (CMIC) 03 Jun 2021; Unified Social Credit Code (USCC) 91110000717828569P (China) [CMIC–EO13959].

D. On December 16, 2021, OFAC updated the entry on the Sectoral Sanctions Identification List for the following person, who remains subject to the prohibitions in Executive Order 13662 of March 20, 2014, ''Blocking Property of Additional Persons Contributing to the Situation in Ukraine.''

Entity

1. OJSC NOVOKUYBYSHEV REFINERY (a.k.a. NOVOKUIBYSHEVSK REFINERY; a.k.a. OJSC NOVOKUYBYSHEV REFINERY), Novokuibyshevsk, Samara region 446207, Russia; Email Address *sekr@nknpz.rosneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; alt. Executive Order 13662 Directive Determination—Subject to Directive 4; For more information on directives, please visit the following link: *http://www.treasury.gov/resourcecenter/sanctions/Programs/Pages/ukraine.aspx#directives.* [UKRAINE–EO13662] (Linked To: OPEN JOINT–STOCK COMPANY ROSNEFT OIL COMPANY).

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OJSC NOVOKUYBYSHEV REFINERY (a.k.a. NOVOKUIBYSHEVSK REFINERY), Novokuibyshevsk, Samara region 446207, Russia; Email Address *sekr@nknpz.rosneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; alt. Executive Order 13662 Directive Determination—Subject to Directive 4; For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives.* [UKRAINE–EO13662] (Linked To: OPEN JOINT–STOCK COMPANY ROSNEFT OIL COMPANY).

Dated: December 16, 2021.

Andrea M. Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2021–27695 Filed 12–21–21; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Non-SDN Chinese Military-Industrial Complex Companies List (NS–CMIC List). Any purchase or sale of any publicly traded securities, or any publicly traded securities that are derivative of such securities or are designed to provide investment exposure to such securities, of any of these persons, by any United States person in violation of the Order is prohibited.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The NS–CMIC List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Actions

On December 16, 2021, OFAC determined that the following persons

are subject to the prohibitions set forth in E.O. 13959, as amended.

Entities

BILLING CODE 4810–AL–P

1. CLOUDWALK TECHNOLOGY CO., LTD. (Chinese Simplified: 云从科技集团股份有限公司) (a.k.a. "CLOUDWALK"), Room 501, No. 37, Jinlong Road, Nansha District, Guangzhou, Guangdong 511457, China; Building 11, Zhangjiang Artificial Intelligence Island, Chuanhe Road, Pudong New Area, Shanghai, China; Effective Date (CMIC) 14 Feb 2022; Purchase/Sales For Divestment Date (CMIC) 16 Dec 2022; Listing Date (CMIC) 16 Dec 2021; Unified Social Credit Code (USCC) 914401153314442716 (China) [CMIC-EO13959].

   Identified pursuant to section 1(a)(i) of E.O. 13959, as amended, for operating or having operated in the surveillance technology sector of the economy of the People's Republic of China (PRC).

2. DAWNING INFORMATION INDUSTRY CO., LTD (Chinese Simplified: 曙光信息产业股份有限公司) (a.k.a. "SUGON"), Zhongguancun Software Park, Sugon Building 36, 8, Dongbeiwang West Road, Haidian District, Beijing 100193, China; Equity Ticker 603019CN; Issuer Name Sugon Information Industry Co., Ltd.; ISIN CNE100001TW7; Effective Date (CMIC) 14 Feb 2022; Purchase/Sales For Divestment Date (CMIC) 16 Dec 2022; Listing Date (CMIC) 16 Dec 2021; Unified Social Credit Code (USCC) 91120000783342508F (China) [CMIC-EO13959].

   Identified pursuant to section 1(a)(i) of E.O. 13959, as amended, for operating or having operated in the surveillance technology sector of the economy of the PRC; and section 1(a)(ii) of E.O. 13959, as amended, for owning or controlling, directly or indirectly, a person who operates or has operated in the surveillance technology sector of the economy of the PRC.

3. LEON TECHNOLOGY COMPANY LIMITED (a.k.a. LEON TECHNOLOGY CO., LTD.; a.k.a. "LEON TECHNOLOGY"), High-Tech Zone, Century Pacific International Centre, 416, South Beijing Road, Urumqi 830000, China; Equity Ticker 300603 CN; Issuer Name Leon Technology Co., Ltd.; ISIN CNE100002Q17; Effective Date (CMIC) 14 Feb 2022; Purchase/Sales For Divestment Date (CMIC) 16 Dec 2022; Listing Date (CMIC) 16 Dec 2021; Unified Social Credit Code (USCC) 916501002999341738 (China) [CMIC-EO13959].

   Identified pursuant to section 1(a)(i) of E.O. 13959, as amended, for operating or having operated in the surveillance technology sector of the economy of the PRC.

4. MEGVII TECHNOLOGY LIMITED (Chinese Simplified: 旷视科技有限公司), PO Box 309, Ugland House, Grand Cayman KY1-1104, Cayman Islands; Block A, Raycom Infotech Park, No. 2 Kexueyuan South Road, Haidian District, Beijing, China; Effective Date (CMIC) 14 Feb 2022; Purchase/Sales For Divestment Date (CMIC) 16 Dec 2022; Listing Date (CMIC) 16 Dec 2021 [CMIC-EO13959].

   Identified pursuant to section 1(a)(i) of E.O. 13959, as amended, for operating or having operated in the surveillance technology sector of the economy of the PRC; and section 1(a)(ii) of E.O. 13959, as amended, for owning or controlling, directly or indirectly, a person who operates or has operated in the surveillance technology sector of the economy of the PRC.

5. NETPOSA TECHNOLOGIES LIMITED (a.k.a. NETPOSA; a.k.a. NETPOSA TECHNOLOGIES, LTD.), Wangjing Soho, 2nd Tower, 26th Floor, 1, Futong Avenue, Chaoyang District, Beijing 100102, China; Equity Ticker 300367 CN; Issuer Name NetPosa Technologies, Ltd.; ISIN CNE100001S40; Effective Date (CMIC) 14 Feb 2022; Purchase/Sales For Divestment Date (CMIC) 16 Dec 2022; Listing Date (CMIC) 16 Dec 2021; Unified Social Credit Code (USCC) 91110000721497432T (China) [CMIC-EO13959].

   Identified pursuant to section 1(a)(ii) of E.O. 13959, as amended, for owning or controlling, directly or indirectly, a person who operates or has operated in the surveillance technology sector of the economy of the PRC.

6. SZ DJI TECHNOLOGY CO., LTD. (Chinese Simplified: 深圳市大疆创新科技有限公司), 14 F, West Block of Skyworth Semiconductor Design Building, No. 18 Gaoxin South 4th Road, Nanshan District, Shenzhen, Guangdong 518057, China; Effective Date (CMIC) 14 Feb 2022; Purchase/Sales For Divestment Date (CMIC) 16 Dec 2022; Listing Date (CMIC) 16 Dec 2021; Unified Social Credit Code (USCC) 914403007954257495 (China) [CMIC-EO13959].

   Identified pursuant to section 1(a)(i) of E.O. 13959, as amended, for operating or having operated in the surveillance technology sector of the economy of the PRC.

7. XIAMEN MEIYA PICO INFORMATION CO., LTD., 2nd Phase of Xiamen Software Park, Meiya Pico Building, 12 Guanri Road, Xiamen 361008, China; Equity Ticker 300188 CN; Issuer Name Xiamen Meiya Pico Information Co., Ltd.; ISIN CNE100001120; Effective Date (CMIC) 14 Feb 2022; Purchase/Sales For Divestment Date (CMIC) 16 Dec 2022; Listing Date (CMIC) 16 Dec 2021; Unified Social Credit Code (USCC) 91350200705420347R (China) [CMIC-EO13959].

   Identified pursuant to section 1(a)(i) of E.O. 13959, as amended, for operating or having operated in the surveillance technology sector of the economy of the PRC.

8. YITU LIMITED (Chinese Simplified: 依图科技有限公司), Suite #4-210, Governors Square, 23 Lime Tree Bay Avenue, PO Box 23211, Grand Cayman KY1-1209, Cayman Islands; Effective Date (CMIC) 14 Feb 2022; Purchase/Sales For Divestment Date (CMIC) 16 Dec 2022; Listing Date (CMIC) 16 Dec 2021 [CMIC-EO13959].

   Identified pursuant to section 1(a)(ii) of E.O. 13959, as amended, for owning or controlling, directly or indirectly, a person who operates or has operated in the surveillance technology sector of the economy of the PRC.

Dated: December 16, 2021.

Bradley T. Smith,

Deputy Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2021–27642 Filed 12–21–21; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Internal Revenue Service Exempt Organization Forms: 990, 990–BL, 990–EZ, 990–N, 990–PF, 990–T, 990–W, 990 SCH E, 990 SCH I, 990 SCH M, 990 SCH D, 990 SCH F, 990 SCH H, 990 SCH J, 990 SCH K, 990 SCH R, 990/990–EZ SCH A, 990/990–EZ SCH C, 990/990–EZ SCH G, 990/990–EZ SCH L, 990/990–EZ SCH N, 990/990–EZ SCH O, 990/990–EZ/990–PF SCH B, 1023, 1023–EZ, 1023–Interactive, 1024, 1024–A, 1028, 1120–POL, 4720, 5578, 5884–C, 6069, 6497, 8038, 8038–B, 8038–CP, 8038–G, 8038–GC, 8038–R, 8038–T, 8038–TC, 8282, 8328, 8330, 8453–E.O., 8453–X, 8718, 8868, 8870, 8871, 8872, 8879–E.O., 8886–T, 8899 and Related Attachments

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before January 21, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Molly Stasko by emailing *PRA@treasury.gov,* calling (202) 622–8922, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION: Approximately 73 percent of all tax-exempt organization returns are prepared using software by the taxpayer or with preparer assistance. Section 3101 of the Taxpayer First Act, Public Law 116–25, requires all tax-exempt organizations to electronically file statements or returns in the Form 990 series or Form 8872.

These are forms used by tax-exempt organizations. These include Forms 990, 990–BL, 990–EZ, 990–N, 990–PF, 990–T, 990–W, and related forms and schedules tax-exempt organizations attach to their tax returns (see Appendix-A to this notice). In addition, there are numerous regulations, notices and Treasury Decisions that are covered by the burden estimate provided in this notice. See Appendix B for a list.

Taxpayer Compliance Burden

Tax compliance burden is defined as the time and money taxpayers spend to comply with their tax filing responsibilities. Time-related activities include recordkeeping, tax planning, gathering tax materials, learning about the law and what you need to do, and completing and submitting the return. Out-of-pocket costs include expenses such as purchasing tax software, paying a third-party preparer, and printing and postage. Tax compliance burden does not include a taxpayer's tax liability, economic inefficiencies caused by sub-optimal choices created to tax deductions or credits, or psychological costs.

PRA Submission to OMB

Title: U.S. Tax-Exempt Income Tax Return.

OMB Control Number: 1545–0047.

Form Numbers: Forms 990, 990–BL, 990–EZ, 990–N, 990–PF, 990–T, 990–W, 1023, 1023–EZ, 1024, 1024–A, 1028, 1120–POL, 4720, 5578, 5884–C, 5884–D, 6069, 6497, 7203, 8038, 8038–B, 8038–CP, 8038–G, 8038–GC, 8038–R, 8038–T, 8038–TC, 8282, 8328, 8330, 8453–TE., 8453–X, 8718, 8868, 8870, 8871, 8872, 8879–TE, 8886–T, 8899 and all other related forms, schedules, and attachments.

Abstract: These forms and schedules are used to determine that tax-exempt organizations fulfill the operating conditions within the limitations of their tax exemption. The data is also used for general statistical purposes.

Current Actions: There have been changes in regulatory guidance related to various forms approved under this approval package during the past year. There has been additions and removals of forms included in this approval package. It is anticipated that these changes will have an impact on the overall burden and cost estimates requested for this approval package.

Type of Review: Revision of currently approved collection.

Affected Public: Tax-Exempt Organizations.

Estimated Number of Respondents: 1,740,100.

Total Estimated Time: 58,220,000 hours.

Total Estimated Out-of-Pocket Costs: $1,726,900,000.

Total Estimated Monetized Burden: $4,811,900,000.

Note: Amounts below are estimates for FY 2022. Reported time and cost burdens are national averages and do not necessarily reflect a ''typical'' case. Most taxpayers experience lower than average burden, with taxpayer burden varying considerably by taxpayer type. Totals may not add due to rounding.

FISCAL YEAR 2022 ICB ESTIMATES FOR FORM 990 SERIES OF RETURNS AND RELATED FORMS AND SCHEDULES

	FY 21		FY 22
Number of Taxpayers	1,599,000	141,100	1,740,100
Burden in Hours	52,470,000	5,750,000	58,220,000
Burden in Dollars	$1,473,100,000	$253,800,000	$1,726,900,000
Monetized Total Burden	$4,084,100,000	$727,800,000	$4,811,900,000

Note: FY22 is most recent approved burden estimates for OMB Control Number 1545–0047.

FISCAL YEAR 2022 FORM 990 SERIES TAX COMPLIANCE COST ESTIMATES

	Form 990	Form 990–EZ	Form 990–PF	Form 990–T	Form 990–N
Projections of the Number of Returns to be Filed with IRS	330,400	260,200	131,800	263,400	754,300

FISCAL YEAR 2022 FORM 990 SERIES TAX COMPLIANCE COST ESTIMATES—Continued

	Form 990	Form 990–EZ	Form 990–PF	Form 990–T	Form 990–N
Estimated Average Total Time (Hours)	85	45	47	40	2
Estimated Average Total Out-of-Pocket Costs	$2,700	$600	$2,100	$1,500	$10
Estimated Average Total Monetized Burden	$8,200	$1,300	$4,000	$4,600	$30
Estimated Total Time (Hours)	28,000,000	11,760,000	6,140,000	10,660,000	1,660,000
Estimated Total Out-of-Pocket Costs	$903,100,000	$147,500,000	$272,000,000	$397,200,000	$7,100,000
Estimated Total Monetized Burden	$2,719,300,000	$331,900,000	$529,800,000	$1,204,800,000	$26,100,000

Note: Amounts above are for FY2022. Reported time and cost burdens are national averages and do not necessarily reflect a ''typical'' case. Most taxpayers experience lower than average burden, with taxpayer burden varying considerably by taxpayer type. Totals may not add due to rounding.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: December 17, 2021.

Molly Stasko,

Treasury PRA Clearance Officer.

Appendix A

Number	Title	Description
990		Return of Organization Exempt From Income Tax.
990	BL	Information and Initial Excise Tax Return for Black Lung Benefit Trusts and Certain Related Persons.
990	EZ	Short Form Return of Organization Exempt From Income Tax.
990	N	Electronic Notice (e-Postcard) for Tax-Exempt Organizations Not Required to File Form 990 or Form 990EZ.
990	PF	Return of Private Foundation or Section 4947(a)(1) Trust Treated as Private Foundation.
990	T	Exempt Organization Business Income Tax Return and Proxy Tax.
990	T SCH A	Unrelated Business Taxable Income From an Unrelated Trade or Business.
990	T SCH M	UBTI Calculation Form Unrelated Trade or Business.
990	W	Estimated Tax on Unrelated Business Taxable Income for Tax-Exempt Organizations.
990, 990–EZ, 990–PF	SCH B	Schedule of Contributors.
990 OR 990–EZ	SCH A	Public Charity Status and Public Support.
990 OR 990–EZ	SCH C	Political Campaign and Lobbying Activities.
990 OR 990–EZ	SCH E	Schools.
990 OR 990–EZ	SCH G	Supplemental Information Regarding Fundraising or Gaming Activities.
990 OR 990–EZ	SCH L	Transactions With Interested Persons.
990 OR 990–EZ	SCH N	Liquidation, Termination, Dissolution, or Significant Disposition of Assets.
990 OR 990–EZ	SCH O	Supplemental Information to Form 990 or 990–EZ.
990	SCH D	Supplemental Financial Statements.
990	SCH F	Statement of Activities Outside the United States.
990	SCH H	Hospitals.
990	SCH I	Grants and Other Assistance to Organizations, Governments, and Individuals in the United States.
990	SCH J	Compensation Information.
990	SCH K	Supplemental Information on Tax-Exempt Bonds.
990	SCH M	Noncash Contributions.
990	SCH R	Related Organizations and Unrelated Partnerships.
1023		Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code.
1023	EZ	Streamlined Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code.
1024		Application for Recognition of Exemption Under Section 501(a).
1024	A	Application for Recognition of Exemption Under Section 501(c)(4) of the Internal Revenue Code.
1028		Application for Recognition of Exemption Under Section 521 of the Internal Revenue Code.
1120	POL	U.S. Income Tax Return for Certain Political Organizations.
4720		Return of Certain Excise Taxes Under Chapters 41 and 42 of the Internal Revenue Code.
5578		Annual Certification of Racial Nondiscrimination for a Private School Exempt From Federal Income Tax.
5884	C	Work Opportunity Credit for Qualified Tax-Exempt Organizations Hiring Qualified Veterans.
5884	D	Employee Retention Credit for Certain Tax-Exempt Organizations Affected by Qualified Disasters.

Number	Title	Description
6069		Return of Excise Tax on Excess Contributions to Black Lung Benefit Trust Under Section 4953 and Computation of Section 192 Deduction.
6497		Information Return of Nontaxable Energy Grants or Subsidized Energy Financing.
7203		S Corporation Shareholder Stock and Debt Basis Limitations.
8038		Information Return for Tax-Exempt Private Activity Bond Issues.
8038	B	Information Return for Build America Bonds and Recovery Zone Economic Development Bonds.
8038	CP	Return for Credit Payments to Issuers of Qualified Bonds.
8038	CP Schedule A	Specified Tax Credit Bonds Interest Limit Computation.
8038	G	Information Return for Government Purpose Tax-Exempt Bond Issues.
8038	GC	Consolidated Information Return for Small Tax-Exempt Government Bond Issues.
8038	R	Request for Recovery of Overpayment Under Arbitrage Rebate Provisions.
8038	T	Arbitrage Rebate and Penalty in Lieu of Arbitrage Rebate.
8038	TC	Information Return for Tax Credit and Specified Tax Credit Bonds as the result of the new Hire bill..
8282		Donee Information Return.
8328		Carry forward Election of Unused Private Activity Bond Volume.
8330		Issuer's Quarterly Information Return for Mortgage Credit Certificates (MCCs).
8453	EO	Exempt Organization Declaration and Signature for Electronic Filing.
8453	TE	Tax Exempt Entity Declaration and Signature for Electronic Filing.
8453	X	Political Organization Declaration for Electronic Filing of Notice of Section 527 Status.
8718		User Fee for Exempt Organization Determination Letter Request.
8868		Application for Automatic Extension of Time To File an Exempt Organization Return.
8870		Information Return for Transfers Associated With Certain Personal Benefit Contracts.
8871		Political Organization Notice of Section 527 Status.
8872		Political Organization Report of Contributions and Expenditures.
8879	EO	IRS e-file Signature Authorization for an Exempt Organization.
8879	TE	IRS e-file Signature Authorization for a Tax Exempt Entity.
8886	T	Disclosure by Tax-Exempt Entity Regarding Prohibited Tax Shelter Transaction.
8899		Notice of Income From Donated Intellectual Property.
8976		Notice of Intent to Operate Under Section 501(c)(4).

Appendix B

Title/Description

EE–111–80 (TD 8019–Final) Public Inspection of Exempt Organization Return
TD 8033 (TEMP) Tax Exempt Entity Leasing (REG–209274–85)
Revenue Procedure 98–19, Exceptions to the notice and reporting requirements of section 6033(e)(1) and the tax imposed by section 6033(e)(2)
REG–246256–96 (Final TD 8978) Excise Taxes on Excess Benefit Transactions
T.D. 8861, Private Foundation Disclosure Rules
Notice 2006–109—Interim Guidance Regarding Supporting Organizations and Donor Advised Funds
Disclosure by taxable party to the tax-exempt entity
Reinstatement and Retroactive Reinstatement for Reasonable Cause (Rev. Proc. 2014–11) and Transitional Relief for Small Organizations (Notice 2011–43) under IRC § 6033(j)
TD 8086—Election for $10 Million Limitation on Exempt Small Issues of Industrial Development Bonds; Supplemental Capital Expenditure Statements (LR–185–84 Final)
Arbitrage Restrictions and Guidance on Issue Price Definition for Tax Exempt Bonds
TD 8712 (Final), Definition of Private Activity Bonds; TD 9741, General Allocation and Accounting Regulations Under Section 141; Remedial Actions for Tax-Exempt Bonds
FI–28–96 (Final) Arbitrage Restrictions on Tax-Exempt Bonds
REG–121475–03 (TD 9495–Final) Qualified Zone Academy Bonds: Obligations of States and Political Subdivisions
Notice 2009–26, Build America Bonds and Direct Payment Subsidy Implementation
Notice 2012–48: Tribal Economic Development Bonds
TD 7925 7952—Indian Tribal Governments Treated As States For Certain Purposes
Revenue Procedure 97–15, Section 103—Remedial Payment Closing Agreement Program
EE–12–78 Non-Bank Trustees
TD 9099 Disclosure of Relative Values of Optional Forms of Benefit
EE–147–87 (Final) Qualified Separate Lines of Business
T.D. 8619 (Final) (EE–43–92l) Direct Rollovers and 20-percent Withholding Upon Eligible Rollover Distributions from Qualified Plans
T.D. 8802—Certain Asset Transfers to a Tax-Exempt Entity
PS–100–88(TD8540) (Final) Valuation Tables
Revenue Procedure 2017–4
TD 8769 (Final)—(REG–107644–97) Permitted Elimination of Pre-retirement Optional Forms of Benefit
Notice 97–45, Highly Compensated Employee Definition
Compensation Deferred Under Eligible Deferred Compensation Plans (TD 9075)
TD 8816 (Final) Roth IRAs
REG–108639–99 (Final) Retirement Plans; Cash or Deferred Arrangements Under Section 401(k) and Matching Contributions or Employee Contributions Under Section 401(m); TD 9169
Revenue Ruling 2000–35 Automatic Enrollment in Section 403(b) Plans
Notice 2002–27—IRA Required Minimum Distribution Reporting
TD 9142 (Final), Deemed IRAs in Qualified Retirement Plans (REG–157302–02)
REG–146459–05—TD 9324 (Final) Designated Roth Contributions Under Section 402A
TD 9467 (REG–139236–07) and Notice 2014–53
TD 9641—Suspension or Reduction of Safe Harbor Contributions (REG–115699–09)
Waiver of 60-Day Rollover Requirement
TD 7898—Employers Qualified Educational Assistance Programs
TD 8864 (Final); EE–63–88 (Final and temp regulations) Taxation of Fringe Benefits and Exclusions From Gross Income for Certain Fringe Benefits; IA–140–86 (Temporary) Fringe Benefits
TD 8073 (Temporary Regulations)—Effective Dates and Other Issues Arising Under the Employee Benefit Provisions of the Tax Reform Act of 1984
REG–209484–87 (TD 8814 final) Federal Insurance Contributions Act (FICA) Taxation of Amounts Under Employee Benefit Plans
REG–164754–01 (FINAL) Split-Dollar Life Insurance Arrangements
T.D. 9088, Compensatory Stock Options Under Section 482
T.D. 9083—Golden Parachute Payments
Revenue Procedure 2014–55, Election Procedures and Information Reporting with Respect to Interests in Certain Canadian Retirement Plans
Substitute Mortality Tables for Single Employer Defined Benefit Plans
T.D. 8802—Certain Asset Transfers to a Tax-Exempt Entity

REG–113572–99 (TD 8933) Qualified Transportation Fringe Benefits
Revenue Procedure 2016–1, Rulings and determination letters—26 CFR 601–.201
26 CFR 31.6001–1 Records in general; 26 CFR 31.6001–2 Additional Records under FICA; 26 CFR 31.6001–3, Additional records under Railroad Retirement Tax Act; 26 CFR 31.6001–5 Additional records
IA–44–94 (Final) Deductibility, Substantiation, and Disclosure of Certain Charitable Contributions
Notice 2005–41, Guidance Regarding Qualified Intellectual Property Contributions
De Minimis Error Safe Harbor to the I.R.C. §§ 6721 and 6722 Penalties
Substantiation of Charitable Contributions—TD 8002
Qualified Conservation Contributions
TD 7852—Registration Requirements with Respect to Debt Obligations (NPRM, LR–255–82)
Notice 2007–70—Charitable Contributions of Certain Motor Vehicles, Boats, and Airplanes. Reporting requirements under Sec. 170(f)(12)(D)
TD 8124—Time and Manner of Making Certain Elections Under the Tax Reform Act of 1986
EE–14–81 (NPRM) Deductions and Reductions in Earnings and Profits (or Accumulated Profits) With Respect to Certain Foreign Deferred Compensation Plans Maintained by Certain Foreign Corporations
TD 9724—Summary of Benefits and Coverage Disclosures
TD 7845—Inspection of Applications for Tax Exemption and Applications for Determination Letters for Pension and Other Plans (Final)
REG–130477–00; REG–130481–00 (TD 8987—Final), Required Distributions From Retirement Plans
EE–175–86 (Final) Certain Cash or Deferred Arrangements and Employee and Matching Contributions under Employee Plans: REG–108639–99 (NPRM) Retirement Plans; Cash or Deferred Arrangements
Change in Minimum Funding Method (Rev. Proc. 2000–41)
REG–109481–99 (TD 9076—Final) Special Rules Under Section 417(a)(7) for Written Explanations Provided by Qualified Retirement Plans After Annuity Starting Dates
TD 9472 (Final)—Notice Requirements for Certain Pension Plan Amendments Significantly Reducing the Rate of Future Benefit Accrual
T.D. 9079—Ten or More Employer Plan Compliance Information
Waivers of Minimum Funding Standards—Revenue Procedure 2004–15
Election of Alternative Deficit Reduction Contribution and Plan Amendments
Revenue Procedure 2010–52, Extension of the Amortization Period for Plan Sponsor of a Multiemployer Pension Plan
Designated Roth Contributions to Cash or Deferred Arrangements Under Section 401(k)
Notice 2005–40, Election to Defer Net Experience Loss in a Multiemployer Plan
Notice 2006–107—Diversification Requirements for Qualified Defined Contribution Plans
Holding Publicly Traded Employer Securities
Revised Regulations Concerning Section 403(b) Tax-Sheltered Annuity Contracts—TD 9340 (Final)
TD 9447 (Final) Automatic Contribution Arrangements
NOT–2009–31—Election and Notice Procedures for Multiemployer Plans under Sections 204 and 205 of WRERA
Relief and Guidance on Corrections of Certain Failures of a Nonqualified Deferred Compensation Plan to Comply with § 409A(a)
Suspension of Benefits Under the Multiemployer Pension Reform Act of 2014; Administration of Multiemployer Plan Participant Vote
REG–209823–96 (TD 8791)—Guidance Regarding Charitable Remainder Trusts and Special Valuation Rules for Transfer of Interests in Trusts

[FR Doc. 2021–27745 Filed 12–21–21; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; U.S. Income Tax Return Forms for Individual Taxpayers

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before January 21, 2022 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Spencer W. Clark by emailing *PRA@treasury.gov,* calling (202) 927–5331, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

Title: U.S. Income Tax Return for Individual Taxpayers.

OMB Control Number: 1545–0074.

Forms: Form 1040 and affiliated return forms.

Type of Review: Revision of a currently approved collection.

Description: IRC sections 6011 & 6012 of the Internal Revenue Code require individuals to prepare and file income tax returns annually. These forms and related schedules are used by individuals to report their income subject to tax and compute their correct tax liability. This information collection request (ICR) covers the actual reporting burden associated with preparing and submitting the prescribed return forms, by individuals required to file Form 1040 and any of its' affiliated forms as explained in the attached table.

There have been changes in regulatory guidance related to various forms approved under this approval package during the past year. There have been additions and removals of forms included in this approval package. A summary of the burden on respondents is given below and fuller discussion is available in the supporting documents submitted to OMB.

Affected Public: Individuals or Households, Farms.

Estimated Number of Respondents: 163,600,000.

Frequency of Response: Annually.

Estimated Total Number of Annual Responses: 163,600,000.

Estimated Time per Response: 12 hours, 31 minutes.

Estimated Total Annual Burden Hours: 2,048,000,000.

Authority: 44 U.S.C. 3501 et seq.

Dated: December 16, 2021.

Spencer W. Clark,

Treasury PRA Clearance Officer.

ESTIMATED AVERAGE TAXPAYER BURDEN FOR INDIVIDUALS FILING A 1040 BY ACTIVITY

Primary form filed or type of taxpayer	Percentage of returns	Time burden					Money burden	
		Average time burden (Hours) ***					Average cost (dollars)	Total monetized burden (dollars)
		Total time	Record keeping	Tax planning	Form completion and submission	All other		
All Taxpayers	100	13	6	2	4	1	$240	$460
Type of Taxpayer								
Nonbusiness **	72	9	3	1	3	1	160	290
Business **	28	22	12	4	5	2	470	900

Note: This table does not include 1040NR, 1040NR–EZ, and 1040X filers.
Detail may not add to total due to rounding. Dollars rounded to the nearest $10.
** A ''business'' filer files one or more of the following with Form 1040: Schedule C, C–EZ, E, F, Form 2106, or 2106–EZ. A ''non-business'' filer does not file any of these schedules or forms with Form 1040.
*** Times are rounded to nearest hour.

The following table shows the average burden estimate for individual entities by total positive income. Total positive income is defined as the sum of all positive income amounts reported on the return.

TAXPAYER BURDEN STATISTICS BY TOTAL POSITIVE INCOME QUINTILE

All filers	Average time (hours)	Average out-of-pocket costs	Average total monetized burden
Total positive income quintiles:			
0 to 20	8.1	$79	$144
20 to 40	11.2	130	237
40 to 60	11.6	172	318
60 to 80	12.8	241	455
80 to 100	19.2	600	1,161
Wage and Investment Filers			
Total Income Decile:			
0 to 20	7.2	70	$127
20 to 40	9.6	117	212
40 to 60	9.0	150	273
60 to 80	8.9	198	370
80 to 100	10.1	333	658
Self Employed Filers			
Total Income Decile:			
0 to 20	12.9	126	$228
20 to 40	19.2	190	358
40 to 60	20.9	250	475
60 to 80	21.4	333	642
80 to 100	27.1	833	1,599

[FR Doc. 2021–27704 Filed 12–21–21; 8:45 am]
BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Tribal and Indian Affairs, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2., that the Advisory Committee on Tribal and Indian Affairs will virtually meet on January 25, 26, and 27, 2022 via our using Zoom platform. The meeting session will begin and end as follows:

Date	Time
January 25, 2022	1:00 p.m.–5:00 p.m. Eastern Standard Time (EST).
January 26, 2022	1:00 p.m.–5:00 p.m. EST.
January 27, 2022	1:00 p.m.–5:00 p.m. EST.

These meeting sessions are open to the public. To access the meetings, please use the following registration link: *https://www.zoomgov.com/meeting/register/vJItcO2hpzMsG9dbmWEES3Gw8mE2rJMry8U.* Participants need to register for the meeting then will receive a link to access it each day.

The purpose of the Committee is to advise the Secretary on all matters relating to Indian Tribes, tribal organizations, Native Hawaiian organizations, and Native American Veterans. This includes advising the Secretary on the administration of healthcare services and benefits to American Indians and Alaska Native Veterans; thereby assessing those needs and whether VA is meeting them. The Advisory Committee on Tribal and Indian Affairs is a newly formed FACA Committee. The Committee provides advice and guidance to the Secretary of Veterans Affairs on all matters relating to Indian tribes, tribal organizations, Native Hawaiian organizations, and Native American Veterans.

On January 25, 2022, the agenda will include opening remarks and VA welcoming remarks by Secretary of Veterans Affairs; Committee member introductions; briefing by VA Advisory Committee Management Office; remarks and briefing updates by other VA officials. On January 26, 2022, the Committee will receive briefing updates from VA officials on rural health; community care; COVID–19 efforts; tribal HUD/VASH, homeless; Indian Health Service and Urban Indian Health; and the Vet Center program. On January 27, 2022, the Committee will receive briefing updates from the Veterans Benefits Administration; Native American Journey Map; National Cemetery Administration, Office of General Counsel-Tribal Veteran Representative Experience Project; and Smithsonian Native American Veterans Memorial. The Committee will receive public comment from those public members who have provided a written summary. The Committee will hold open discussion on topics relevant to the Committee and address follow-up and action items including dates for next meeting.

Individuals who speak are invited to submit a 1–2 page summary of their comments no later than January 14, 2022 for inclusion in the office meeting record. Members of the public may also submit written statements for the Committee's review to Mr. David Clay Ward, at *David.Ward@va.gov.* Any member of the public seeking additional information should contact Mr. David Clay Ward at 202–461–7445.

Dated: December 16, 2021.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2021–27640 Filed 12–21–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Joint Biomedical Laboratory Research and Development and Clinical Science Research and Development Services Scientific Merit Review Board, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Federal Advisory Committee Act, 5 U.S.C. App.2, that a meeting of the Joint Biomedical Laboratory Research and Development and Clinical Science Research and Development Services Scientific Merit Review Board (JBL/CS SMRB) will be held Tuesday, January 11, 2022, via WebEx. The meeting will begin at 3:00 p.m. and end at 5:00 p.m. ET. The meeting will have an open session from 3:00 p.m. until 3:30 p.m. and a closed session from 3:30 p.m. until 5:00 p.m.

The purpose of the Board is to provide expert review of the scientific quality, budget, safety and mission-relevance of investigator-initiated research applications submitted for VA merit review consideration and to offer advice for research program officials on program priorities and policies.

The purpose of the open session is to meet with the JBL/CS Service Directors to discuss the overall policies and process for scientific review, as well as disseminate information among the Board members regarding the VA research priorities.

The purpose of the closed session is to provide recommendations on the scientific quality, budget, safety and mission relevance of investigator-initiated research applications submitted for VA merit review evaluation. Applications submitted for review include various medical specialties within the general areas of biomedical, behavioral and clinical science research. The JBL/CS SMRB meeting will be closed to the public for the review, discussion and evaluation of initial and renewal research applications, which involve reference to staff and consultant critiques of research applications. Discussions will deal with scientific merit of each application and qualifications of personnel conducting the studies, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Additionally, premature disclosure of research information could significantly obstruct implementation of proposed agency action regarding the research applications. As provided by subsection 10(d) of Public Law 92–463, as amended by Public Law 94–409, closing the subcommittee meetings is in accordance with Title 5 U.S.C. 552b(c)(6) and (9)(B).

Members of the public who wish to attend the open JBL/CS SMRB meeting should join via WebEx. Meeting number (access code): 2760 282 3977. Meeting password: n4JDgxm5R*3.

Meeting link: *https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=m3d6d42bf7c6a4b70cbfe35618b111e6a.*

Those who would like to submit written comments for the open session, or obtain a copy of the minutes from the closed subcommittee meetings and rosters of the subcommittee members, should contact Michael Burgio, Ph.D., Designated Federal Officer (14RD) Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, at 202–603–4667 or at *Michael.Burgio@va.gov.*

Dated: December 17, 2021.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2021–27765 Filed 12–21–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Veterans Health Administration (VHA), Department of Veterans Affairs (VA).

ACTION: Notice of a modified system of records.

SUMMARY: As required by the Privacy Act of 1974, notice is hereby given that the Department of Veterans Affairs (VA) is modifying the system of records entitled ''VHA Corporate Data Warehouses-VA'' (172VA10A7) as set forth in the **Federal Register**. VA is modifying the system of records by revising the System Number; System Manager; Purposes of the System; Categories of Records in the System; Record Source Categories; Policies and Practices for Storage of Records; Physical, Procedural and Administrative Safeguards; Record Access Procedure; Notification Procedure; and Appendix. VA is republishing the system notice in its entirety.

DATES: Comments on this modified system of records must be received no later than 30 days after date of publication in the **Federal Register**. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by VA, the modified system of records will become effective a minimum of 30 days after date of publication in the **Federal Register.** If VA receives public comments, VA shall review the comments to determine whether any changes to the notice are necessary.

ADDRESSES: Comments may be submitted through *www.Regulations.gov* or mailed to VA Privacy Service, 810 Vermont Avenue NW, (005R1A), Washington, DC 20420. Comments should indicate that they are submitted in response to ''VHA Corporate Data Warehouses-VA'' (172VA10A7). Comments received will be available at *regulations.gov* for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: Stephania Griffin, VHA Privacy Officer,

Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420; telephone number (704) 245–2492 (Note: not a toll-free number); *Stephania.Griffin@va.gov.*

SUPPLEMENTARY INFORMATION: The System Number is being updated from 172VA10A7 to 172VA10 to reflect the current VHA organizational routing symbol.

The System Manager is being modified to change Assistant Deputy Under Secretary for Health Informatics to the Chief Health Informatics Officer.

Record Access Procedure and Notification Procedure are being modified to change 10A7 to 105HIG.

The Purpose of the System is being modified to include, the system may perform calculations and derive data using machine learning, natural language processing, and other artificial intelligence tools to create additional data that is validated, stored, and then made available to system users for the other purposes described within this section.

Categories of Records in the System is being modified to change Virtual Lifetime Electronic Record (VLER)-VA (168VA10P2) to Health Information Exchange—VA (168VA005). Number 13 is being added to include personal medical device data, *e.g.* glucometers and step counters. Being added is Number 14, Data derived from the above via calculations, machine learning, automated natural language processing, and other artificial intelligence tools, and in addition, may include manually entered data confirming derived data results.

The Record Source Categories is being modified to add VA electronic health record system and State Agencies. In addition, an example of a Federal Agency in the form of the Centers for Disease Control (CDC) and the following VA systems of records, namely, Patient Medical Records—VA (24VA10A7); Patient National Databases—VA (121VA10A7) and from Health Information Exchange—VA (168VA005); and Revenue Program Billing and Collection Records—VA (114VA10).

Policies and Practices for Storage of Records is being modified to include Austin Information Technology Center and the VA Enterprise Cloud.

Physical, Procedural and Administrative Safeguards is being modified to include Number 6, VA Enterprise Cloud data storage conforms to security protocols as stipulated in VA Directives 6500 and 6517. Access control standards are stipulated in specific agreements with cloud vendors to restrict and monitor access.

VA Appendix A is being modified to include VA Enterprise Cloud, Microsoft Azure Data Lake and VA Common Operating Picture, Palantir Foundry, both are located at participating servers in the United States.

The Report of Intent to Modify a System of Records Notice and an advance copy of the system notice have been sent to the appropriate Congressional committees and to the Director of the Office of Management and Budget (OMB) as required by the Privacy Act of 1974 and guidelines issued by OMB, December 12, 2000.

Signing Authority

The Senior Agency Official for Privacy, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Neil C. Evans, M.D., Chief Officer, Connected Care, Performing the Delegable Duties of the Assistant Secretary for Information and Technology and Chief Information Officer, approved this document on November 15, 2021 for publication.

Dated: December 17, 2021.

Amy L. Rose,

Program Analyst, VA Privacy Service, Office of Information Security, Office of Information and Technology, Department of Veterans Affairs.

SYSTEM NAME AND NUMBER:

''VHA Corporate Data Warehouses—VA'' (172VA10).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are located in VA National Data Centers and contracted data centers listed in Appendix A.

SYSTEM MANAGER(S):

Officials responsible for policies and procedures: Charles Hume, Chief Health Informatics Officer (105), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420. Telephone number (202) 461–5834 (Note: Not a toll-free number); *Charles.Hume@va.gov.*

Officials maintaining this system of records: John Quinn, Director, National Data Systems (105HIG), Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772. Telephone number (512) 326–6188 (Note: Not a toll-free number); *John.Quinn@va.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 38, United States Code, Section 501.

PURPOSE(S) OF THE SYSTEM:

The records and information may be used for clinical decision support, mobile applications presenting patient data, statistical analysis to produce various management, workload tracking, and follow-up reports; to track and evaluate the ordering and delivery of equipment, services and patient care; for the planning, distribution and utilization of resources; to monitor the performance of Veterans Integrated Service Networks (VISNs); and to allocate clinical and administrative support to patient medical care. The data may be used for VA's extensive research programs in accordance with VA policy and to monitor for bio-terrorist activity. In addition, the data may be used to assist in workload allocation for patient treatment services including provider panel management, nursing care, clinic appointments, surgery, diagnostic and therapeutic procedures; to plan and schedule training activities for employees; for audits, reviews and investigations conducted by the Network Directors Office and VA Central Office; for quality assurance audits, reviews and investigations; for law enforcement investigations; for reporting purposes for Veterans Authorizations and Preferences and other Veterans Health Information Exchange (VHIE) reporting needs; and for health care operations and for personnel management, evaluation and employee ratings, and performance evaluations. The system may perform calculations and derive data using machine learning, natural language processing, and other artificial intelligence tools to create additional data that is validated, stored, and then made available to system users for the other purposes described within this section.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records contain information for all individuals:

(1) Receiving health care from VHA;

(2) receiving health care from Department of Defense (DoD);

(3) providing the health care;

(4) or working for VA or DoD.

Individuals encompass Veterans, members of the armed services, current and former employees, trainees, caregivers, contractors, sub-contractors, consultants, volunteers, and other individuals working collaboratively with VA.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records may include information related to:

1. Patient health record detailed information, including information from Patient Medical Records—VA (24VA10A7) and Patient National Databases—VA (121VA10A7) and from Health Information Exchange—VA (168VA005).

2. The record may include identifying information (*e.g.,* name, birth date, death date, admission date, discharge date, gender, Social Security number, taxpayer identification number); address information (*e.g.,* home and/or mailing address, home telephone number, emergency contact information such as name, address, telephone number, and relationship); prosthetic and sensory aid serial numbers; health record numbers; integration control numbers; information related to medical examination or treatment (*e.g.,* location of VA medical facility providing examination or treatment, treatment dates, medical conditions treated or noted on examination); information related to military service and status;

3. Patient health insurance information, including information from Revenue Program Billing and Collection Records—VA (114VA10);

4. Medical benefit and eligibility information, including information from Revenue Program Billing and Collection Records—VA (114VA10);

5. Patient aggregate workload data such as admissions, discharges, and outpatient visits; resource utilization such as laboratory tests, x-rays, pharmaceuticals, prosthetics and sensory aids; employee workload and productivity data;

6. Information on services or products needed in the provision of medical care (*i.e.,* pacemakers, prosthetics, dental implants, hearing aids, etc.); data collected may include vendor name and address, details about and/or evaluation of service or product, price/fee, dates purchased and delivered;

7. Health care practitioners' name, identification number and other demographic information related to position;

8. Employees salary and benefit information;

9. Financial Information from the Financial Management System;

10. Human resource information including employee grade, salary, and tour of duty;

11. Compensation and pension determinations, Veteran eligibility, and other information associated administering Veteran benefits by the Veterans Benefit Administration;

12. Data from other Federal agencies;

13. Patient self-entered data (online forms, personal medical device data, *e.g.,* data from glucometers and step counters);

14. Data derived from the above via calculations, machine learning, automated natural language processing, and other artificial intelligence tools, and in addition, may include manually entered data confirming derived data results.

RECORD SOURCE CATEGORIES:

Information in this system of records is provided by Veterans, VA employees, VA computer systems, Veterans Health Information Systems and Technology Architecture (VistA), VA electronic health record system, contracted computer systems, VA Medical Centers, VA Program Offices, VISNs, DoD, other Federal Agencies, such as the Centers for Disease Control (CDC), State Agencies, and non-VA health care providers, and the following VA systems of records, namely, Patient Medical Records—VA (24VA10A7); Patient National Databases—VA (121VA10A7) and from Health Information Exchange—VA (168VA005); and Revenue Program Billing and Collection Records—VA (114VA10).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

To the extent that records contained in the system include information protected by 45 CFR parts 160 and 164, *i.e.,* individually identifiable health information, and 38 U.S.C. 7332, *i.e.,* medical treatment information related to drug abuse, alcoholism or alcohol abuse, sickle cell anemia or infection with the human immunodeficiency virus, that information cannot be disclosed under a routine use unless there is also specific statutory authority in 38 U.S.C. 7332 and regulatory authority in 45 CFR parts 160 and 164 permitting disclosure.

1. VA may disclose information that, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, to a Federal, state, local, territorial, tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing such law. The disclosure of the names and addresses of Veterans and their dependents from VA records under this routine use must also comply with the provisions of 38 U.S.C. 5701.

2. Disclosure may be made to any source from which additional information is requested (to the extent necessary to identify the individual, inform the source of the purpose(s) of the request, and to identify the type of information requested), when necessary to obtain information relevant to an individual's eligibility, care history, or other benefits.

3. VA may disclose information to a Federal agency, except the United States Postal Service, or to the District of Columbia government, in response to its request, in connection with that agency's decision on the hiring, transfer, or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit by that agency.

4. VA may disclose information to a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

5. VA may disclose information to National Archives and Records Administration (NARA) in records management inspections conducted under 44 U.S.C. 2904 and 2906, or other functions authorized by laws and policies governing NARA operations and VA records management responsibilities.

6. VA may disclose information to the Department of Justice (DoJ), or in a proceeding before a court, adjudicative body, or other administrative body before which VA is authorized to appear, when:

(a) VA or any component thereof;

(b) Any VA employee in his or her official capacity;

(c) Any VA employee in his or her individual capacity where DoJ has agreed to represent the employee; or

(d) The United States, where VA determines that litigation is likely to affect the agency or any of its components,

is a party to such proceedings or has an interest in such proceedings, and VA determines that use of such records is relevant and necessary to the proceedings.

7. VA may disclose information to a Federal agency, a state or local government licensing board, the Federation of State Medical Boards, or a similar non-governmental entity that maintains records concerning individuals' employment histories or concerning the issuance, retention, or revocation of licenses, certifications, or registration necessary to practice an occupation, profession, or specialty, to inform such non-governmental entities about the health care practices of a

terminated, resigned, or retired health care employee whose professional health care activity so significantly failed to conform to generally accepted standards of professional medical practice as to raise reasonable concern for the health and safety of patients in the private sector or from another Federal Agency. These records may also be disclosed as part of an ongoing computer matching program to accomplish these purposes.

8. VA may disclose to a Federal agency, licensing boards or the appropriate non-government entities about the health care practices of a terminated, resigned or retired health care employee whose professional health care activity so significantly failed to conform to generally accepted standards of professional medical practice, as to raise reasonable concern for the health and safety of patients receiving medical care in the private sector or from another Federal agency.

9. VA may disclose information to survey teams of the Joint Commission, College of American Pathologists, American Association of Blood Banks, and similar national accreditation agencies or boards with which VA has a contract or agreement to conduct such reviews, as relevant and necessary for the purpose of program review or the seeking of accreditation or certification.

10. VA may disclose to a national certifying body which has the authority to make decisions concerning the issuance, retention or revocation of licenses, certifications or registrations required to practice a health care profession, when requested in writing by an investigator or supervisory official of the national certifying body for the purpose of making a decision concerning the issuance, retention or revocation of the license, certification or registration of a named health care professional.

11. VA may disclose information identified in 5 U.S.C. 7114(b)(4) to officials of labor organizations recognized under 5 U.S.C. Chapter 71 when relevant and necessary to their duties of exclusive representation concerning personnel policies, practices, and matters affecting working conditions.

12. VA may disclose to the VA-appointed representative of an employee of all notices, determinations, decisions, or other written communications issued to the employee in connection with an examination ordered by VA under medical evaluation (formerly fitness-for-duty) examination procedures or Department filed disability retirement procedures.

13. VA may disclose information to the Merit Systems Protection Board (MSPB) and the Office of the Special Counsel in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions promulgated in 5 U.S.C. 1205 and 1206, or as authorized by law.

14. VA may disclose information to the Equal Employment Opportunity Commission (EEOC) in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or other functions of the Commission as authorized by law.

15. VA may disclose information to the Federal Labor Relations Authority (FLRA) in connection with: The investigation and resolution of allegations of unfair labor practices, the resolution of exceptions to arbitration awards when a question of material fact is raised; matters before the Federal Service Impasses Panel; and the investigation of representation petitions and the conduct or supervision of representation elections.

16. VA may disclose information from this system to epidemiological and other research facilities approved by the Under Secretary for Health for research purposes determined to be necessary and proper, provided that the names and addresses of Veterans and their dependents will not be disclosed unless those names and addresses are first provided to VA by the facilities making the request.

17. VA may disclose the names and address(e of present or former members of the armed services or their beneficiaries: (1) To a nonprofit organization if the release is directly connected with the conduct of programs and the utilization of benefits under Title 38, and (2) to any criminal or civil law enforcement governmental agency or instrumentality charged under applicable law with the protection of the public health or safety, if a qualified representative of such organization, agency, or instrumentality has made a written request that such names or addresses be provided for a purpose authorized by law; provided that the records will not be used for any purpose other than that stated in the request and that organization, agency, or instrumentality is aware of the penalty provision of 38 U.S.C. 5701(f).

18. VA may disclose information to contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for VA, when reasonably necessary to accomplish an agency function related to the records.

19. VA may disclose to other Federal agencies to assist such agencies in preventing and detecting possible fraud or abuse by individuals in their operations and programs.

20. VA may disclose any information or records to appropriate agencies, entities, and persons when (1) VA suspects or has confirmed that there has been a breach of the system of records; (2) VA has determined that as a result of the suspected or confirmed breach there is a risk to individuals, VA (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, or persons is reasonably necessary to assist in connection with VA efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

21. VA may disclose information from this system to a Federal agency for the purpose of conducting research and data analysis to perform a statutory purpose of that Federal agency upon the prior written request of that agency, provided that there is legal authority under all applicable confidentiality statutes and regulations to provide the data and VA has determined prior to the disclosure that VA data handling requirements are satisfied.

22. VA may disclose information from this system of records to OMB for the performance of its statutory responsibilities for evaluating Federal programs.

23. VA may disclose this information to the DoD for joint ventures between the two Departments to promote improved patient care, better health care resource utilization, and formal research studies.

24. VA may disclose information from this system to another Federal agency or Federal entity, when VA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

25. VA may disclose relevant information to health plans, quality review and/or peer review organizations in connection with the audit of claims or other review activities to determine

quality of care or compliance with professionally accepted claims processing standards.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained on Storage Area Networks, both in Austin Information Technology Center and the VA Enterprise Cloud.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by name, Social Security number or other assigned identifiers of the individuals on whom they are maintained.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained and disposed of in accordance with General Records Schedule 20, item 4, which provides for deletion of data files when the agency determines that the files are no longer needed for administrative, legal, audit, or other operational purposes.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

1. Access to and use of VA data warehouses are limited to those persons whose official duties require such access, and the VA has established security procedures to ensure that access is appropriately limited. Information security officers and system data stewards review and authorize data access requests. VA regulates data warehouse access with security software that relies on network authentication. VA requires information security training to all staff and instructs staff on the responsibility each person has for safeguarding data confidentiality.

2. Physical access to computer rooms housing VA data warehouses are restricted to authorized staff and protected by a variety of security devices. Unauthorized employees, contractors, and other staff are not allowed in computer rooms.

3. Data transmissions between VA operational systems and VA data warehouses maintained by this system of record are protected by state-of-the-art telecommunication software and hardware. This may include firewalls, intrusion detection devices, encryption, and other security measures necessary to safeguard data as it travels across the VA Wide Area Network.

4. In most cases, copies of back-up computer files are maintained at off-site locations.

5. Access to Cerner Technology Centers is generally restricted to Cerner employees, contractors or associates with a Cerner issued ID badge and other security personnel cleared for access to the data center. Access to computer rooms housing Federal data, hence Federal enclave, is restricted to persons Federally cleared for Federal enclave access through electronic badge entry devices. All other persons, such as custodians, gaining access to Federal enclave are escorted.

6. VA Enterprise Cloud data storage conforms to security protocols as stipulated in VA Directives 6500 and 6517. Access control standards are stipulated in specific agreements with cloud vendors to restrict and monitor access.

RECORD ACCESS PROCEDURE:

Individuals seeking information regarding access to and contesting of records contained in this system of records may write to the Director of National Data Systems (105HIG), Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772. Inquiries should include the person's full name, Social Security number, location and dates of employment or location and dates of treatment, and their return address.

CONTESTING RECORD PROCEDURES:

(See Record Access Procedures above.)

NOTIFICATION PROCEDURE:

Individuals who wish to determine whether this system of records contains information about them should contact the Director of National Data Systems (105HIG), Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772. Inquiries should include the person's full name, Social Security number, location and dates of employment or location and dates of treatment, and their return address.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

Last full publication provided in 85 FR 52415 dated August 25, 2020.

VA Appendix A

Database name	Location
Corporate Data Warehouse	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
HealtheIntent at Cerner Technology Centers (CTC)	Primary Data Center, Kansas City, MO.√ Continuity of Operations/Disaster Recovery (COOP/DR) Data Center, Lee Summit, MO.
VA Common Operating Picture, Palantir Foundry	Participating servers in the United States.
VA Enterprise Cloud, Microsoft Azure Data Lake	Participating servers in the United States.
VA Informatics and Computing Infrastructure (VINCI)	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.

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Part II

Department of Justice

Drug Enforcement Administration

Gulf Med Pharmacy; Decision and Order; Notice

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 20–06]

Gulf Med Pharmacy; Decision and Order

On November 18, 2019, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OSC) to Gulf Med Pharmacy (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1. The OSC informed Respondent of the immediate suspension of its DEA Certificate of Registration Number FG6290061 (hereinafter, registration or COR) and proposed its revocation, the denial of any pending applications for renewal or modification of such registration, and the denial of any pending applications for additional DEA registrations pursuant to 21 U.S.C. 824(a)(4) and 823(f), because Respondent's ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(4) and 823(f)).

In response to the OSC, Respondent timely requested a hearing before an Administrative Law Judge. ALJ Ex. 2. The hearing in this matter was conducted from July 20–23, 2020, from August 12–13, 2020, and on August 20, 2020, at the DEA Hearing Facility in Arlington, Virginia, with the parties and their witnesses participating through video-teleconference. On November 25, 2020, Administrative Law Judge Mark M. Dowd (hereinafter, ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD). On December 15, 2020, Respondent filed exceptions to the Recommended Decision (hereinafter, Resp Exceptions), and on December 28, 2020, the Government filed a response to Respondent's exceptions (hereinafter, Gov Response). Having reviewed the entire record, I find Respondent's Exceptions without merit and I adopt the ALJ's Recommended Decision with minor modifications, as noted herein.*[A] I have addressed each of Respondent's Exceptions and I issue my final Order in this case following the Recommended Decision.

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge*[B] [1] [2] [3]

The issue ultimately to be adjudicated by the Administrator, with the assistance of this Recommended Decision, is whether the record as a whole establishes by a preponderance of the evidence that the DEA Certificate of Registration, No. FG6290061, issued to the Respondent should be revoked, and any pending applications for modification or renewal of the existing registration be denied, and any applications for additional registrations be denied, because its continued registration would be inconsistent with the public interest under 21 U.S.C. 823(f) and 824(a)(4).

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

The Allegations

The Respondent repeatedly issued prescriptions in violation of the minimum practice standards that govern the practice of pharmacy in Florida. ALJ Ex. 1 at ¶ 4. Specifically, from March 22, 2017, until at least August 8, 2019, Gulf Med Pharmacy repeatedly ignored obvious red flags of abuse or diversion and filled prescriptions without exercising its corresponding responsibility to ensure that they were issued for a legitimate medical purpose, in violation of federal and state law, including 21 CFR 1306.04(a) and 1306.06, and Fla. Admin. Code r. 64B16–27.800, .810, and .831. ALJ Ex. 1.

The Order to Show Cause also alleged the following:

1. Gulf Med Pharmacy is registered with the DEA to handle controlled substances in Schedules II–V under DEA COR No. FG6290061. Gulf Med Pharmacy's registered address is 4106 Del Prado Boulevard South, Cape Coral, Florida 33904. Gulf Med Pharmacy's COR expires by its own terms on September 30, 2022.

2. Gulf Med Pharmacy's DEA COR should be revoked and any pending application should be denied because Gulf Med Pharmacy has committed such acts as would render its registration inconsistent with the public interest under 21 U.S.C. 823(f). *See* 21 U.S.C. 824(a)(4). From March 22, 2017, until at least August 8, 2019, Gulf Med Pharmacy repeatedly ignored obvious red flags of abuse or diversion and filled prescriptions without exercising its corresponding responsibility to ensure that they were issued for a legitimate medical purpose, in violation of federal and state law. Given Gulf Med Pharmacy's longstanding and pervasive violations of legal requirements relating to the practice of pharmacy, Gulf Med Pharmacy's continued registration constitutes an ''imminent danger'' as that term is defined by 21 U.S.C. 824(d).

Legal Requirements

3. A ''prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice.'' 21 CFR 1306.06. Pharmacists at Gulf Med Pharmacy were permitted to fill prescriptions ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). Although ''[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription.'' *Id.* ''DEA has consistently interpreted this provision as prohibiting a pharmacist from filling a prescription for a controlled substance when [s]he either knows or has reason to know that the prescription was not written for a legitimate medical purpose.'' *Wheatland Pharmacy,* 78 FR 69441, 69445 (2013) (internal quotation marks and citation omitted, alteration in original).

4. In addition to complying with federal statutes and regulations, Gulf Med Pharmacy and its pharmacists also must comply with applicable Florida law. In particular, Florida pharmacists must ''review the patient record and each new and refill prescription presented for dispensing'' to identify, among other things, ''[o]ver-utilization or under-utilization,'' ''[t]herapeutic duplication,'' ''drug-drug interactions,'' and ''[c]linical abuse/misuse.'' Fla. Admin. Code Ann. r. 64B16–27.810(1). Upon recognizing any of these red flags of abuse or diversion, a Florida pharmacist ''shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the

*[A] I have made minor modifications to the RD. I have substituted initials or titles for the names of witnesses and patients to protect their privacy and I have made minor, nonsubstantive, grammatical changes and nonsubstantive, conforming edits. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have noted the edits with in brackets, and I have included specific descriptions of the modifications in the brackets or in footnotes marked with a letter and an asterisk. Within those brackets and footnotes, the use of the personal pronoun ''I'' refers to myself—the Administrator.

*[B] I have omitted the RD's discussion of the procedural history to avoid repetition with my introduction.

[1] [Footnote omitted, *see supra* n.*B.]

[2] [Footnote omitted, *see supra* n.*B.]

[3] [Footnote omitted, *see supra* n.*B.]

prescriber.'' *Id.* at r. 64B16–27.810(2). Florida pharmacies must also maintain a patient record system that documents resolution of red flags. *See id.* at r. 64B16–27.800. Finally, Florida pharmacists must comply with the standards for filling of controlled substance prescriptions. *See id.* at r. 64B16–27.831 (requiring pharmacists, among other things, to ''exercise[ ] sound professional judgment'' and ''attempt to work with the patient and the prescriber to assist in determining the validity of the prescription''). A Florida pharmacy's failure to comply with Florida's prescription review requirements also constitutes a violation of the federal Controlled Substances Act. *See, e.g., Trinity Pharmacy II,* 83 FR 7304, 7329 (2018) (''Thus, [Florida] pharmacists violate Florida law if they fail to identify and resolve the red flags that are part of the prospective drug use review set forth in Rule 64B16–27.810. And if they knowingly fill prescriptions without resolving these red flags during this review, then they violate their corresponding responsibility under 21 CFR 1306.04(a).'').

5. As explained in greater detail below, a Florida pharmacy expert retained by the DEA has reviewed numerous prescriptions filled by Gulf Med Pharmacy and has concluded that from March 22, 2017, until at least August 8, 2019, Gulf Med Pharmacy repeatedly filled prescriptions for controlled substances in violation of binding minimal standards that govern the practice of pharmacy in the State of Florida.

Cocktail Medications

6. As discussed above, both federal and Florida law require pharmacists to identify and resolve red flags of abuse and diversion. *See* paragraph 4, *supra.* One common red flag of drug abuse or diversion is when a practitioner prescribes (via one or more prescriptions) ''cocktail medications.'' Cocktail medications are combinations of controlled substances that are widely known to be abused or diverted, and when taken together, significantly increase a patient's risk of death or overdose. The DEA's expert reviewed numerous prescriptions filled by Gulf Med Pharmacy, as well as Gulf Med Pharmacy's patient profiles for the relevant patients, and concluded that Gulf Med Pharmacy regularly dispensed cocktail medications without addressing or resolving this red flag. For example, the DEA's expert noted that Gulf Med Pharmacy repeatedly dispensed high doses of opioids (in the form of hydromorphone, oxycodone, and morphine sulfate extended release) along with high doses of other central nervous system depressant medications, such as benzodiazepines (*e.g.,* alprazolam, clonazepam, or diazepam) or muscle relaxants (*e.g.,* carisoprodol). The DEA's expert opined that these controlled substances are dangerous when used in combination.

7. Gulf Med Pharmacy repeatedly dispensed ''cocktail medications'' without any indication that its pharmacists addressed or resolved the fact that such prescriptions present a risk of abuse or diversion. Examples of instances when Gulf Med Pharmacy dispensed cocktail medications in the face of unresolved red flags include the following:

a. On at least three occasions between May 22, 2019, and July 17, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician R.D. for Patient A.B. for 120 units of hydromorphone 8 mg, 60 units of morphine sulfate extended release 15 mg, and 30 units of diazepam 10 mg.

b. On at least four occasions between February 9, 2018, and July 17, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician A.N. for Patient B.Di. for 120 units of hydromorphone 8 mg, 60 units of morphine sulfate extended release 30 mg, and 60–90 units of alprazolam 1 mg.

c. On at least five occasions between December 28, 2018, and August 8, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician A.N. for Patient J.B. for 120 units of oxycodone 30 mg, 60 units of morphine sulfate extended release 30 mg, and 90 units of alprazolam 1 mg.

d. On at least four occasions between May 14, 2019, and August 6, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician M.L. for Patient R.R. for 120 units of hydromorphone 8 mg, 60 units of morphine sulfate extended release 60 mg, and 30 units of alprazolam 2 mg.

e. On at least four occasions between May 8, 2019, and August 5, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician M.L. for Patient B.Da. for 120 units of hydromorphone 8 mg, 30 units of morphine sulfate extended release 30 mg, and 30 units of alprazolam 2 mg. On February 12, 2018, Gulf Med Pharmacy also filled prescriptions written on the same day by another physician in the same practice—Physician D.P.—for Patient B.Da. for 150 units of hydromorphone 8 mg, 90 units of methadone 10 mg, and 30 units of alprazolam 2 mg.

8. According to the DEA's expert, the cocktail of an opioid, a benzodiazepine, and carisoprodol—commonly known as the ''Trinity'' cocktail—is a particularly serious red flag because that combination of controlled substances is highly dangerous and is widely known to be abused and/or diverted. Gulf Med Pharmacy repeatedly dispensed Trinity cocktail medications without any indication that its pharmacists addressed or resolved the fact that such prescriptions present a risk of abuse or diversion. Examples of instances when Gulf Med Pharmacy dispensed Trinity cocktail medications in the face of unresolved red flags include the following: Between May 30, 2019, and July 29, 2019, Gulf Med Pharmacy filled three sets of prescriptions from Physicians D.G. and F.M. for Patient J.R. for the Trinity cocktail. For each set of prescriptions, Physician F.M. prescribed Patient J.R. benzodiazepines and muscle relaxants; specifically, 30 units of temazepam 30 mg, 30–60 units of diazepam 5 mg, and 120 units of carisoprodol 350 mg. Meanwhile, Physician D.G. prescribed Patient J.R. opioids; specifically, 120 units of Norco (hydrocodone-acetaminophen) 5–325 mg, 120 units of Percocet (oxycodone-acetaminophen) 5–325 mg, and 120 units of Percocet 10–325 mg.

Improper Dosing for Pain Management

9. As noted above, both federal and Florida law require a pharmacist to identify and address red flags of drug abuse or diversion including over-utilization and under-utilization. *See* 21 CFR 1306.04(a); 21 CFR 1306.06; Fla. Admin. Code. Ann. r. 64B16–27.810. According to the DEA's expert, for a patient receiving treatment with both long-acting and short-acting opioids, the proper pharmacologic dosing for pain management is to use larger, scheduled doses of the long-acting opioid to control chronic pain with smaller, as-needed doses of the short-acting opioid for breakthrough pain. According to the DEA's expert, this method of dosing reduces the amount of the short-acting opioid that the patient must use in order to obtain the same level of pain control. In contrast, the DEA's expert opined that prescriptions that provide a larger daily dose of short-acting opioids, rather than long-acting opioids, do not make pharmacologic sense and thus are a red flag of drug abuse or diversion. From at least March 22, 2017, until at least August 8, 2019, Gulf Med Pharmacy repeatedly filled prescriptions for patients receiving a much greater daily morphine milligram equivalent dosage of short-acting opioids than long-acting opioids. The DEA's expert also noted that each of the short-acting or immediate release opioid prescriptions was scheduled four times a day or every

six hours, even though the patient was also prescribed a scheduled, long-acting opioid. The DEA's expert reviewed Gulf Med Pharmacy's patient profiles for several of these patients. In the expert's view, because these prescriptions were illogical from a pharmacological perspective, they therefore raised a red flag. The DEA's expert further opined that Gulf Med Pharmacy should have attempted to address or resolve this red flag of drug abuse or diversion prior to filling these prescriptions, but, on numerous occasions, its pharmacists failed to do so. Examples of Gulf Med Pharmacy filling such improper prescriptions include the following:

a. On at least 23 occasions between November 8, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for Patient A.B. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 60 units of morphine sulfate extended release 15 mg (equal to 30 mg of morphine per day).

b. On at least 28 occasions between April 21, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for Patient B.Di. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 60 units of morphine sulfate extended release 30 mg (equal to 60 mg of morphine per day).

c. On at least 18 occasions between January 10, 2018, and May 1, 2019, Gulf Med Pharmacy filled prescriptions for Patient S.K. for 110 units of immediate release hydromorphone 8 mg (equal to 125–128 mg of morphine per day), but only 60 units of morphine sulfate extended release 15 mg (equal to 30 mg of morphine per day).

d. On at least 27 occasions between March 22, 2017, and August 8, 2019, Gulf Med Pharmacy filled prescriptions for Patient J.B. for 108–120 units of immediate release oxycodone 30 mg (equal to 162–180 mg of morphine per day), but only 60 units of morphine sulfate extended release 30 mg (equal to 60 mg of morphine per day).

e. On at least eight occasions between October 2, 2018, and August 6, 2019, Gulf Med Pharmacy filled prescriptions for Patient R.R. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 28 units of morphine sulfate extended release 60 mg (equal to 60 mg of morphine per day).

f. On at least eight occasions between January 16, 2019, and August 5, 2019, Gulf Med Pharmacy filled prescriptions for Patient B.Da. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 30 units of morphine sulfate extended release 30 mg (equal to 30 mg of morphine per day).

Long Distances

10. Between October 25, 2017, and August 5, 2019, Gulf Med Pharmacy regularly filled controlled substance prescriptions for individuals who traveled an unusual distance to obtain their prescriptions. The DEA's expert opined that traveling long distances to obtain or fill a controlled substance is indicative of diversion and/or abuse and that such behavior is a red flag that must be addressed prior to dispensing. *See* 21 CFR 1306.04(a); 21 CFR 1306.06; Fla. Admin. Code. Ann. r. 64B16–27.810. Gulf Med Pharmacy did not do so, as illustrated by the following examples of prescriptions that it filled:

11. On at least 20 occasions between November 8, 2017, and July 17, 2017, Patient A.B. traveled 45 miles round trip to obtain prescriptions for hydromorphone 8 mg, morphine sulfate extended release 15 mg, and diazepam 10 mg, which Gulf Med Pharmacy filled.

12. On at least five occasions between October 25, 2017, and February 12, 2018, Patient B.Da. traveled over 48 miles round trip to obtain prescriptions for hydromorphone 8 mg and methadone 10 mg, which Gulf Med Pharmacy filled. On two of those trips—January 15, 2018, and February 12, 2018—Patient B.Da. also obtained prescriptions for alprazolam 2 mg, which Gulf Med Pharmacy also filled. Subsequently, on at least seven occasions between February 13, 2019, and August 5, 2019, Patient B.Da. traveled over 48 miles round trip to obtain prescriptions for hydromorphone 8 mg, morphine sulfate extended release 30 mg, and alprazolam 2 mg, which Gulf Med Pharmacy also filled.

13. On at least 17 occasions between January 17, 2018, and May 8, 2019, Patient R.D. traveled over 41 miles round trip to obtain prescriptions for hydromorphone 8 mg and lorazepam 2 mg, which Gulf Med Pharmacy filled.

Cash Payments and Price Gouging/ Black Market Pricing

14. Another common red flag of abuse or diversion that pharmacists must monitor is the use of cash payments for controlled substances instead of insurance payments. *See* 21 CFR 1306.04(a); 21 CFR 1306.06; Fla. Admin. Code. Ann. r. 64B16–27.810. According to the DEA's expert, when a prescription for a controlled substance is electronically processed through insurance, the insurance company will frequently reject suspicious controlled substance prescriptions that may be related to drug abuse or diversion, such as controlled substance prescriptions for the same patient filled at multiple pharmacies. Consequently, cash payments for controlled prescriptions are a red flag of abuse or diversion because some suspect patients may choose to pay cash in order to avoid an insurance rejection that might alert the pharmacist to potential drug abuse or diversion. Such cash payments are especially suspicious when the patient bills insurance for other prescriptions, but pays cash for controlled substance prescriptions.

15. Similarly, the DEA's expert indicated that price gouging, or charging more than the market rate for prescriptions for a controlled substance, is a separate indicator of drug abuse or diversion. The DEA's expert explained that price gouging is a red flag because a legitimate patient, who could fill his or her prescription at any pharmacy, will switch pharmacies in order to pay the fair market price for that prescription. In contrast, the highly suspect patient can only fill prescriptions at a suspicious pharmacy and must pay whatever price that suspicious pharmacy sets. Consequently, patients paying inflated prices for controlled substance prescriptions are another red flag of drug abuse or diversion, especially when the price paid is substantially higher than the market price available from other nearby pharmacies. *See Jones Total Health Care Pharmacy, L.L.C.,* 81 FR 79188, 79191 (2016). For the same reason, filling controlled substance prescriptions at inflated cash prices shows that a pharmacy has knowledge that it is filling prescriptions that are not legitimate, as its inflated prices reflect a ''risk premium'' that the pharmacy charges to account for the risk it is taking by filling illegitimate prescriptions. *See id.* at 79,199–200 (''[E]ven granting that there are no prohibitions on the prices a pharmacy can charge for controlled substances, when those prices far exceed what other pharmacies would charge, the Agency may properly draw the inference that the pharmacy is charging those prices because it knows it is supplying persons who are seeking the drugs to either abuse them or divert them to others.''). To determine a baseline of normalcy (*i.e.,* legitimate pricing), the DEA's expert contacted representative pharmacies in Cape Coral, Florida, and found that the price of 120–140 units of oxycodone 30 mg varied from about $1.59 to $1.63 per unit, while the sale price of 120–140 units of hydromorphone 8 mg varied from about $1.25 to $1.27 per unit.

16. From March 22, 2017, until at least August 6, 2019, Gulf Med Pharmacy repeatedly filled prescriptions for oxycodone 30 mg and hydromorphone 8 mg for patients who paid for these prescriptions in cash at substantially inflated prices that far exceeded what other area pharmacies charged. The DEA's expert reviewed Gulf Med Pharmacy's patient profiles for several of these patients. The DEA's expert opined that Gulf Med Pharmacy should have attempted to address or resolve these red flags of drug abuse or diversion prior to filling these prescriptions, but failed to do so. Gulf Med Pharmacy dispensed controlled substances at inflated prices to individuals paying cash in the following instances:

17. On at least 15 separate occasions between March 14, 2018, and April 10, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient R.D. On each occasion, Patient R.D. paid for the prescription in cash, and on all but one occasion Patient R.D. paid $4 per unit ($480 in total)—over three times the market rate.

18. On at least six separate occasions between February 26, 2018, and April 22, 2019, Gulf Med Pharmacy filled prescriptions for 84 to 120 units of oxycodone 30 mg for Patient T.G. On each occasion, Patient T.G. paid for the prescription in cash at a price of $4 per unit ($336 to $480 in total)—over three times the market rate.

19. On at least 16 separate occasions between March 7, 2018, and May 1, 2019, Gulf Med Pharmacy filled prescriptions for 108 to 110 units of hydromorphone 8 mg for Patient S.K. On each occasion, Patient S.K. paid for the prescription in cash at a price ranging from $3.56 per unit to $4 per unit ($392 to $432 in total)—in each case at least two-and-a-half times the market rate, and as high as over three times the market rate.

20. On at least 14 separate occasions between March 20, 2018, and April 15, 2019, Gulf Med Pharmacy filled prescriptions for 90 to 120 units of oxycodone 30 mg for Patient L.V. On each occasion, Patient L.V. paid for the prescription in cash at a price ranging from $2.50 per unit to $3.33 per unit ($300 in total)—in each case at least one-and-a-half times the market rate, and as high as twice the market rate. Further, Patient L.V. used insurance to pay for other prescriptions, including prescriptions for controlled substances such as alprazolam and zolpidem.

21. On at least 19 separate occasions between March 22, 2017, and September 7, 2018, Gulf Med Pharmacy filled prescriptions for 108 to 120 units of oxycodone 30 mg for Patient J.B. On each occasion, Patient J.B. paid for the prescription in cash at a price of $3.40 to $4 per unit ($408 to $480 in total)—in each case over twice the market rate.

22. On at least 23 occasions between November 8, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient A.B. On each occasion, Patient A.B. paid for the prescription in cash at a price of $3.73 to $4 per unit ($448 to $480 in total)—in each case over two-and-a-half times the market rate, and as high as three times the market rate.

23. On at least five occasions between October 25, 2017, and February 12, 2018, Gulf Med Pharmacy filled prescriptions for 150 units of hydromorphone 8 mg for Patient B.Da. Subsequently, on at least six occasions between March 13, 2019, and August 5, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient B.Da. On each of these 11 occasions, Patient B.Da. paid for the prescription in cash at a price of $4 per unit ($480 to $600 in total)—over three times the market rate.

24. On at least 28 occasions between April 21, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient B.Di. On each occasion, Patient B.Di. paid for the prescription in cash at a price of $4 per unit ($480 in total)—over three times the market rate.

25. On at least 18 occasions between December 5, 2017, and least August 6, 2019, Gulf Med Pharmacy filled prescriptions for 120 to 168 units of hydromorphone 8 mg for Patient R.R. On each occasion, Patient R.R. paid for the prescription in cash at a price ranging from $4 per unit to $4.60 per unit ($480 to $672 in total)—in each case over three times the market rate. ALJ Ex. 1.

The Hearing

Government's Opening Statement

The Government seeks to revoke the Respondent's DEA certificate of registration, and deny any applications for renewal, or modification of that registration because the Respondent has committed acts that render its continued registration inconsistent with the public interest. Tr. 14–15. The testimony and evidence will show that the Respondent repeatedly ignored red flags of abuse and diversion—many established under prior Agency decisions—and sold prescriptions for controlled substances without exercising their corresponding responsibility to ensure that those prescriptions were issued in the usual course of professional practice, and for a legitimate medical purpose.

With respect to the prescriptions that the Respondent filled for the charged patients in this matter, the Government's expert, Dr. Tracy Schossow, will explain that the Respondent filled prescriptions for controlled substances for those patients in the face of multiple red flags of abuse and diversion. Tr. 15–16. The red flags that the Respondent ignored include filling prescriptions for patients (J.B., A.B., B.Da., R.D., B.Di., R.R., and L.B.) that were cocktail combinations of opioids and benzodiazepines that are dangerous when used in combination, and are widely known to be sought after for drug abuse and diversion.

The Respondent also filled prescriptions for two charged patients (J.B. and R.R.) for the Trinity drug cocktail, which is a non-therapeutic combination of an opiate, a benzodiazepine, and muscle relaxer, Carisoprodol, which is a known dangerous combination and used for drug abuse and diversion.

The Respondent filled prescriptions for Patient J.R. for benzodiazepines, which duplicated the therapeutic effects. The Respondent also filled prescriptions for charged patients (J.B., A.B., B.Da., B.Di., S.K., and R.R.) for both long-acting and short-acting opioids in combinations that do not make pharmacological sense. Tr. 16–17. The Respondent filled prescriptions for Patient R.R. for benzodiazepines at dosages that do not make pharmacological sense.

The Respondent filled prescriptions for charged patients (J.B., A.B., B.Da., R.D., B.Di., T.G., S.K., R.R., and L.B.) despite each paying cash for controlled substances. The Respondent also sold prescriptions for charged patients (J.B., A.B., B.Da., R.D., B.Di., T.G., S.K., R.R., and L.B.) for opioids despite substantial mark-ups in price. The Respondent also filled prescriptions for charged patients (A.D., B.Da., and R.D.) despite these patients travelling long round-trip distances to have the Respondent's pharmacy fill the controlled substance prescriptions.

DI will explain that the DEA executed administrative inspection warrants and served three administrative subpoenas on the Respondent during the investigation. Tr. 17–18. This gave the Respondent several opportunities to provide the DEA with evidence that it identified and resolved red flags of diversion or abuse before dispensing the charged prescriptions. As Dr. Schossow will testify, the Respondent's records

indicate that it failed to address and resolve any of these red flags of diversion or abuse, and that it failed to exercise its corresponding responsibility to ensure that the prescriptions were issued for a legitimate medical purpose by a practitioner acting in the normal course of professional practice. Therefore, the Respondent violated federal and state law when it dispensed the charged prescriptions.

Respondent's Opening

Gulf Med Pharmacy is a small, independent pharmacy in southeast Florida. Tr. 19. Respondent contended that it has been unfairly and inappropriately targeted by the DEA for conduct that does not violate any Florida state or federal statues or regulations. Respondent contended that this action is based upon the DEA's created idea about review of prescriptions retrospectively related to some opiate prescriptions, and combinations of those opiates and benzodiazepines. Respondent contested that the DEA's position is not supported by medical literature or by anything other than supposition and conjecture on the part of the DEA's expert witness.

The Respondent will present testimony from Dr. Daniel Buffington. Dr. Buffington is a professor associated with the University of South Florida in the Departments of Medicine and Pharmacy. Tr. 19–20. He has extensive experience in pharmacy practice, and will describe the appropriateness of the Respondent's actions in filling prescriptions defined in the Order to Show Cause, as well as the appropriateness of the documentation related to those prescriptions.

Respondent contended that what is important in this matter is there has been, and continues to be, a tortured and unsupportable interpretation of the Florida Administrative Code, as it related to the obligation of a pharmacist licensed by the state. Tr. 20. The State of Florida has the right and obligation to control the scope and the manner of the practice of pharmacy and medicine within the state, consistent with the Supreme Court of the United States' precedence.

The Respondent's evidence will be direct and will show that the attempt to characterize the distance that was traveled by the charged patients to the Respondent's pharmacy is nothing short of manufactured. Tr. 20. In order to make the distances seem longer, the Government included round-trip travel as opposed to direct travel or the direct distance between the residence of the patient and the pharmacy. Tr. 20–21. Given the distances in south Florida, since patients are coming from some of the barrier islands, the distance between a straight line and coming from the barrier islands and comparing them to facilities on the mainland, is a significant factor that was not considered by the DEA or its expert witness.

Respondent contended that the DEA's expert witness is neither qualified, nor capable of, having any knowledge or information to justify opinions regarding the price paid for medications by the patients, or on the distance, travel, or mechanism of payment. Tr. 21. Even though it does not have any burden of proof, the Respondent will demonstrate the fallacies of the DEA's position. Tr. 21. It also looks forward to receiving a recommendation that Gulf Med Pharmacy's DEA registration be reinstated and continuing to operate in its usual and appropriate manner. Tr. 21.

Government's Case-in-Chief

Diversion Investigator (DI)

DI has been a Diversion Investigator with the DEA for three years and has been assigned to the Miami Field Division, Western office for most of that time. Tr. 25–27. Prior to working for the DEA, DI worked as a transportation screening officer with the Transportation Security Administration. Tr. 26. As a Diversion Investigator, DI is tasked with enforcing the Controlled Substances Act, which regulates the manufacture, distribution, possession, use, and importation of controlled substances. Diversion Investigators also strive to prevent the diversion of controlled substances to the streets. DI conducts civil and criminal investigations, including administrative actions like the current matter. Tr. 26–27. DI has attended the DEA Academy at Quantico and has conducted approximately twelve investigations with the DEA. Tr. 27–28, 279–81.

The investigation of Gulf Med Pharmacy was initiated because Gulf Med Pharmacy was found to be one of the top ten purchasers of Oxycodone, Hydromorphone, and Hydrocodone in the State of Florida. Tr. 28–29, 362.[4] This was the impetus for the DEA inquiry, to investigate why Gulf Med was a top purchaser of these controlled substances. Tr. 30.

DI became the case agent in approximately December 2018, after DI 2, the original case agent[5] retired. Tr. 28, 39, 315. Upon becoming case agent, DI reviewed the case file, which included the administrative inspection warrant. Tr. 40–42. DI had not reviewed the case file before he became the case agent or before the administrative inspection warrant was served. Tr. 368–70. Based solely upon DEA reports he later reviewed, DI confirmed that Gulf Med Pharmacy was one of the top purchasers in Florida of these controlled substances in 2017. Tr. 362, 365–68. At the hearing, he could not confirm whether the sole supplier of these controlled substances to the Respondent was Cardinal. Tr. 364.

Initially, DI's role in this matter was to assist the case agent with the administrative inspection warrant. Tr. 28. The administrative inspection warrant allows the DEA to inspect and copy records, information, reports, files, inventories, invoices, official order forms, prescriptions, and other documents required to be kept under the Controlled Substances Act. Tr. 302; GX 2 at 1; *see,* 21 U.S.C. 880. The warrant describes what records and information are subject to seizure, including all of the electronic data maintained by the Respondent pharmacy. Tr. 302–03; GX 2 at 2. In terms of the Respondent's compliance with the Controlled Substances Act and the laws applicable to the operation of a pharmacy, the DEA has the authority to go into the pharmacy and seize all of the relevant electronic data. Tr. 304–06. An administrative inspection warrant is used if the investigators suspect that the pharmacy may deny entry to investigators presenting with a notice of inspection. Tr. 289. When an administrative inspection warrant is served, DI follows the instructions of his group supervisors. Tr. 286. During an inspection, one or two agents conduct the inspection during normal business hours. Tr. 288.

The purpose of the inspection warrant was to gather all information relevant to the investigation, including both inculpatory and exculpatory evidence. Tr. 281–85. The warrant was based upon an affidavit by DI 2, the original case agent. DI did not create the warrant and he does not know the circumstances under which it was issued. Tr. 36–38. DI was part of the pre-inspection briefing session, which was conducted by DI 2. Tr. 281. He was advised that the Respondent was one of the top ten

[4] This evidence was admitted as relevant to the allegations. The Respondent probed this evidence, but gave notice that he was delving into this issue only on the basis the evidence was ruled to be relevant to the existing charges, and was not consenting to broaden the scope of the charges. The Tribunal explained to the Respondent that it did not permit the Government to expand the scope of the charges at the hearing, without giving timely notice to the Respondent, so that the Respondent had an opportunity to object. Tr. 359–61.

[5] [Footnote omitted.]

purchasers of oxycodone, hydromorphone, and hydrocodone in the State of Florida by DI 2 during the briefing before the execution of the warrant. Tr. 370–71.

DEA investigators served an administrative inspection warrant on Gulf Med Pharmacy on February 14, 2018. Tr. 31. DI was present when the warrant was served on the Respondent. Tr. 33–35.[6] The inspection of February 14, 2018, was performed by both diversion investigators and armed DEA special agents. Tr. 289–90. DI could not recall if any local law enforcement were present. Tr. 290. Prior to and at the point of service of the administrative inspection warrant, DI did not know where the Respondent kept its records. Tr. 387. DI knew that the employees of the pharmacy would know where the requested documents were located within the pharmacy, including the pharmacy technician and the Pharmacist-in-Charge. Tr. 391–92.

On February 14, 2018, the DEA simultaneously served an administrative subpoena on the Respondent through Dr. Ricard Fertil, the pharmacist in charge of Gulf Med Pharmacy. Tr. 44–45, 57, 393–94; GX 3; *see* 21 U.S.C 876. DI is familiar with administrative subpoenas, and regularly uses them. Tr. 46. DI was present on the day it was served and is familiar with the document. Tr. 46–49. The Respondent produced documents in response to the subpoena, and the DEA seized those documents from the Respondent. Tr. 64. The DEA provided a receipt for seized documents to the Respondent through a DEA–12 form. Tr. 50–60; GX 4. The receipt was signed by DI 2 and Mr. Ricard Fertil. DI did not attend the closeout meeting with the Respondent following the February 14, 2018 inspection. Tr. 356–57.

Items seized, and reflected in the receipt, included patient profiles, reports and printouts. Tr. 61, 63–64.[7] The investigators also seized the original prescriptions from the date the pharmacy opened until the date of the administrative inspection warrant. Tr. 291–92. During the service of the administrative inspection warrant, the DEA seized all of the Respondent's prescriptions and records, including electronic prescriptions for controlled substances. Tr. 73–75; GX 4 at 3–4, 6.

DI identified the prescriptions written and filled for Patient J.B. that were seized. Tr. 75–76; GX 7. These were included in the controlled substance prescriptions that had been filled by the Respondent pharmacy up until the date of the inspection. Tr. 77. The back side of the prescriptions have a filled sticker that show that the prescriptions were filled by Gulf Med Pharmacy. Tr. 78–79; GX 7 at 2. DI identified prescriptions for Patient A.B. that were taken from Gulf Med Pharmacy. Tr. 80–82; GX 8. DI also identified prescriptions for several patients filled by Gulf Med Pharmacy: Patient B.Da. (Tr. 83–85, 88–89; GX 9); Patient R.D. (Tr. 89–92; GX 10); Patient B.Di. (Tr. 95–98; GX 11); Patient P.G. (Tr. 99–101; GX 12); Patient S.K. (Tr. 101–03; GX 13); Patient R.R. (Tr. 111–13; GX 14); and Patient L.V. (Tr. 114–16; GX 15).

Once the prescriptions were seized from the Respondent pharmacy, they were placed into evidence and scanned. Tr. 93. The original prescriptions are maintained in the custody of the DEA evidence custodian. Tr. 94.

Once a warrant is served, the DEA investigators ask the pharmacist-in-charge where the prescriptions are located. Tr. 86. The investigators request a date range of prescriptions and seize them. Here, the prescriptions were in separate folders and were categorized by prescription number. Tr. 86–87. The folders were in various locations, including in drawers, cabinets, boxes, and ''just out in the open.'' Tr. 87.

A DEA technology specialist retrieved dispensing reports for the patient profiles from the pharmacy's computer. Tr. 87–88, 292. The technician downloaded information from the Respondent's computer system, including patient profiles and dispensing reports. Tr. 292. The investigators did not retrieve a mirror image of the Respondent's hard drive. Tr. 306–07.

On the prescription for Patient S.K., there is a fill sticker, which was printed out once the prescription was filled by the pharmacy. Tr. 103–04; GX 13 at 2. On the fill sticker, the prescription number was identified as N–000346, the date of the prescription, and ''PPCash'' to identify the method of payment. This shows that the prescription was paid for with a method of payment other than by insurance, which in this instance was cash. Tr. 104–05. This prescription was for hydromorphone, eight milligrams. In DI's experience, a cash method of payment for a prescription of a controlled substance is significant, because it raises the question why a patient would pay by cash as opposed to insurance. Tr. 106–07. This was a ''red flag'' [8] that the prescription may be illegitimate. Red flag methods of payment include cash, credit, credit card, or check. Tr. 107–08. There is no DEA regulation that prohibits a pharmacy from accepting cash as payment for a prescription. Tr. 373–74. There is no guidance document from the DEA that instructs pharmacists to limit the acceptance of cash as payment for prescriptions for controlled substances. Tr. 374. DI does not know whether patients can pay cash for prescriptions and then submit claims to their own insurance company. Tr. 375. He did not determine whether the charged patients had insurance. Tr. 375.

On the prescription for Patient S.K., below the ''PPCash'' language, there is an indicator of the price paid for the prescription. Tr. 108. The price that is paid for a controlled substance is a significant factor because, if the price paid is two or three times higher than a traditional price, it is an indicator that the patient is willing to pay any cost in order to get the prescription filled. Tr. 109–110. This would be an indication that the prescription may be illegitimate. These red flags are not only true for hydromorphone, but for other controlled substances as well.

Apart from the prescriptions, patient profiles, and dispensing reports previously discussed, there were no other documents pertaining to the specific patients that either the Respondent produced pursuant to the administrative subpoena, or that the DEA seized pursuant to the administrative inspection warrant. Tr. 117–18, *but see* 358–59 (purchase orders, invoices from suppliers, were seized during the administrative inspection warrant).

As the Government's investigation continued, the DEA served two additional administrative subpoenas. Tr. 118–19. The second administrative subpoena was served on the Respondent's attorney in May of 2019 by DI. Tr. 119–22, 350, 396; GX 16. DI was the investigator responsible for collecting and maintaining the evidence received from the Respondent. Tr. 350–51.

Dr. Fertil completed, and DI received, a completed copy of a certificate of authenticity of domestic business records, along with the documents responsive to the second administrative subpoena. Tr. 122–25; GX 18. In response to the May 2019 subpoena, the Respondent produced hard-copy prescriptions, patient profiles, and dispensing reports. DI did not know

[6] DI identified the Respondent's DEA COR. Tr. 32–33; GX 1. He also identified the administrative inspection warrant, dated February 14, 2018. GX 2.

[7] DI identified the patient profiles for Patients J.B., T.G, and L.V. Tr. 65–69; GX 5. DI also identified the patient dispensing reports for Patient J.B., T.G., and L.V. Tr. 69–71; GX 6.

[8] A ''red flag'' serves as an indication that a ''prescription may be illegitimate.'' Tr. 107.

who actually gathered the documents that were responsive to the subpoena. Tr. 396–97. The DEA provided a receipt for these documents. Tr. 125–28; GX 17. The second administrative subpoena required documents dated from February 15, 2018 to May 3, 2019, which begins the day after the end of time period of the administrative inspection warrant. Tr. 129, 347; GX 2.

DI identified patient profile printouts for Patient R.D. (Tr. 129–31; GX 19); Patient P.G. (Tr. 132–33; GX 20); Patient S.K. (Tr. 135–37; GX 21); and Patient L.V. (Tr. 137–39; GX 22).

The Respondent also produced hard copy prescriptions in response to the second administrative subpoena. Tr. 142, 348–49. The prescriptions were for Schedule II to V controlled substance prescriptions. DI identified prescriptions and fill stickers for Patient J.V. (Tr. 143–46; GX 23); Patient A.B. (Tr. 146–48; GX 24); Patient B.Da. (Tr. 148–51; GX 25); Patient R.D. (Tr. 151, 156–58; GX 26); Patient B.Di. (Tr. 158–60; GX 27); Patient P.G. (Tr. 160–62; GX 28); Patient S.K. (Tr. 163–65; GX 29); Patient J.R. (Tr. 165–70; GX 30), which includes prescription drug monitoring reports (GX 30, pp. 16–17, 26); Patient R.R. (Tr. 170–75; GX 31), which includes an E–FORCSE PDMP reports, a Florida Department of Health license verification printout for Dr. M.L., and a DEA website printout for Dr. M.L. (GX 31, pp. 19–21, 26, 31, 36, 39); Patient L.V. (Tr. 175–77; GX 32). No other documents were produced by the Respondent pursuant to the second administrative subpoena served in May of 2019, including dispensing reports. Tr. 178, 349–50.

A third administrative subpoena was served in August of 2019 by DI. Tr. 179–82; GX 33. DI served the administrative subpoena on Respondent's counsel on behalf of Gulf Med Pharmacy. Tr. 396. Ricard Fertil produced documents in response to the third administrative subpoena to DI. Tr. 183. DI did not know who actually gathered the documents responsive to the third subpoena. Tr. 396–97. The Respondent completed a certificate of authenticity of domestic business records. Tr. 184–85; GX 34. The documents produced include patient profiles, hard copy prescriptions, dispensing reports, and any notes for the patients. DI identified the produced records for Patient J.B. (Tr. 186–89; GX 35); Patient A.B. (Tr. 189–92; GX 36); Patient B.Da. (Tr. 192–94; GX 37); Patient B.Di. (Tr. 194–96; GX 38); Patient J.R. (Tr. 196–98; GX 39); Patient R.R. (Tr. 198–201; GX 40).

DI is familiar with the E–FORCSE program. Tr. 201–02, 206–08. E–FORCSE is the Florida prescription drug monitoring program, which is a database of controlled substance prescriptions filled, as reported by pharmacists or pharmacies to the State of Florida. Tr. 202–03. During the investigation, DI obtained information from the E–FORCSE database about the prescriptions that were filled by the Respondent. He logged onto the website and set his search query. Tr. 203–04, 206–07. A request then generated an electronic report. The report is produced after the database pulls all of the requested information and it is approved by a PDMP administrator. Tr. 205. An E–FORCSE PDMP report was generated for dates between January 1, 2018 and May 16, 2019 for Gulf Med Pharmacy. Tr. 205–06, 208–10; GX 41. Not including the title bar, there are 2,566 lines of data in the spreadsheet. Tr. 383. A second E–FORCSE PDMP report was generated for dates between February 14, 2018 and August 27, 2019 for Gulf Med Pharmacy. Tr. 211–17; GX 42. Not including the title bar, there are 2,912 lines of data in the spreadsheet. Tr. 384. Each line of data represents a separate prescription. Tr. 385. DI did not compare the E–FORCSE data with the data provided by the Respondent. Tr. 385. He did not do any investigation regarding the E–FORCSE data available prior to February 14, 2018 for the charged patients. Tr. 385–86.

During the service of the administrative inspection warrant in February of 2018, electronic printouts of purchase orders, patient profiles, dispensing reports, and other documents related to the charged patients were seized from the Respondent's computers. Tr. 237. The computers were not seized. Tr. 237–38. Copies of the software and hard drives were not taken. DI was aware that the pharmacy uses the PioneerRx software on their computers. During the investigation, the DEA obtained a declaration from a representative of PioneerRx, concerning the function of the software. Tr. 238–48; GX 48. DI received it from PioneerRx's attorney. Tr. 239, 242.

DI never spoke to Jenny Roe directly. Tr. 343. Because DI had a printout, he did not perform any investigation to determine what information was in the computer system behind the tabs of information on the computer program. Tr. 343–46; GX 5. The administrative subpoena asked for all documents maintained in patient profiles, so if the Respondent only provided one page, then the investigators assumed that is all the Respondent had. Tr. 346. The Respondent is expected to produce what is listed in the subpoena. Tr. 347.

DI is familiar with the term National Average Drug Acquisition Cost (NADAC). Tr. 249, 255.[9] DI first became familiar with it during the investigation of the Respondent. Tr. 255. It is a database monitored by the Center for Medicare and Medicaid Services, where a survey is sent out to pharmacies throughout the country. Tr. 256. The pharmacies will voluntarily submit acquisition costs for the drugs that they purchase from the manufacturers. Tr. 256, 275. The Center for Medicare and Medicaid Services is a government agency, whose role with respect to the NADAC is to determine prices to be compensated for insurance purposes. Tr. 256–57. The results of the survey are updated monthly and posted online. There is data that relates to different controlled substances. Tr. 257–58. DI reviewed the data for Oxycodone 30 mg and Hydrocodone 8 mg. Other data available include the name of the substance, cost per unit, NDC number, and effective date. DI identified the NADAC results for Hydrocodone 8 mg and Oxycodone 30 mg. Tr. 259–62; GX 44–45.[10]

DI found NADAC by doing a Google search. Tr. 272. He had never worked with it before. There is a fact sheet which explains how NADAC gathers their information and its use. Tr. 273. DI did not communicate with anyone at NADAC. For the Center for Medicare and Medicaid Services, the data only applies to patients whose medications are being paid for by Medicare or Medicaid. Tr. 273–74.

DI does not know if any of the NADAC volunteered information is from independent pharmacies in the Fort Meyers or Cape Coral area, or any in southeast Florida. Tr. 275. He is aware that prices are different in terms of acquisition cost for chain pharmacies versus independent pharmacies. Tr. 276. He does not know whether chain pharmacies have a greater buying power than independent pharmacies, or whether there are different reimbursements that are paid by insurance companies compared to private pay price. Tr. 277–78. He does not know whether independent pharmacies are reimbursed at a lower rate than chain pharmacies. Tr. 357–58.

DI became familiar with the term ''federal upper limit'' as part of his duties. Tr. 263. He became familiar of the term through the NADAC database. Federal upper limit is a multiplier that the Center for Medicare and Medicaid

[9] [Footnote omitted, *see infra* n.*P.]

[10] Pursuant to the Tribunal's previous ruling, Government's Exhibits 44 and 45 were not admitted. Tr. 262.

Services uses from the NADAC average. Tr. 264–65.[11] When the Center determines the federal upper limit, it is provided online on their database website. Tr. 267–68. The federal upper limit is available with respect to particular drugs, including controlled substances. DI reviewed the data for Oxycodone 30 mg and Hydrocodone 8 mg. DI identified the NADAC federal upper limit results for Hydrocodone 8 mg and Oxycodone 30 mg. Tr. 268–71; GX 46–47.[12]

The federal upper limit pertains to people who are not using insurance to pay. Tr. 274. It does not matter where a person fills their prescriptions if they are a Medicare patient. The same upper limit of what can be charged applies. Tr. 274–75.

DI's intention through the second and third administrative subpoenas was to obtain the same type of information and documents that the DEA sought at the time of the administrative inspection warrant and administrative subpoena on February 14, 2018. Tr. 293–98; GX 3, 16, 33. DI did not draft the first administrative subpoena, but he did draft the second and third administrative subpoenas. Tr. 308–09. He is familiar with the process for the service of an administrative subpoena, which includes identifying a return date for the person on whom the subpoena is served to produce information. Tr. 310. The first administrative subpoena directs the person to whom that subpoena is served to respond to DI 2 by February 9, 2018. Tr. 310–11; GX 3 at 2. The return date had already passed by five days by the time the subpoena was served. Tr. 311. DI explained that when drafting administrative subpoenas, the system auto-populates the date at the bottom of the subpoena that is within two weeks or ten business days. Tr. 312. Taking into consideration travel and getting appropriate signatures, these subpoenas are drafted ahead of time. The date of issue on this subpoena is the date that the document was printed and submitted. Tr. 312–13.

The return date for the third administrative subpoena was for was February 9, 2018. Tr. 314. The date and time for appearance auto-populates, so it appeared that the drafter forgot to change the date, but DI was not sure. It would be impossible for the Respondent to timely respond to the subpoena as the Respondent did not receive it until February 14, 2018. Tr. 314–15.

DI did not interview any of the physicians that prescribed the charged prescriptions. Tr. 319–20. He also did not interview any of the charged patients. Tr. 320. DI did not do any investigation to determine the distances from the charged patients' home to the pharmacy. Tr. 377–78. DI did not have any evidence that any of the charged patients were abusing or diverting their medications. Tr. 321–24.[13] He did not know the number of patients that had been served by the Respondent prior to February 14, 2018, and did not know what percentage of patients in the Order to Show Cause are of the Respondent's total patients. Tr. 325–26.

DI did not receive training at the DEA Academy regarding the Florida administrative code or Florida law. Tr. 327. In the administrative subpoenas, DI referenced Florida Administrative Rule 64B16–27.800. Tr. 331. DI has previously read Florida Administrative Rule 64B16–27.800. Tr. 351. He understood that investigators were looking for the same types of profile information that the DEA technology specialist had downloaded during the administrative inspection warrant on February 14, 2018. Tr. 331–32.[14]

When he was assigned as the case agent, DI reviewed all of the information that the DEA had then collected. Tr. 339. Following the service of the second and third administrative subpoenas, he compared the patient profiles that were seized on February 14, 2018 to the patient profile information that was obtained in response to the second and third administrative subpoenas. Tr. 339–40, 342–43.

DI transmitted the documents collected in response to the administrative subpoenas to Dr. Schossow. Tr. 378. The subpoenas were not issued at the request of the expert. Tr. 379. DI did not review any of the information with Dr. Schossow. Dr. Schossow provided a written report to DI before the OSC was issued, but he did not recall the exact date. Tr. 379–80.

All of DI's interactions with Ricard Fertil and Gulf Med Pharmacy were both pleasant and cooperative. Tr. 399.

Dr. Tracey Schossow

Dr. Schossow is a contracted expert with the Drug Enforcement Administration. Tr. 863–64. She expects to make $15,000 on the instant case. Tr. 879–80. She has only testified as an expert for government agencies. Tr. 865. Although she was not averse to defending someone charged by the Government, she has never been hired to defend anyone charged by the Government or by the State. Tr. 876–78. Dr. Schossow is a licensed pharmacist in the State of Florida. Tr. 404. She has a Bachelor's of Science Degree in Pharmacy from Florida A&M, and later received her Doctorate in Pharmacy from the University of Florida in 2001. Tr. 881. Although she has written non-peer reviewed articles, she has not published a peer reviewed article. Tr. 939–40. She worked in retail pharmacy for a total of fifteen years, including time as a drug clerk and pharmacy tech for her father, who was a pharmacist. She worked as a pharmacist in retail pharmacy for approximately twelve years. She has also worked as a pharmacy intern, assistant manager, a pharmacy manager, and then as a ''floater'' for other pharmacy chains. Tr. 406–07, 417. She has worked in over 200 different pharmacies during her retail pharmacy experience, but never one in southwest Florida. Tr. 988. However, she has not worked in a retail pharmacy since 2012. Tr. 417, 881. Since 2012, she has only worked for pharmacy benefit managers. Tr. 883. Her last position in retail pharmacy was with Publix Pharmacies from July 2008 to October 2012. Tr. 418, 930. She last served a customer at a pharmacy approximately seven years ago. Tr. 880.

She has worked for ProCare, a hospice-centered company, as a clinical pharmacist. Tr. 404, 418–19. In that capacity, she worked with patients who were dying, and managed cocktail medications for comfort management, while still maintaining cost effectiveness. Tr. 404–05, 419–20. She was also part of the PNT committee, which decided which medications were non-formulary based on cost and efficacy. Tr. 405. She additionally managed a rejection queue, where claims are rejected for being excessively priced. Dr. Schossow offered more cost-effective therapies.

[11] [Footnote omitted, *see infra* n.*P.]

[12] Pursuant to the Tribunal's previous ruling, Government's Exhibits 46 and 47 were not admitted. Tr. 270–71.

[13] The Tribunal sustained the Government's objection as to being outside the scope of the Government's direct examination and that this information is irrelevant. The Tribunal found that the Government does not require evidence of diversion or abuse to initiate or pursue an investigation, and they do not require evidence of diversion or improper behavior by the pharmacist to initiate an investigation. The Tribunal permitted the Respondent to make a proffer, but advised that the Government's theory is set out in the Order to Show Cause and Immediate Suspension of Registration and the Government's prehearing statements, which will serve as the focus of the hearing. Tr. 321–23.

[14] The Tribunal sustained the Government's objection to relevancy of the underlying Government investigation. The Tribunal found that the focus of the hearing is not on whether there were mistakes or missteps in the investigation, but rather on the evidence that was seized and noticed with the allegations set out in the Order to Show Cause. Tr. 333–39.

Dr. Schossow presently works as a pharmacist at Florida Blue Cross/Blue Shield. Tr. 403. As part of her duties, she reviews ''high-dollar reports'' (meaning high cost medications) and makes sure that the medications are being issued for a legitimate medical purpose. Tr. 403. If she determines they are being issued for a legitimate medical purpose, she works with the patient and provider to offer cost-effective alternatives. Tr. 403–04. If, upon speaking to the pharmacy and patient, she determines the medications are not for a legitimate medical purpose, she reports those findings and opens up an investigation through Blue Cross's fraud, waste, and abuse department for further investigation. She also works on a team of ''complex members'' with a nursing team and reviews medications with patients. Blue Cross provides pharmaceutical education and offers cost-effective alternatives to its members.

Blue Cross also submits test claims at different pharmacies, including independent pharmacies, to determine costs at different pharmacies in the area where patients reside. Tr. 405. Dr. Schossow did not actually prescribe medications in these roles, but she made recommendations to physicians based on the patient's symptoms. Tr. 406. She was a member of an interdisciplinary team, which made medication recommendations that the physicians generally followed. In that role, she served as a clinical pharmacist. Tr. 406.

There are differences between a regional pharmacist and a clinical pharmacist. Tr. 407. A regional pharmacist receives the prescriptions from the physician. The pharmacist evaluates it, looks at the computerized patient profile and ensures the medication is safe for the patient before dispensing. A clinical pharmacist makes the recommendations saved on the computer patient profile. In Dr. Schossow's current position, she looks at all of the claims that the patient has, from the insurance perspective. She can review all of the medications the patient has received, and then she can make a recommendation based on the profile, and by talking to the patient and physician. Dr. Schossow has similar responsibilities as a regional pharmacist, except she does not dispense medications. Tr. 407. There is no difference in licensure between a clinical pharmacist and a community pharmacist. Tr. 419.

Dr. Schossow has been a pharmacist for approximately twenty-six years. Tr. 408. All of her experience is in the state of Florida. She has experience filling approximately one million prescriptions. Dr. Schossow also holds a consultant license in the state of Florida. The consultant license allows her to perform additional duties, including nursing home inspections.

Dr. Schossow has taught in the pharmacy field. Tr. 409. She taught at a pharmacy technician school, teaching subjects including diversion, red flags, and issues involving opioids. Tr. 409–10. She also worked at the Veterans Administration (VA) for six years. Tr. 412. In this role, she was a clinical pharmacy specialist and mentored residents and interns. Tr. 412. At the VA, Dr. Schossow prescribed medication. Tr. 419. While with the VA, Dr. Schossow could prescribe medications because she operated under the VA regulations. Tr. 422–23. However, with the hospice and retail positions, she cannot prescribe medications and can only make recommendations. Tr. 423. She has never had the ability or authority to prescribe Schedule II controlled substances. Tr. 423. At ProCare, she was a trainer in regards to high-dollar cost rejections, including training pharmacists on these rejections, how to handle them, and how to offer cost-effective alternatives. Tr. 412, 936–38. She also worked for Caremark, a PBM, where her role was to control costs for contracted healthcare plans. Tr. 972–73. Dr. Schossow conceded that, outside the realm of insurance subsidization, there is no limit on the mark up a pharmacy can charge for medications. Tr. 1035.

Dr. Schossow is familiar with DEA regulations with respect to dispensing of controlled substances. Tr. 408–09, 888–92, 927–28. She has previously testified as an expert witness three times in DEA administrative cases. Tr. 411–12, 423–24. She has been qualified each time she has been offered as an expert. She has only testified in administrative hearings, not in courts. Tr. 928. Her opinions have been accepted by the DEA Administrator. Through her education and professional experience,[15] she is familiar with the responsibilities of a retail pharmacist in the detection and prevention of abuse and diversion of controlled substances. Tr. 414. She is familiar with the standard of care [16] and professional obligations of a pharmacist in the state of Florida. Tr. 888–92.

In the instant case, Dr. Schossow was offered as an expert in Florida pharmacy practice and the standard of care for the practice of pharmacy in Florida. Tr. 414, 416. She reviewed all of the exhibits in this matter, including prescriptions, patient profiles, E–FORCSE reports, and documents provided by Gulf Med Pharmacy. She asked the Government to gather information that a responsible pharmacist would look at before determining whether a prescription could be safely filled for a legitimate medical purpose. So she asked for those items that she would look for if she was standing in the pharmacy filling the prescriptions. Tr. 415–16.

Dr. Schossow was qualified as an expert in Florida pharmacy practice and the standard of care for the practice of pharmacy in Florida.[17] The duties of a Florida pharmacist with respect to filling controlled substance prescriptions include exercising a corresponding responsibility to make sure that medications are being issued for a legitimate medical purpose by the practitioner acting within their usual course of professional practice. Tr. 431. The pharmacist is responsible for evaluating prescriptions based on the manufacturer's guidelines and for the safety for the patient. Tr. 432. Florida Administrative Rule 64B16 lists responsibilities regarding what should be maintained in the patient record systems, including the patient's name address, allergies, pharmacist's comments, and a Drug Use Review (DUR) for each new prescription and refilled prescription. A DUR includes side effects, drug interactions, whether the medication is being clinically abused or misused, and dosages.

Dr. Schossow is familiar with Florida Administrative Rules 64B16–27.800, 27.810, and 27.831. Tr. 434–36, 891–92. These provisions inform the standard of care of a pharmacist working in Florida. Tr. 434–36, 891–94, 912–16.[18] They provide an outline of the minimal requirements for Florida pharmacists in regards to patient safety and continuity of care. Florida Administrative Rule

[15] Dr. Schossow identified her curriculum vitae. Tr. 412–13; GX 43.

[16] The term of art, ''standard of care'' was used by the Tribunal, the parties and sometimes witnesses as a shorthand reference to a pharmacist's professional obligations, or acting within the ''course of professional practice of pharmacy.'' *See* Florida Statute XLVI § 893.04. However, the term ''standard of care'' is defined in § 766.102, and has a different usage and application. This distinction will be discussed in detail below.

[17] The Respondent objected to the Government's offer of Dr. Schossow as a proposed expert witness and to restriction on voir dire as to her opinions relating to specific aspects of the standard of care. The Tribunal overruled the Respondent's objections and Dr. Schossow was qualified as offered. Tr. 424–27. The Tribunal noted that the burden to qualify an expert is by a preponderance of the evidence. Thereafter, apparent limitations to expertise will impact the weight given to the expert's testimony.

[18] Dr. Schossow testified that the pharmacist is required to apply the version of the regulation or statute applicable at the time the subject prescription is filled. Tr. 896–97, 904–05.

64B16–27.831 describes methods a pharmacist should use to validate a prescription. Tr. 897–900. This provision also requires pharmacists to maintain a computerized record of controlled substances dispensed, which the Respondent did in this case as to the charged patients. Tr. 908–12. The Florida statutes define requirements for patient care and for maintaining a patient records system. Tr. 437. These statutes provide that the pharmacist shall ensure a reasonable effort is made to obtain, record, and maintain certain information, including the patient's full name, address, date of birth, gender, and prescription list, as well as the pharmacist's comments relating to allergies, drug interactions or any idiosyncrasies, and any conversations that the pharmacist had with the healthcare provider in regards to the patient's individual drug therapy. Tr. 438, 913–20. The Florida statutes also require prescription drug review, including therapeutic inappropriateness, which the pharmacist must address for drug therapies that do not fall within the guidelines of the standard of care. This ensures continuity of care with the next pharmacist reviewing the medication protocol, as well as to assure that the medication is safe for the patient. Tr. 927–30. These concerns include over or under-utilization of medication, therapeutic duplications, drug interactions, incorrect dosage forms, drug allergy interactions, and clinical abuse. The pharmacist must take appropriate steps to resolve these issues and to record those resolutions. Tr. 438–39, 888, 918–26. Dr. Schossow conceded that the relevant federal regulations that she relied on to inform the standard of care do not specifically require documentation of the resolution of red flags. Tr. 927–28.

A prospective drug use review is a checklist that a pharmacist should go through when reviewing each new and refilled prescription to ensure therapeutic appropriateness and patient safety. Tr. 439–40. Additional concerns include therapeutic duplication, drug interactions, correct dosages, clinical abuse and misuse, and drug allergy interactions. Prospective drug utilization review is discussed in the Florida Administrative Rules under section 27.810. Tr. 440–41. Upon recognizing any therapeutic inappropriateness, the pharmacist is supposed to take appropriate steps to resolve the issue and to record the resolution in the patient records. It is important to document the results of a review for continuity of care, so that when the next pharmacist reviews the medication protocol, he will have the information readily available and the prescription can be filled without delay. Tr. 441–42. It also represents a safety issue. In Dr. Schossow's opinion, the Florida standard of care requires documentation of the resolution of these matters. Tr. 442.

Dr. Schossow is familiar with DEA regulations regarding a pharmacist's corresponding responsibility. Tr. 442. The pharmacist has just as much responsibility as the doctor to ensure that the medication is for a legitimate medical purpose and that the practitioner is acting in the usual course of professional practice. Tr. 442–43. It applies to all pharmacists. This responsibility is in addition to all of the requirements under the Florida rules and regulations. A pharmacist's corresponding responsibility is not satisfied by simply verifying that a doctor wrote the prescription. The pharmacist has an independent responsibility to evaluate each prescription. Tr. 444.

Dr. Schossow is familiar with the phrase ''in the usual course of professional practice.'' Tr. 444. This means that the doctor is issuing prescriptions in an effective and safe manner and ''within his training.'' This is a requirement for a pharmacist. ''Within his training'' means within the scope of his practice. Tr. 444–45. Pharmacists are required to fill prescriptions in the usual course of their profession.

Apart from the requirements for pharmacists set forth by the State of Florida and the DEA, Dr. Schossow testified that she believed that a pharmacist's standard of care is also informed by past DEA administrative cases.*[C] Tr. 445–46. Pharmacists learn about the DEA administrative decisions through mandatory CMEs and during education seminars, including those required by § 27.831. Tr. 457–62.

Dr. Schossow is familiar with the term ''red flag.'' Tr. 446. Red flags are circumstances surrounding a prescription that cause a pharmacist to take pause, including signs of diversion or the potential for patient harm. These concerns are codified under clinical abuse and misuse within the DUR in Florida's Administrative Rule 64B16. The section also talks about abuse under Chapter 893, in which abuse is defined. Tr. 446. Pharmacists in the State of Florida ''must learn three main statutes'' in order to pass the Florida Board: ''64B16, 893, and 465.'' Tr. 449, 1004–05, 1039–40. Pharmacy students learn these statutes for the Florida Board of Pharmacy. Chapter 893 informs the Florida standard of care for pharmacists as it defines potential for abuse, which relates back to 64B16. Tr. 449–50. The prospective DUR requires that one of the things a pharmacist must review is clinical abuse or misuse, so a pharmacist must understand what abuse means.

Florida pharmacists become familiar with red flags through their training in pharmacy school and through their on-the-job training. Tr. 451, 888. This training includes the opioid crisis in the United States, which led to mandatory continuing education in Florida for the validation of prescriptions for controlled substances. Tr. 451–53. This additional training includes, use of the PDMP, appropriate therapeutic values for opioids, legitimate medical purpose and the laws and rules around it, as well as protocol that addresses how to resolve red flags, and the CDC Guidelines for Prescribing Opioids for Chronic Pain, 2016. The CDC guidelines relating to opioid prescribing are reviewed in the Continuing Medical Education (CME) courses. Tr. 454. The CDC guidelines cover appropriate dosing, which is part of the mandatory CME that all Florida pharmacists must attend every other year, as well as risks of certain dosages of Morphine Milligram Equivalent (MME). Tr. 455. The training covers dosing and risks to patients, as well as combining central nervous system depressive medications that may lead to overdose and death. Tr. 456. The training also covers dosage concerns based on clinical studies, for which the pharmacist is responsible to know. The standard of care requires pharmacists to remain current as to the therapeutic appropriateness findings of these studies. The items outlined in Florida Administrative Rule 64B16–27.810 represent red flags. Tr. 457.

The presence of a red flag itself does not mean that a pharmacist cannot fill a prescription. Tr. 462. Consistent with the standard of care, a red flag means that there is a potential concern with the prescription, which the pharmacist must address and resolve, and to make a record of its resolution, assuming it is resolvable. Tr. 462–63, 906–07. If the pharmacist is unable to resolve the red flag, he should not fill the prescription. Tr. 907–08. This is something that a Florida pharmacist acting in the usual course of professional practice would do upon encountering one or more red flags relating to a prescription. The lack of documentation identifying and resolving of a red flag warrants the

*[C] It is noted that DEA administrative cases rely on expert testimony to establish the standard of care.

conclusion under the standard of care that the prescription was treated as falling within the guidelines for a legitimate medical purpose and is safe for the patient to take. Tr. 463–66.

Dr. Schossow was asked by the DEA to review material relating to Gulf Med Pharmacy. Tr. 466, 983–84. She reviewed the front and back of hard-copy prescriptions, the computer printouts of the patients' pharmacy files, which included any pharmacist comments, medical records from the pharmacy, dispensing reports, and patient profiles, including the PDMP reports for patients. Tr. 466–71. Dr. Schossow does not know if she received all of the relevant information from the Respondent's computer system used to fill the subject prescriptions. Tr. 976–78. Specifically, Dr. Schossow confirmed the screen shots of the patient profile only depicted one of five tabs. Tr. 978; GX 19. The tab opened in the relevant Government exhibits was the ''comment'' tab. The tab identified as ''profile'' was not revealed. Tr. 978–79. Similarly, the tab, ''RX history'' is not revealed. Tr. 979.

Dr. Schossow is familiar with pharmacy management software, which maintains patient records. Tr. 471. She is familiar with how it generally works and has worked with different systems of pharmacy management software. However, she is not familiar with the Respondent's system, PioneerRx. Generally, when a prescription is submitted to a pharmacy, the technician types up the prescription, which then goes through the system. Tr. 472. Most pharmacies perform the DUR. It is the responsibility of the pharmacist to override it or to document that issues revealed by the DUR were addressed. Tr. 475. Not all red flags are flagged in the computer system, but red flags that are flagged include major drug interactions, including central nervous system (CNS) depressant medications that fall under an X interaction according to the DEA and the CDC, and the FDA black box warnings on things such as benzodiazepines combined with opioids. Tr. 476.

After a warning appears in the electronic program, that is considered a DUR [19] and the severity of the DUR should be addressed by the pharmacist with either the patient or the doctor to assure patient safety going forward and how it was resolved. There is generally a click-through function on the program and documentation must be provided. Tr. 476–77. For example, in the system at Walgreens, the pharmacist has to document what they did to resolve the red flag. If the software program does not allow the pharmacist to document in the computer, then the pharmacist must either document in the computer program under the patient notes or somewhere in the patient records system, or on the prescription, as to how the DUR was resolved in terms of patient safety, for the continuity of care for the next pharmacist. A click-through does not count as documentation of a red flag. Tr. 477–78. A click-through allows the pharmacist to override a DUR. For example, at Publix, the pharmacist has a lanyard that the pharmacist clicks to override the DUR. However, a higher level DUR requires more documentation because of patient safety concerns. Tr. 478–79.

A pharmacist practicing in the normal course of pharmacy practice in Florida would record what the resolution of the red flag was for continuity of care and to assure patient safety. Tr. 479–80. In a pharmacy, the pharmacist is responsible for resolving any potential red flag of abuse or diversion. Tr. 480. A pharmacy technician cannot resolve or sign off on the resolution of a red flag.

Dr. Schossow is familiar with a combination of controlled substances known as a ''trinity''. Tr. 480–81. A trinity is usually an opioid like Hydromorphone or Oxycodone, plus a benzodiazepine like Alprazolam, Temazepam, Diazepam, plus Soma or Carisoprodol, which is a controlled muscle relaxant. Tr. 481. It is a dangerous combination. In Dr. Schossow's experience and training, the trinity is commonly sought by drug abusers. Tr. 482–83. A trinity is a red flag.

Patient J.B.

Dr. Schossow identified a patient medication dispensing report printout for Patient J.B. Tr. 483–84; GX 6. The number in the quantity column is the amount of dosage units dispensed by the pharmacy of the controlled substance. Tr. 485. On March 22, 2017, six prescriptions were filled. The bottom-listed controlled substance is Carisoprodol. Tr. 485; GX 6 at 2. The prescription immediately above is Oxycodone 30 mg. Tr. 486. The prescription above that is another controlled substance, listed as Alprazolam. Two lines above Alprazolam, Morphine Sulfate Extended is listed. Morphine Sulfate Extended is an opioid, Alprazolam is a benzodiazepine, Oxycodone is an opioid, and Carisoprodol is a controlled substance muscle relaxant. Together, these controlled substances form a trinity. Dispensing these controlled substances on the same day represents a red flag for the pharmacy. Tr. 486–87.

Dr. Schossow noted prescriptions paid for in cash indicated a red flag.[20] Tr. 851–53; GX 6 at 1–2; GX 23 at 61–63. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 852–53, GX 6 at 2. Dr. Schossow identified prescriptions demonstrating a red flag for combining extended release and immediate release opioids. Tr. 853–57; GX 23 at 57, 61–63, 66–69, 72–74, 77–80; GX 35 at 10, 21, 11–14, 19, 20, 24–27.

On April 19, 2017, another series of prescriptions were filled, including Morphine Sulfate, Oxycodone 30 mg, 90 units of Alprazolam, and Carisoprodol. Tr. 487–88; GX 6. This is a trinity combination. In addition, the patient was also on Gabapentin and Butalbital, Aspirin, and Caffeine, which are also additional CNS depressants, which make this combination even more dangerous. These were prescription numbers 734 through 737; GX 6 at 2. On May 19, 2017, another series of prescriptions were filled, including Morphine Sulfate, Oxycodone 30 mg, Alprazolam, and Carisoprodol. Tr. 488; GX 6 at 2. This is a trinity combination and a red flag. Tr. 488–89.

On June 16, 2017, another series of prescriptions were filled, including Morphine Sulfate, Oxycodone 30 mg, Alprazolam, and Carisoprodol. Tr. 489. This is a trinity combination and a red flag. These included prescription numbers 1306, 1317, 1319, and 1321.

On July 14, 2017, another series of prescriptions were filled, including Morphine Sulfate, Oxycodone 30 mg, Alprazolam, and Carisoprodol. Tr. 489–90. This is a trinity combination and a red flag. These included prescription numbers 1627, 1628, 1633, and 1634.

On August 11, 2017, another series of prescriptions were filled, including Morphine Sulfate Extended Release, Oxycodone 30 mg, Alprazolam 10 mg, and Carisoprodol. Tr. 490. This is a trinity combination and a red flag. These included prescription numbers 1946, 1947, 1950, and 1951.

On September 8, 2017, another series of prescriptions were filled, including Morphine Sulfate, Oxycodone 30 mg, and Alprazolam 10 mg. Tr. 491. These included prescription numbers 2250, 2251, and 2252. There was no Carisoprodol issued on this date. It is still a dangerous combination because all of those drugs suppress the central

[19] Dr. Schossow appeared to use the term DUR in place of ''red flag'', as per the subject question.

[20] Dr. Schossow conceded that she was not aware whether the charged patients, who paid cash for the subject controlled substances, later sought reimbursement from their insurance companies. Tr. 1036.

nervous system and can lead to respiratory depression, overdose, and death.

The records indicate which pharmacist actually filled the prescription. Tr. 492. At the top of the patient record, the initial RPH, which means registered pharmacist, lists the initials of the pharmacist that filled the prescription. Tr. 492; GX 6 at 1.

On October 6, 2017, another series of prescriptions were filled, including Morphine Sulfate, Oxycodone 30 mg, Alprazolam, and Carisoprodol. Tr. 497–98; GX 6. This is a trinity combination and a red flag. These included prescription numbers 2603 to 2606.

On November 3, 2017, prescriptions were filled, including Oxycodone 30 mg and Alprazolam. On November 6, 2017, prescriptions were issued, including Morphine Sulfate and Carisoprodol. Tr. 498–99. This is a trinity combination and a red flag. These included prescription numbers 3034, 3036, 3062, and 3064. It is a red flag as the medications were dispensed so close in time.

On December 1, 2017, another series of prescriptions were filled, including Oxycodone 30 mg and Alprazolam. Tr. 499. These included prescription numbers 3474 and 3475. These prescriptions represent a red flag. Tr. 500. Both of these drugs depress the central nervous system and the Oxycodone dosage is the highest strength available, which in itself is a red flag. These prescriptions fall under the FDA black box warning and 2016 CDC guidelines that specifically recommend against taking benzodiazepines with opioids. Although familiar with the 2016 CDC Guidelines, and upon which she relied in forming her opinions herein, Dr. Schossow was unfamiliar with the clarification issued, which clarified that the 2016 Guidelines did not apply to patients on long-term opioid treatment. Tr. 992–94. Dr. Schossow conceded that if a patient had been on a long-term drug regimen, that would be a consideration of the pharmacist in conducting the DUR analysis. Tr. 1035. Dr. Schossow clarified that she had previously reviewed the CDC's clarification to the 2016 CDC Guidelines, and noted it did not change her opinion as it did not relate to the combination of benzodiazepines and opioids. Tr. 1060–64.

On December 29, 2017, another series of prescriptions were filled, including Oxycodone 30 mg, Alprazolam, Morphine Sulfate, and Carisoprodol. Tr. 503; GX 6. These included prescription numbers 3973, 3975, 3976, and 3979. These prescriptions represent a trinity and thus a red flag.

On January 26, 2018, another series of prescriptions were filled, including Oxycodone 30 mg and Alprazolam. Tr. 503. These included prescription numbers 4549 and 4550. On January 31, 2018, Morphine Sulfate Extended Release was issued, which includes prescription number 4658. Tr. 504. These prescriptions are a combination of opioid and benzodiazepine and thus represent a red flag.

Dr. Schossow identified the actual prescriptions for Patient J.B. Tr. 504–05; GX 7. She did not see any resolution of red flags documented for any of the subject prescriptions that were filled. Tr. 505–06; GX 7 at 1–69. The notation ''PDMP'' on the back of the prescription would mean that the pharmacist checked the PDMP before filling the prescription. Tr. 506; GX 7 at 18. This does not resolve the red flag as there are several red flags present regarding that prescription. Tr. 507. The red flags include the high strength of the Oxycodone at 30 mg. The second is that the medication is over 50 mg MME, which puts the patient at risk for CNS depression, overdose, and death. The third red flag is the scheduling of an immediate relief opioid. Checking the PDMP did not resolve or address any of those red flags, but only satisfied part of the law that requires the pharmacist to check the PDMP to ensure the patient is not doctor or pharmacy shopping and to check the total milligram of MME. Reference to the PDMP does not contribute to resolving any of the red flags related to the prescription. Tr. 507–08. Dr. Schossow identified a patient computer profile for Patient J.B. Tr. 529–30; GX 35.[21] She did not see any documentation or resolution of the red flags previously discussed on the first page. Tr. 530, 857–58; GX 35, p. 1. She did not see any documentation of red flags, or the resolution thereof, in the patient profile, particularly under the critical comments section where the pharmacist can fill in comments. Tr. 493–96, 504, 857–58. Nor did she see any indication the medical records or dispensing log for J.B. indicated the subject red flags as to J.B. were addressed, resolved or documented. Tr. 858–59; GX 35 at 2–5, 8, 9.

There were additional prescriptions of the same opioid and benzodiazepine (Oxycodone 30mg, and Xanax) that were also red flags, based upon the cocktail created by the controlled substances, which are central nervous system depressants, which can cause sedation, respiratory depression, overdose, coma, and death. Tr. 530–34; GX 35, pp. 6–7, 10, 11–16, 21. There were additional prescriptions for Oxycodone, Xanax, and Morphine that were red flags for the same reasons. Tr. 533–34; GX 35 at 17–20, 22–27. Dr. Schossow did not see any indication of red flags being documented or resolved on the prescriptions. Tr. 534, 857–58, 860; GX 35 at 2–27.

Dr. Schossow opined that a pharmacist, acting within the relevant standard of care, when confronted with the red flags revealed within the subject records for Patient J.B., would not have filled the subject prescriptions without addressing, resolving, and documenting the red flags discussed. Tr. 859–60; GX 5 at 1.

Patient L.V.

Dr. Schossow identified a patient medication dispensing report printout for Patient L.V. Tr. 510; GX 6 at 6. On March 2, 2017, prescriptions for Morphine Sulfate, Alprazolam, and Oxycodone were filled. Tr. 511. They are included as prescription numbers 308 to 310. Dispensing these medications on the same day causes concern and serves as a red flag as they each suppress the CNS and fall under the FDA black box warning for risk of sedation, respiratory depression, coma, and death.

Oxycodone is an opioid and Xanax is a benzodiazepine. Tr. 513. Looking at fill stickers, these prescriptions were issued on February 23, 2018. Tr. 513–14; GX 23 at 2, 4. These prescriptions are a red flag since they both depress the central nervous system and fall under the prospective DUR for drug interaction and side effects. Tr. 514–15. Viewing additional prescriptions, Oxycodone 30, Xanax 1 mg, and Soma were both filled on March 21, which again, represents a trinity. Tr. 515; GX 23 at 8–10. There are two more prescriptions for Xanax and Oxycodone 30 mg, which indicate a red flag because an opioid and benzodiazepine were filled on the same day. Tr. 516; GX 23, p. 11, 14.

A prescription for an opioid, Oxycodone 30 mg, and a benzodiazepine, Alprazolam 2 mg, prescriptions 5127 and 5129, are a red flag. Tr. 520; GX 7 at 1–4. There were additional prescriptions of the same opioid and a benzodiazepine (Oxycodone 30mg and Xanax) that were also red flags, based upon the cocktail created by the controlled substances, which are a central nervous system depressant, and can cause sedation,

[21] Although both parties used the term, ''patient profile'', Dr. Schossow confirmed the Florida subject regulations did not define the term. Tr. 1035.

respiratory depression, overdose, coma, and death. Tr. 521–28; GX 7 at 8–9, 10–11, 14–17, 22–25, 26, 28–29, 31–36, 37, 40–42, 43, 46–47, 49, 55–59, 60–65, 66–71, 72–76, 77–82. When checking both the front and back of the prescriptions, Dr. Schossow did not see any indications that any of the red flags were documented or resolved as to any of the subject prescriptions. Tr. 529.

Additional red flags for cash payments were present. Tr. 758, 767–68, 772–74, 776, 778; GX 15 at 1–6, 7–12, 13–8, 19–21, 25, 27, 31–36, 38, 40, 43–48, 50, 52, 56, 58, 62, 64, 75–80. Red flags for the unusually high amount of the cash payment were also present. Tr. 758–64, 767–68, 772, 775–78; GX 15 at 8, 16, 22, 34, 50, 58, 64, 76.

An additional matter of suspicion arose in L.V.'s alternate use of insurance to pay for benzodiazepine prescriptions in lieu of the many cash payments for opioids, especially considering the high prices L.V. paid for them. Tr. 768–76, 677–78; GX 15 at 30, 31–36, 42, 48, 54, 60, 71, 72, 75.

Patient A.B.

Dr. Schossow identified patient computer profiles and prescriptions for Patient A.B. Tr. 534–35, 538; GX 8, 24. Viewing the prescriptions in the patient profile, she found that the listed prescriptions, which included combinations of a benzodiazepine and an opioid to create a cocktail, which are a central nervous system depressants, again were red flags. Tr. 535–38; GX 3 at 1–6, 7–12, 13–18, 19–24; GX 24 at 1–6, 7–12, 13–18, 19–24, 26–31, 32, 33, 35, 38, 39, 40, 42–45. These prescriptions included additional controlled substances, including Diazepam (a benzodiazepine), Hydromorphone, OxyContin, and Valium (a benzodiazepine). Tr. 540–41. She did not see any of the subject red flags documented or resolved in the prescriptions that she reviewed. Tr. 539; GX 8.

Patient T.G.

Dr. Schossow identified a patient medication dispensing report printout for Patient T.G. Tr. 509–10; GX 6 at 3. She also identified the patient profile prescriptions for Patient T.G. Tr. 556; GX 12. She identified ''ACQ Cost'' in the record, as referring to acquisition cost. Tr. 556; GX 1 at 2. Viewing the second column, she saw an acquisition price of $43.19. Tr. 557. Further up on the same page in the record, there was a ''price paid'' in the same column. The price paid was $480. This accounting occurred with additional groups of prescriptions for this patient. Tr. 563; GX 12 at 5–8, 10. In Dr. Schossow's opinion, the amount paid by a customer can be a red flag. Tr. 563–65.[22]

Dr. Schossow's experience in the pricing of medications in Florida reflected an approximate twenty percent mark-up from acquisition cost. Tr. 570–72. She also did research on her own of the pricing of the subject medications within the subject locale. She phoned pharmacists at Walgreens and CVS and obtained the actual prices for the subject medications.[23]

Viewing Patient T.G.'s patient profile prescriptions, the type of payment was an ''RX-lock'', which Dr. Schossow understood to mean a cash payment. Tr. 579; GX 12 at 13–16. It applied to both prescriptions. The method of payment and the amount paid by the customer are red flags. This also applied to additional prescriptions for Patient T.G.[24] Tr. 580–83, 589–94; GX 12 at 17–20, 21–24, 25–28, 29–32, 33–34, 35–38, 39–42; GX 28 at 1–4, 5–8, 9–10, 11–12, 13–14, 15–17. There was no documentation that the red flags relating to payments in cash or high prices paid were flagged or addressed by the pharmacy. Tr. 595–96; GX 5 at 2; GX 20. A pharmacist acting in the usual course of professional practice would not have filled the charged prescriptions without addressing those red flags and documenting the resolution. Tr. 596–97.

Patient S.K.

Dr. Schossow identified the patient profile prescriptions for Patient S.K. Tr. 597; GX 13. All of the prescriptions were paid for in cash, which is a red flag. Tr. 597–98; GX 13, pp. 1–6. It is also a red flag for the high amount of cash paid by the customer. Tr. 598; GX 13 at 2. There are additional concerns for these prescriptions. Looking at the first prescription, the first concern is that the doctor is writing for the highest dosage of immediate release Hydromorphone; the second is that the doctor scheduled the medication, which is usually given as a PRN (''take as needed'') dosing or breakthrough medication; and the third is that the prescription was written for an anxiety disorder, while Hydromorphone is not indicated for anxiety. Tr. 598–99; GX 13 at 1.

Another prescription written for this patient included concerns that the doctor wrote a prescription for Morphine ER 15 mg, one tablet, twice daily. Tr. 599. This prescription was concerning because the prescription was for an opioid. It was also concerning because the pharmacist did not address that the prescription was for an anxiety disorder, for which Morphine is not indicated. Another concern was that long-acting opioid prescriptions were developed by the manufacturers to limit the number of PRN medications the patient would have to take. In this case, the lowest dosage of Morphine was 15 mg twice a day, along with the Hydromorphone 8 mg, which is equivalent to around 32 mg of Morphine four times per day. It is not within the standard of care for a low-dose Morphine to be prescribed with the highest dose of another opioid. Tr. 599–600.

In order for a pharmacist to safely dispense medication, she must know the dosing and how long the drug lasts in the body. Tr. 603. Pharmacists know that Hydromorphone lasts in the body from two to four hours, while a long-acting opioid like MS Contin lasts in the body eight to twelve hours. Long-acting opioids were meant to reduce the amount of immediate release opioids given. In this case, there are very high doses of immediate release opioids, which are usually given on an as-needed basis because they only last a short time. When working in pain management, the doctor determines the total daily dose of the MME and schedules that dose on the basis of the long-acting opioid; the doctor does not

[22] Dr. Schossow has experience working in retail for twelve years in different pharmacies all over the State of Florida, but not including southwest Florida. Tr. 564. There are regional variations for the prices of medication, but the typical mark-up of medications is around 20 to 25 percent. Tr. 565. Dr. Schossow is familiar with the price of these medications during the charged period from her time working in hospice. Tr. 566. She worked with the rejection queue with high-cost medications for patients all over the State of Florida. Tr. 566–67. She was the lead of the team, and a trainer for the queue, so everyone who she trained understood normal pricing for Oxycodone and Hydromorphone. The mark-up is about 20 percent over the pharmacy's acquisition cost. There are slight variations regionally in different counties and different areas of Florida, but the typical mark-up is 20 to 25 percent over the acquisition. Tr. 569. When Dr. Schossow sees very high prices, it is a red flag. Hospice also would not pay for it, so she would contact the pharmacy and inquire how much they paid for it. Dr. Schossow could not definitively quantify what the slight variations would be, but it would typically be around 20 percent at most. Tr. 569–70. I overruled the Respondent's objections to Dr. Schossow's testimony and allowed her to testify about the acquisition cost and how she determined that the price paid is much higher than what would normally be charged in Florida, even with slight variations in prices regionally. Tr. 571–72.

[23] The Respondent objected to this hearsay evidence, and it was ruled inadmissible as the individuals who provided the pricing information were not identified in the Government's Supplemental Prehearing Statement, as required by the Order for Prehearing Statements. Tr. 572–78, 1009–10; ALJ Ex. 6.

[24] I sustained the Respondent's objections to Dr. Schossow speculating on the connection between the price paid for the prescription and how the drug-seeking community is taking advantage of using this system, including the pharmacy's reputation within the community as without established foundation. Tr. 583–89.

give more immediate release medication than a long-acting opioid. Tr. 1036–37. In this case, because the way the doctor wrote the prescription did not make pharmacological sense, the pharmacist should have done his due diligence to address the inappropriate dosing of the medications. Tr. 605. Dr. Schossow did not see any documentation on the resolution of these red flags, including the pharmacist contacting the doctor. Improper pharmacological drug dosing is discussed in ''Florida Rule 64B16–27.810.'' Tr. 605. The lower dose of the long-acting opioid with the higher doses of the short-acting opioid is a red flag. Tr. 606. This is something the pharmacy should have addressed.

The first two prescriptions for the patient are opioids and the third prescription is for Clonazepam, which is a benzodiazepine. Tr. 606; GX 13 at 1–6. Taken together, these prescriptions represent a cocktail, which is a red flag. Additional prescriptions given to the patient indicate red flags for cash payments, the high price paid by the patient, the dosages of the medications, improper medications for listed conditions, and cocktail combinations. Tr. 606–11, 612–24, 626–40; GX 13 at 7–12, 13–18, 19–24, 25–30, 31–36, 37–42, 43–48, 49–54, 55–60, 61–66, 67–72, 73–78; GX 29 at 1–6, 7–12, 13–18, 19–24, 25–30, 31–33, 34–39, 40–45, 46–49, 50–53, 54–57, 58–61, 62–65, 66–69, 70–73, 74–79.

A Florida pharmacist operating within the standard of care should have resolved the red flags and documented that resolution that were identified for Patient S.K. for subsequent pharmacists to assure continuity of care and patient safety, assuming the red flags were resolvable. Tr. 640–41. Looking at the patient profile, there was nothing in the patient profile or prescriptions for Patient S.K. to suggest that any sort of investigation was done or that the red flags were addressed, resolved, or documented. Tr. 641; GX 21. A reasonable pharmacist acting in the usual course of professional practice would not have filled these prescriptions without addressing, resolving, and documenting such resolution of the red flags. Tr. 641.

Patient R.R.

Dr. Schossow identified the patient profile prescriptions for Patient R.R. Tr. 641–42; GX 14. The prescriptions present red flags for cash payment. Tr. 642; GX 14 at 1–7. They also indicate a red flag for high prices paid by the patient. Tr. 642; GX 14 at 2. They also indicate a red flag for cocktail medications. An additional prescription is for Alprazolam or Xanax 2 mg, which is the highest strength available. Tr. 643; GX 14 at 5–6. This drug is called ''Xany Bars'' on the street, and is a highly sought-after diverted medication. Although it is not usual to dose this medication to half a tablet, it raises a red flag with this particular drug that the instructions were to dispense 30, which is the entire tablet. The pharmacist should address why the patient is prescribed 2 mg in order to take half a tablet of a highly sought-after medication, when Xanax 1 mg is available. Tr. 643–44. Dr. Schossow has never seen Xanax directions like this. This prescription represents a red flag with respect to the nature of the dispensing order of the controlled substance. Tr. 644–45. The additional prescriptions issued to the patient demonstrated these red flags, including red flags for clinical abuse use under Florida Regulation 810,[25] inappropriate clinical and therapeutic dosing, and extended release opioids combined with immediate release opioids. Tr. 645–47, 648–66, 666–73; GX 14 at 8–13, 14–19; GX 31 at 1–6, 7–12, 13–18, 22–25, 27–28, 29–30, 32–33, 34–35, 37–38, 40–41, 42–47, 48–51, 52–55, 56–59, 60–63, 64–69, 70–75; GX 40 at 8–11, 12–13, 14–15, 16–19, 20–23, 24–29, 30–31.

A Florida pharmacist operating within the standard of care should have acknowledged the therapeutic inappropriateness of the prescriptions, and should have contacted the patient or the provider and recorded the resolution of those red flags, if they were resolvable. Tr. 673. Dr. Schossow believed all red flags herein were resolvable. Tr. 1038, 1068. Dr. Schossow did not see any indication on the prescriptions for Patient R.R. that any specific red flags were identified or documented or resolved on any of the prescriptions. There is nothing in the patient profile to suggest that an investigation was done or that the red flags were identified, resolved or documented in the patient profile. Tr. 673; GX 40 at 1. The critical comments listed did not address or show how the red flags or DURs were resolved. Tr. 673–74. None of the documents in the dispensing log address the red flags for the prescriptions. Tr. 674; GX 40 at 2–7. Based on a review of the prescriptions, the patient profile, or any other documents for Patient R.R., Dr. Schossow opined that a reasonable pharmacist acting in the usual course of profession practice would not have filled the charged prescriptions without addressing, resolving, and documenting the red flags for this patient. Tr. 674.

[25] Florida Administrative Rule 64B16–27.810.

Patient R.D.

Dr. Schossow identified the patient profile prescriptions for Patient R.D. Tr. 675–76; GX 10. She noted that Ativan is a benzodiazepine. Tr. 676. The prescriptions indicate a red flag for cocktail medications. Tr. 676; GX 10 at 1–4. They also indicate a red flag for payment of cash for controlled substance prescriptions. They further indicate a red flag for the high amount of cash paid for controlled substances. Dr. Schossow explained that one of the medications is Hydromorphone 8 mg, which is the highest dosage of medication commercially available for this medication. Tr. 677. Although the prescribing physician said the medication was not only for anxiety, but also to manage hypertension, this medication does not treat anxiety or hypertension. This is very dangerous because there were no records that the pharmacist attempted to contact the physician to discuss the red flag. Tr. 677.

There was an additional red flag present with Patient R.D. Tr. 678. The red flag involved long distances traveled by the patient. Tr. 678–79; GX 10 at. 1–2. Dr. Schossow looked up the address of the doctor, the patient, and the pharmacy, which she characterized as an abnormally long distance. Additionally, there were other pharmacies that were very close. Dr. Schossow had concerns with the patient traveling longer than necessary to get to the Respondent pharmacy and then paying ''double the amount'' for the prescription. Tr. 679. A community pharmacist knows her community and the area around it, so this presents a safety issue. Tr. 682, 1032. Dr. Schossow would defer to a local community pharmacist's knowledge of the subject area. Tr. 1032. For example, central nervous system depressant drugs suppress the central nervous system and cause drowsiness, dizziness, and profound sedation, including a warning on operating heavy machinery. If a patient can drive across the street to obtain her medication versus driving further, it is safer for the patient. Tr. 950–53.

Dr. Schossow did not suggest that distance is a reason not to fill a prescription, but it is a reason to ask more questions and clear up concerns. Tr. 682–83, 954–58. In this case, there was no such documentation. Dr. Schossow mapped all of the relevant cities and determined the route that the patient used. The patient lived very far west, had to cross over three bridges to get to the prescribing physician, and then crossed over another bridge to get

to the pharmacy. These prescriptions issued to Patient R.D. thus presented a red flag for distance. Tr. 684; GX 10 at 1–4.

The additional prescriptions issued to the patient demonstrated the previously discussed red flags. Tr. 685–701; GX 10 at 5–8, 9–12; GX 26 at 1–4, 5–8, 9–12, 13–16, 17–20, 21–23, 24–27, 28–31, 32–35, 36–39, 40–43, 44–47, 48–51, 52–55, 56–59.

A Florida pharmacist operating within the standard of care must make a reasonable effort to address each red flag for therapeutic appropriateness through either the patient and/or the physician, document if the red flag is resolved, and maintain those records. Tr. 701. Looking at the patient profile and prescriptions, there is nothing to suggest that an investigation or assessment was done of any of the red flags identified by Dr. Schossow. Tr. 701–02; GX 10, 19, 26. In the patient profile, the comments in the critical comments popup box do not address the red flags identified by Dr. Schossow. Tr. 702; GX 19. Based on her review of the prescriptions and patient profile, Dr. Schossow opined that a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient R.D. without addressing, identifying, resolving, and documenting the red flags observed and charged by the Government. Tr. 702.

Patient J.R.

Dr. Schossow identified the patient profile prescriptions for Patient J.R. Tr. 702–03; GX 30. The prescriptions issued to the patient present a red flag for cocktail combinations or a trinity. Tr. 703; GX 30, p. 47–54. The prescriptions contain two benzodiazepines, Carisoprodol or Soma, and an opioid, Hydrocodone. Tr. 703–04. The prescriptions also indicate another red flag that falls under Regulation 810[26] of the DUR for therapeutic duplication. Tr. 704; GX 10 at 49–50, 53–54. Therapeutic duplication means two drugs that are in the same class, and thus act in the same way. With Patient J.R., there are two medications that are benzodiazepines and they are both long-acting benzodiazepines. They are Temazepam and Diazepam. This represents a dangerous combination. The two medications duplicate effects and are therapeutically inappropriate because they can compound the side effects of each other. These side effects include CNS depression, leading to respiratory depression, pronounced sedation, overdose, and death. Tr. 704–05.

[26] Florida Administrative Rule 64B16–27.810.

Additional prescriptions to Patient J.R. also indicated these red flags. Tr. 705–07; GX 30 at 55–60, 61–68.

Patient J.R. was prescribed additional trinity cocktails. Tr. 708–09; GX 39 at 3–4, 13–14, 31–34. The patient received an opioid, the muscle relaxer Carisoprodol, and two long-acting benzodiazepines. Tr. 710. The prescriptions also indicated a red flag of therapeutic duplication of benzodiazepines. Tr. 710; GX 39 at 31–34. Additional prescriptions indicated these red flags. Tr. 710–16; GX 39 at 2, 7–10, 11–12, 15–16, 35–38.

A Florida pharmacist operating within the standard of care should have made a reasonable effort to contact the patient and/or the doctor and inquire about the therapeutic inappropriateness of the medication, the risk involved in taking the medications together, and if the therapeutic inappropriateness was resolvable, to document the resolution and maintain those records. Tr. 716–17. There is nothing in the patient profile or prescriptions that suggests that an investigation was done of any of the red flags or that the red flags were resolved. Tr. 717; GX 39 at 1. A reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient J.R. without addressing, resolving, and documenting the red flags that have been charged by the Government. Tr. 717.

Patient B.Di.

Dr. Schossow identified the patient profile prescriptions for Patient B.Di. Tr. 718–19; GX 11. Prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 719; GX 11 at 1–6. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 719; GX 11 at 2. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Finally, the prescriptions for Dilaudid 8mg and MS Contin 30 mg, extended release, indicate a red flag for opioid dosing. Tr. 719–20; GX 11 at 1, 3. Additional prescriptions indicated the previously discussed red flags. Tr. 720–43; GX 11 at 7–12, 13–18, 19–24, 25–30, 31–36, 37–42, 43–48, 49–54, 55–60; GX 27 at 1–6, 7–12, 13–18, 19–23, 24, 26–27, 29–30, 32–35, 36–39, 41–42, 43–44, 46–49, 50–55, 56–61, 62–67, 68–73, 74–79, 80–83, 86–93; GX 38, pp. 5–6, 7–10, 11–14, 15–16, 17–18, 19–20, 21–22.

A Florida pharmacist operating within the standard of care should have addressed each red flag of concern, documented it appropriately in his patient record, and maintained those records. Tr. 743–44. There is nothing in the patient profile or in the prescriptions to suggest that any sort of investigation or resolution was made or attempted or documented with respect to the identified red flags. Nothing in the patient profile indicated that any of the prescriptions were reviewed. A reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient B.Di. without first addressing, resolving, and documenting the specific red flags identified by Dr. Schossow. Tr. 744.

Patient B.Da.

As to Patient B.D.a., prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 745–46; GX 9 at 1–6. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 745; GX 9 at 4. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 745–46; GX 9 at 1–6. Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 746; GX 9 at 7–12. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Finally, the prescriptions demonstrate a red flag for long distance travel. Tr. 747; GX 9 at 7–12.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 747; GX 9 at 13–18. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 747; GX 9 at 14. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748; GX 9 at 13–18.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 748; GX 9 at 19–24. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 749; GX 9 at 20. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 749; GX 9 at 19–24.

Additional prescriptions indicated a red flag for cash payment for controlled

substance prescriptions. Tr. 749; GX 9 at 25–30. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 749; GX 9 at 30. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 749; GX 9 at 25–30. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 750; GX 25 at 1–3. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 751; GX 25 at 1–3. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 751; GX 25 at 1–3. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 752; GX 25 at. 7–12. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 752; GX 25 at 8. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 752; GX 25 at 7–12. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 752; GX 25 at 13–18. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 752; GX 25 at 13–18. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 752; GX 25 at 13–18. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 752; GX 25 at 19–24. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 752; GX 25 at 22. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 752; GX 25 at 19–24. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 753; GX 25 at 19–24. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 753; GX 37 at 24–25, 28–31. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 753; GX 37 at 29. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 753; GX 37 at 28–31. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 754; GX 37 at 28–31. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 754; GX 37 at 18–19, 22–23, 26–27. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 754; GX 37 at 27. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 754; GX 37 at 28–31. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 754; GX 37 at 28–31. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 755; GX 37 at 8–9, 16–17, 20–21. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 755; GX 37 at 8–9, 16–17, 20–21. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 755; GX 37, pp. 8–9, 16–17, 20–21. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 755; GX 37 at 10–15. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 755; GX 37 at 11. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 756; GX 37 at 10–15. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 756; GX 37 at 10–15. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Dr. Schossow opined that a pharmacist, acting within the relevant standard of care, when confronted with the red flags revealed within the subject records for Patient B.D.a., would have investigated the therapeutic appropriateness of the subject prescriptions by contacting the prescribing physician or patient, document if the red flags were resolvable, and to maintain that documentation. Tr. 756. Nothing in the patient profile, prescriptions nor medical records suggest any investigation to identify, resolve or document the subject red flags. Tr. 756–57; GX 37 at 1, 4–8.

Patient L.V.

Dr. Schossow identified prescriptions revealing the red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 791, 794, 796, 797, 798–807; GX 32 at 1–8, 9–16, 25–28, 37–42, 44–51, 53–60, 61–68, 69–74, 75–80, 83–90, 91–98, 101–08, 109–114, 117–124. Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 794, 796–807; GX 32 at 9–16, 23, 24, 25–28, 37–42, 44–51, 53–60, 61–68, 69–74, 75–80, 83–90, 91–98, 101–108, 109–114, 117–124. Dr. Schossow noted a further red flag with some prescriptions paid for by cash, while others were paid for by insurance. Tr. 792–93, 794; GX 32 at 6, 8, 9–16. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 793–807; GX 32 at 2, 10, 24, 26, 37, 47, 54, 64, 70, 75, 84, 94, 102, 110, 120.

Dr. Schossow opined that a pharmacist, acting within the relevant standard of care, when confronted with the red flags revealed within the subject records for Patient L.V., would not have filled the subject prescriptions without addressing, resolving and documenting the red flags discussed. Tr. 812–13. Nothing in the patient profile, prescriptions nor medical records suggest any investigation to identify, resolve or document the subject red flags. Tr. 808–09, 812–13; GX 5 at 3; GX 6 at 5–6; GX 22.

Patient A.B.

Dr. Schossow identified prescriptions demonstrating a red flag for combining extended release and immediate release opioids. Tr. 813–16, 819–823, 825, 827–28, 830, 831, 832, 833–34, 835–41, 842–43, 845–48; GX 8 at 1–4, 7–10, 13–16, 19–22; GX 24 at 1–4, 7–10, 13–16, 26–

29, 32–33, 37–38, 40–41, 44–47, 50–53, 56–59, 62–63, 68–71, 74–77, 80–83, 86–89, 92–95; GX 36 at 17–20, 21–24, 27–30. Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 814, 820–21, 823, 827, 828, 830, 831–34, 836–41, 843, 845–47, 848–49; GX 8 at 1–4, 7–10, 13–16; GX 24 at 1–4, 7–10, 26–29, 32–33, 37–38, 40–41, 44–47, 50–53, 56–59, 62–63, 68–71, 74–77, 80–83, 86–89, 92–95; GX 36 at 17–20, 21–24, 27–30. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 816–17, 820, 821–23, 825–27, 828–29, 830–32, 833–37, 839, 841, 842–44, 845–47, 848–49; GX 8 at 2, 8, 14, 20; GX 24 at 10, 20, 27, 32–33, 38, 47, 51, 53, 59, 63, 71, 77, 83, 87, 95; GX 36 at 20, 24, 30. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748, 816–17, 820–21, 822, 824, 826, 827, 829–30, 832–37, 838–40, 841–44, 847, 848–50; GX 8 at 2, 8; GX 24, p. 4, 7–10, 13–16, 26–29, 33, 41, 44–47, 51, 53, 59, 63, 71, 77, 83, 87, 95; GX 36 at 17–20, 21–24, 30.

Nothing in the patient profile, prescriptions nor medical records suggest any investigation to identify, resolve or document the subject red flags. Tr. 844–45; GX 36 at 1–12. Dr. Schossow opined that a pharmacist, acting within the relevant standard of care, when confronted with the red flags revealed within the subject records for Patient A.B., would not have filled the subject prescriptions without addressing, resolving and documenting the red flags discussed. Tr. 850–51.[27]

Respondent's Case-in-Chief

The Respondent presented its defense through the testimony of five witnesses: Dr. Daniel Buffington, L.V., J.R., Dr. N., and Dr. Ricard Fertil.

J.R.[28]

J.R. lives in Cape Coral, Florida and is a disabled Vietnam veteran. Tr. 1310. He has service-connected disabilities as a result of back problems, including four back surgeries, eye cancer, and suffers from post-traumatic stress disorder. Tr. 1310–1313. Dr. D. has been his pain management doctor for three or four years. Tr. 1313. J.R. began seeing Dr. D. at his practice in Fort Myers, but Dr. D.'s practice has since moved to Naples, Florida. Tr. 1314. Despite Dr. D.'s relocation, J.R. drives to Dr. D.'s new office. Tr. 1314–15. Dr. D. has prescribed J.R. Oxycodone, hydrocodone, and extended-release morphine sulfate. Tr. 1315. J.R.'s primary care doctor, Dr. M., also prescribed J.R. diazepam, temazepam, and carisopridol, also known as Soma. Tr. 1316.

J.R. was a customer with Gulf Med Pharmacy for about two or three years. Tr. 1317. J.R. provided the pharmacy a disk with his MRI from the VA. Tr. 1317. Prior to becoming a customer at Gulf Med, J.R. filled his prescriptions with Walgreens. Tr. 1318. Walgreens failed to provide him with a prescription after a surgery so he went to the closest pharmacy that could fill his prescription, Gulf Med. Tr. 1318. Gulf Med is even closer than Dr. D.'s office in Naples, Florida. Tr. 1319. Gulf Med always answered his questions to his satisfaction and provided him with written or printed materials like brochures or informational material for his opioid prescriptions. Tr. 1319. J.R. discussed information regarding his medical history, treatment, and prescriptions with Gulf Med staff that he had previously discussed with his doctors. Tr. 1320. He spoke with Mr. Fertil about medication he was taking and the ways he could wean himself off some medications and Mr. Fertil appeared very knowledgeable about this. Tr. 1321. J.R. did in fact taper off some of his medicines.

L.V.

L.V. lives at 1103 Northeast 32nd Terrace in Cape Coral, Florida and serves as a billing manager for Charlotte Compassionate Care. Tr. 1292. She suffers from anxiety, cervical disc degeneration, cervicalgia, lumbar or lumbrosacral disc degeneration, lumbago, partial tear of a rotator cuff, chronic pain syndrome, breast cancer and was diagnosed with COVID–19 in July 2020. Tr. 1293–94, 1298. She is a patient of Dr. N. in Fort Myers, Florida. Tr. 1194. Dr. N. prescribed certain medications to L.V. including 30 milligrams of oxycodone and extended-release MS Contin 60 milligram and L.V. had previously been prescribed alprazolam or Xanax. Tr. 1294.[29] L.V. was previously a customer of Gulf Med, but could not recall how many years she was a customer there. Tr. 1301. She had gone to a different pharmacy, Myerlee, but changed to Gulf Med because there was a delay in Myerlee filling her prescriptions, which caused her a lot of pain for weeks at a time until the prescriptions were filled. Tr. 1301–02.

L.V. had tried using other pharmacies. Tr. 1302–03. Walgreens told her to never come back to the pharmacy after putting her name in the computer and Publix told her that it could not run the prescriptions through her insurance and it would not fill her prescriptions. Tr. 1303. She then went to Gulf Med, where her prescriptions were filled in a timely fashion at a reasonable price. Tr. 1303. She selected Gulf Med over other pharmacies because it always had her medications at cheaper prices. Tr. 1305. Gulf Med also provided her with informational materials/brochures regarding the prescriptions it was dispensing to her, which included a CDC pamphlet about prescription opioids. Tr. 1306. Based on discussions with her physician, Dr. N., she learned that Dr. N. had been in contact with Gulf Med regarding her prescriptions. Tr. 1307.

[27] The Government offered various statistical evidence regarding average national prices for controlled substances, average miles driven to the pharmacy by patients nationally, a high percentage of the Respondent's patients traveling long distances to the Respondent's pharmacy, the relatively high percentage of the Respondent's patients paying by cash, the high percentage of the Respondent's controlled substance dispensations versus non-controlled, the extremely high percentage of compounded hydromorphone 8 mg dispensed versus the commercially available hydromorphone 8 mg tablet dispensed by the Respondent, the extremely high percentage of oxycodone 30 mg, and Alprazolam 2 mg (the highest dosage units commercially produced) prescriptions issued as compared with lower dosage units dispensed, that the Respondent dispensed almost twice as many oxycodone 30 mg capsules as tablets. Tr. 235–38, 241, 244–46, 250–51. This evidence was admitted as it related to the prompting and evaluation of various red flags. It was not admitted, and will not be considered, as probative evidence that specific prescriptions were filled contrary to the standard of care in Florida, which determination requires individualized proof and individualized analysis.

[28] The testimony of patients of the Respondent was relevant as relates to information they shared with the Respondent prior to the filling of prescriptions, the protocols employed by the Respondent in filling prescriptions, the reasons they traveled some distance to fill their prescriptions, and as relates to the Respondent's experience in filling prescriptions under 21 U.S.C. 823(f)(2). Any patient testimony relating to the efficacy of their physician's treatment and prescribing, whether their physician performed consistent with professional standards, and whether the Respondent's professional performance was consistent to professional standards will not be considered herein. *See* ALJ Exs. 11, 14.

[29] At this point in the testimony the Respondent's counsel asked L.V. if she had ever discussed the risks associated with taking an opioid and a benzodiazepine together. Tr. 1294. The Government's counsel objected based on relevance and that the information was not provided in the Respondent's prehearing statement. Tr. 1295. The Tribunal sustained the objection of relevance, *see* Tr. 1295, and after reviewing the Respondent's first Supplemental Prehearing Statement, overruled the Government's second objection about the testimony being unnoticed. Tr. 1298. The Respondent's counsel next asked if L.V. takes her medications as prescribed, the Government's counsel objected, and the Tribunal sustained the objection based on relevance. Tr. 1298–99.

Dr. N.[30]

Dr. N. has been a licensed physician since 1979 and is licensed in New York, New Jersey, Massachusetts, Connecticut, and Florida. Tr. 1324–25. He completed his residency at Mount Sinai in New York and currently practices in Fort Myers, Florida with a specialty in pain management and anesthesiology. Tr. 1325.

Dr. N. is aware of what an FDA black box warning is.[31] Dr. N. treated a patient by the name of L.V., but could not recall how long he treated her or what medications he prescribed her. Tr. 1327. It has been in Dr. N.'s practice in the past to include an ICD–10 diagnosis code on prescriptions he writes for his patients, which is a diagnosis that Dr. N. gave for the patient. Tr. 1327–28.[32]

Dr. N. could not recall whether pharmacies ever contacted him or his office to verify prescriptions or ask questions about some of the drug therapies he prescribed to his patient. Tr. 1332. Dr. N. is not familiar with Gulf Med Pharmacy and could not recall whether he or his staff communicated with Gulf Med Pharmacy or its staff about verifying prescriptions or drug therapies. Tr. 1333.

Dr. Daniel Buffington

Dr. Daniel Buffington is a pharmacist practicing in Tampa, Florida. Tr. 1081, 1087. Dr. Buffington received his PharmD degree from Mercer University in Atlanta, Georgia and then completed a post-doctorate degree residency and fellowship in clinical pharmacology at Emory University. Tr. 1079. He has practiced as a pharmacist for over thirty years. Tr. 1078, 1087.

Dr. Buffington has training in conducting drug diversion investigations and has worked with attorneys general, states attorneys' offices, the DEA, and local law enforcement. Tr. 1159. He helped these agencies identify how healthcare investigations are different from other investigations involving drug gangs or illicit drug sales. Tr. 1159–60. Dr. Buffington is active with the National Association of Investigators and Drug Diversion Investigators, which is a multidisciplinary organization that aids healthcare professionals in understanding how to conduct and design investigations and look for healthcare fraud, drug divergence, and substance abuse. Tr. 1160.

Dr. Buffington currently practices as a pharmacist in Tampa, Florida at a practice where patients are referred who are typically prescribed high-risk medications. Tr. 1080–85. Dr. Buffington also provides consulting services to pharmacists, medical practitioners, healthcare facilities and organizations, and law enforcement agencies. Tr. 1080, 1085, 1087, 1091. This includes consulting with practices in both Southeast and Southwest Florida. Tr. 1097. Dr. Buffington has served in several capacities as a pharmacist, including direct dispensing roles, administrative roles, and as a medication safety and review officer. Tr. 1088. Although it is unclear how many prescriptions Dr. Buffington has dispensed in the last year or five years, he has experience making determinations about whether or not a particular prescription should be filled for a controlled substance based on the legitimacy or medical reason for its prescription. Tr. 1088–89.

Dr. Buffington also serves on the faculty at the University of South Florida's Colleges of Medicine and Pharmacy where he teaches toxicology, pharmacy law, and other healthcare administration and practice management aspects. Tr. 1076, 1096. He has served as a guest lecturer or taught pharmacy law at the University of Florida, Florida A&M, Nova, Southeastern, Palm Beach, Mercer University, Marshall University, and the University of Pittsburgh. Tr. 1097. Through teaching these courses, Dr. Buffington must review applicable Florida administrative code provisions and is therefore familiar with Florida Administrative Rules 4B16–27.800, 64B16–27.810, and 64B16–27.831. Tr. 1098. Dr. Buffington is also familiar with the standard of care that applies to pharmacists in the State of Florida as the standard of care relates to these administrative code provisions, and corresponding statutes of the federal Controlled Substances Act. Tr. 1099.[33]

Dr. Buffington reported he has testified as an expert witness on over 300 occasions in state, federal, and administrative proceedings. Tr. 1077–78, 1083, 1094. Dr. Buffington reported he has previously testified in DEA administrative hearings before a DEA Administrative Law Judge, but could not recall when or the names of any participants. Tr. 1230. He has appeared as an expert with respect to the Florida standard of care in a DEA administrative proceeding, but is unsure if his testimony was credited by the DEA administrator in a final opinion. Tr. 1230–31.[34]

In approximately February 2020, Dr. Buffington was contacted by a firm representing Gulf Med Pharmacy and reviewed documents in the instant case including copies of prescriptions, dispensing logs, and PDMP data that was produced by the DEA as well as all exhibits offered by both parties in this case. Tr. 1076–77. This included the Order to Show Cause, the Government's Prehearing Statements, and other documents such as CDC guidelines, statutes, administrative rules, and stakeholder challenges. Tr. 1198–99. He also reviewed different statutes and regulations, including Florida statute 766.102, which includes pharmacists in the definition of a ''healthcare practitioner.'' Tr. 1233–34. Dr. Buffington also wrote the summaries of his testimony in concert with counsel. Tr. 1198. He spent approximately ten to fifteen hours preparing for this hearing. Tr. 1201.

Dr. Buffington testified that the standard of care in Florida does not require a pharmacist to document in writing any specific resolution of ''red

[30] Dr. N. is a treating physician of one of the charged patients. His relevant testimony is limited to his interactions with the Respondent prior to the filling of the subject prescriptions and as relates to the Respondent's experience in dispensing controlled substances. 21 U.S.C. 823(f)(2); ALJ Ex. 11.

[31] At this point in the testimony, the Respondent's counsel asked Dr. N. about the black box warning pertaining to the prescribing of a combination of drug therapies and whether Dr. N. prescribed certain medications. Tr. 1325–26. The Government's counsel objected to both questions and the Tribunal sustained both objections noting that the relevance of Dr. N.'s testimony was limited to his interaction with the pharmacy. Tr. 1326.

[32] After reviewing the Government's Exhibit 15, Page 1, Dr. N. noted that the prescription in the exhibit was for 30 milligrams of oxycodone and instructed the patient to take the medication up to four times per day only when necessary to alleviate breakthrough pain. Tr. 1330–31; GX 15 at 1. Government's Exhibit 15 on Page 3 is for MS Contin, 60 milligrams. Tr. 1331; GX 15 at 3. Page 5 of Exhibit 15 depicts a prescription for Xanax. Tr. 1331; GX 15 at 5. MS Contin and oxycodone are opiate medications and Xanax is a benzodiazepine. Tr. 1331.

[33] Dr. Buffington testified that the Federal Controlled Substances Act does not have jurisdiction over the practice of pharmacy in Florida. Tr. 1099.

[34] During cross-examination, the Government questioned Dr. Buffington regarding his CV. Tr. 1201–1209. Dr. Buffington stated that he was not admonished in a district court case in Ohio and his testimony was not stricken for failing to include his legal experience as part of his CV. Tr. 1208. Instead, Dr. Buffington asserts that there was an issue with an Ohio court where the opposing counsel claimed that Dr. Buffington's CV did not follow Federal Rule 26 formatting and opposing counsel petitioned the court for more detail. This updated information for Dr. Buffington's CV was not provided by the deadline and therefore the testimony was withheld and not permitted. Tr. 1209. Unlike the Government counsel's assertion that the district court had found that this was the third time Dr. Buffington failed to disclose legal testimony, *see* Tr. 1210, 13–14, Dr. Buffington asserts that instead there was simply a formatting issue and the court requested for him to include more detail in another case with the same parties, and that the corrected report was done but was missing a case. Tr. 1214.

flags'' [35] and in fact, he testified that the term ''red flags'' is not mentioned in the Florida regulatory documents or the DEA guidance documents, but rather is a DEA slang term.[36] Tr. 1100, 1124, 1145. Dr. Buffington testified that Florida Code 64B16–27.810 merely states what exercise a pharmacist is supposed to perform professionally in the process of evaluating the prescription, not what is required documentation. Tr. 1100. Dr. Buffington stated that the standard of care for a pharmacist in Florida is based on the level of care that a reasonable pharmacist would use in like circumstances and reasonable pharmacists could disagree about what the requirements are for documentation of prescriptions in the state of Florida. Tr. 1101, 1249.

Dr. Buffington testified that Florida's guidelines are clear that a pharmacist must exercise his or her professional judgment in evaluating each prescription and such judgment should have the patient's safety and therapeutic outcomes in mind. Tr. 1101–02, 1135.[37] He testified that, based on a review of all the prescriptions identified in the Government's exhibits that were admitted into evidence, as well as Respondent's exhibits, the pharmacists at Gulf Med Pharmacy complied with the applicable standard of care as it relates to documentation of the resolution of red flags and the DEA provided no substantive evidence to presume otherwise. Tr. 1109, 1112. Furthermore, Dr. Buffington testified that Florida Administrative Rule 64B–27.810 provides categories of elements that pharmacists would consider in their determination of both legally validated and clinically validated prescriptions based on the record they had while performing prescription fulfillment and dispensing, and the code does not state that a written report is required. Tr. 1110.

Dr. Buffington testified that Rule 64B16–27.800 specifically requires that the pharmacist provide the full name, address, phone number, age, date of birth, gender, and the refill details as well as any related information provided by the healthcare professional. Tr. 1111. Furthermore, he testified that it is in the pharmacist's professional judgment as to what is relevant to address and/or record because there is no specific Florida pharmacy law that clearly states what steps are required for each patient. Tr. 1111.

Dr. Buffington reviewed Florida Administrative Rule 64B16–27.831 as it relates to validating a prescription in the retail setting. Tr. 1112. He testified that the administrative code requires that there must be a valid or eligible prescription to move forward and that if the pharmacist has specific concerns (that does not necessarily mean a red flag), then the pharmacist could resolve any issues by speaking to the prescriber or the patient or taking consultation with the prescription drug monitoring program. Tr. 1112–13, 1122. Furthermore, he testified that if a pharmacist learns that a physician is writing a prescription for non-legitimate purpose or ill-intent by the patients, then the pharmacist has a duty to report this to the Florida Department of Public Health. Tr. 1113.

Dr. Buffington testified that there are pharmacy software programs that identify potential issues through an alert system. Tr. 1113–14. He testified that an alert is not inherently a stop and is a pop-up message that prompts the pharmacist to consider something at the time, but the pharmacist may accept or move past the prompt. Tr. 1114. He testified that when a pharmacist ''clicks through'' the pop-up prompt, the software program records this through a ''click tracking'' program. Tr. 1114, 1115. He testified that this click tracking is a key way to track individual activity. Tr. 1114. He testified that when a person has a prescription for both a benzodiazepine and opiate, an alert does not require a stop because these prescriptions are routinely prescribed together. Tr. 1115–16. He testified that it routinely happens that different prescribers prescribe medications that interact and although a pharmacist with concerns should have an assessment with a patient and a provider, there is no requirement set forth in the Florida administrative code that requires such concerns be put in writing. Tr. 1118.

Dr. Buffington testified that as to the specific software program used by Gulf Med, PioneerRx, there are certain boxes that must be clicked, called pathways, in order to fill a prescription. Tr. 1239. He testified that the PioneerRx system allows someone to run a specific report to see how long a pharmacist spent on a particular pathway click. Tr. 1240. Although Dr. Buffington does not recall seeing a report being run, he thinks he saw a ''time change.'' He testified that whether a pharmacist spent ten minutes or five seconds on a particular box looking at a pathway, however, is irrelevant to the instant case given that there is not a single requirement for documentation formatting and the documentation may not have transpired during that pathway.

Dr. Buffington testified that opiates and benzodiazepines, or Class II drugs in general, are routinely prescribed together and although such a combination is not always justified, there is no default presumption that the two drugs cannot be prescribed together. Tr. 1115–16, 1241. Furthermore, he testified that even if two sets of Class II prescriptions are prescribed, this would not be a hard stop. Tr. 1116. [Omitted. *See infra* n.*L.]

Dr. Buffington testified that if a pharmacist receives a prescription for an opiate, benzodiazepine, and a muscle relaxant, there must be an analysis of clinical oversight. Tr. 1118–19. In particular, he testified that the first analysis would be to evaluate for duplicity and whether other muscle relaxants have been prescribed and whether such an addition should be communicated with the prescriber or assessed with the patient based on the pharmacist's professional judgment. Tr. 1119–20.

Furthermore, Dr. Buffington testified that even a black box warning does not serve as a stop if the pharmacist consults with the patient and the E–FORSCE data demonstrates that a patient has been on a certain treatment regimen for a significant period of time. Tr. 1118. He testified that if a muscle relaxant is prescribed with an opiate and benzodiazepine, the analysis as a clinician changes and a pharmacist would then need to make a professional judgment. Tr. 1119–20. Dr. Buffington testified that pursuant to Section 1306.04 of the Controlled Substances Act,[38] the physician has certain responsibilities and makes decisions based on the needs of the patient and selecting a medication by name, product formulation, and dose. Tr. 1120. [Omitted discussion of confusing testimony purporting to interpret federal and state law.] *D

Dr. Buffington testified that although the combination of three controlled substances—colloquially known as the ''holy trinity'' or ''trinity'' [39]—heightens a risk to a patient, there is the same risk when combining many types of

[35] [Omitted for brevity.]

[36] Dr. Buffington noted that these items should be referred to as ''yellow flags'' or ''yellow lights'' as opposed to ''red flags'' because these are things that should be factored and considered. Tr. 1124.

[37] Dr. Buffington's analysis was a direct contradiction to Dr. Schossow's testimony regarding her analysis of the guidelines for a pharmacist in Florida.

[38] 21 CFR 1306.04.

*D Dr. Buffington's testimony addressed the level of intent required for a violation of 21 CFR 1306.06, which is outside of his expertise as a pharmacy expert.

[39] According to Dr. Buffington, the slang term, ''trinity,'' refers to an opiate, a benzodiazepine, and Carisoprodol being prescribed to one patient at the same time. Tr. 1255.

medications including over-the-counter medications. Tr. 1243. He testified that the circumstance of prescribing this combination of prescriptions alone would not automatically raise a reasonable suspicion. Tr. 1265–68. Therefore, he testified that there is need and merit to evaluate and counsel the patient, but it is not necessarily inappropriate to prescribe three controlled substance together as it is commonplace for physicians to prescribe this combination. Tr. 1243–44. Dr. Buffington testified that it is a clinical question as to whether there is inappropriate use as opposed to a law enforcement question. Tr. 1253–54. Furthermore, he testified that although these three combined substances can also produce a high by illicit drug use, alcohol use and other base medications can have the same effect and this is irrelevant to the case. Tr. 1255. Furthermore, he testified that the practice of prescribing these three drugs together is declining based on the research that Carisoprodol is of less utility. Tr. 1255. Dr. Buffington testified that even if ''red flags'' are an inference to things that a pharmacist should look at and evaluate, these are not something that should be counted and a person is in trouble if his count hits a threshold. Tr. 1254. In Dr. Buffington's view, this would be a disingenuous attempt at an investigation.[40]

Dr. Buffington compared the Florida Administrative Codes to the federal regulations and the Controlled Substances Act, noting that the statute is very clear that the responsibility of the prescriber or the dispenser is to knowingly demonstrate that a prescription was written or dispensed for an appropriate purpose whereas the Florida law speaks to the duty of the pharmacist and the requirement to report. Tr. 1120. Furthermore, he testified that ''combination therapy'' or ''multidrug regimen'' [41] are routine and the Respondent in this case had not failed in its responsibility nor was there evidence that the Respondent breached its standard of pharmacy practice with regards to such medications. Tr. 1121–22.

Dr. Buffington testified that the quantity of the dosage of a product formulation should not itself be a ''red flag'' because pharmacists will instruct patients to take multiples of whatever that formulation is at the time of dosing which makes product formulation an irrelevant basis of a ''red flag.'' [42] Tr. 1124–25. He testified that even lower dosages carry the possibility of adverse side effects. Tr. 1125. He testified that it is not a deviation from a Florida pharmacist's standard of care or corresponding responsibility to fill a prescription that includes a long-acting or extended release opiate (some of which are twelve or twenty-four hours) along with an immediate release for breakthrough pain. Tr. 1129–30.[43]

Dr. Buffington testified that there were no breaches of the pharmacist's responsibilities or that the pharmacist had breached a duty. Tr. 1131–32.[44] Specifically, he testified that there was no evidence presented in this case that a pharmacist in the State of Florida at Gulf Med Pharmacy was knowingly aware. Tr. 1134. He testified that Gulf Med also did not ''turn a blind eye'' or ''bur[y] [its] head in the sand'' when Gulf Med pharmacists were presented with issues due to red flags because the Florida pharmacy statutes, and administrative rules require a pharmacist use professional judgment and there is no requirement that this needs to be documented. Tr. 1135.

Dr. Buffington testified that there is no restriction on the distance a patient may travel to a pharmacy and there are in fact now mail order pharmacists. Tr. 1136. Furthermore, he testified that a patient travelling a distance of thirty miles is not a reason to cause a pharmacist pause because many people like to stay engaged with a particular practitioner or the pharmacy is near their work or doctor.[45] Tr. 1138–39. Furthermore, he testified that the Florida Administrative Code does not require a pharmacist to identify or document the distance a patient travelled to their doctor or the pharmacy. Tr. 1141.

As to payment, Dr. Buffington testified that there is nothing that prohibits a patient from paying in cash and even when a patient pays in cash, this is reported through PDMP and E–FORCSE. Tr. 1144–45. He testified that there is no circumventing the system when a patient pays in cash. Tr. 1145. He testified that E–FORCSE data includes the name of the prescriber, the prescriber's address, the name of the patient, the patient's address, the price that was paid, the date the prescription was issued, and the date it was filled, and the manner of payment. Tr. 1145, 1274. He testified that a pharmacist must evaluate many other data elements including a patient's response to medications and medical history. Tr. 1145. Furthermore, he testified that a patient may pay with cash because there is a better pathway for their out-of-pockets costs, including a discount plan. Tr. 1146. He testified that even paying for an opioid prescription with cash would not change this analysis. Tr. 1151–52.

Dr. Buffington testified that there are also many variables pharmacists consider when choosing how much to charge a patient.[46] Tr. 1147. In Dr. Buffington's view, a pharmacy is like any other business and requires sufficient practice revenue and pricing tables evolve. Tr. 1148. He testified that cash price is usually higher because there is counter-contract similar to Medicaid or Medical programs that will contract at a reduced price.

Dr. Buffington testified that pharmacies must also take into consideration their overhead costs including rent, payroll, taxes, and utilities. Tr. 1149. Furthermore, he testified that whether Gulf Med has a debt or rent against the building is a nonissue because nothing regulates what a physician charges for a medical service, a surgery, a hospital admission,

[40] At this point in the testimony the Tribunal directed Dr. Buffington not to give his opinion about whether the investigation was appropriate as he had not been qualified to give that opinion. Tr. 1254. The Tribunal reiterated that this not a criminal matter, but rather an administrative proceeding, and directed Dr. Buffington to focus on his expertise as it relates to pharmacy practice and to pharmacy law. Tr. 1254–55.

[41] Respondent's counsel referred to ''cocktail medications'' when questioning Dr. Buffington, however, Dr. Buffington asserted that this was a ''colloquial'' or ''slang'' term, and the proper terminology was ''combination therapy'' or ''multidrug regimen''. Tr. 1121, 1122.

[42] Dr. Buffington specifically disagreed with Dr. Schossow's opinion that there should be an inference of an alert or caution if a medication is prescribed at a magnitude or dose in relation to product formulation that the manufacturer produces. Tr. 1123. In fact, Dr. Buffington described such an inference as ''preposterous'' and stated that it is a complete misrepresentation to make such an inference. However, when later prompted by the Tribunal regarding his critique of Dr. Schossow, Dr. Buffington declined, stating that he did not come to testify about Dr. Schossow's findings, but rather to testify about his own findings in the case. Tr. 1248.

[43] Dr. Buffington testified that the long-acting release are also supposed to provide baseline relief, not 100%. Tr. 1129. Dr. Buffington also described that aggravated pain could occur, which can be triggered by things such as a patient's lifestyle and can vary from patient to patient and even with one patient. Tr. 1129–30, 1248.

[44] Respondent had posed a question asking whether there was any evidence that the Respondent pharmacist deviated or violated the Florida standard of care for a pharmacist as to over- or underutilization, therapeutic duplication, drug disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug allergy interactions, or clinical abuse or misuse. Tr. 1132

[45] Dr. Buffington testified that it is ''particularly offensive to infer the opposite.'' Tr. 1139.

[46] At one point Dr. Buffington stated that payment options were unique to each pharmacy; however, he later went on to state that he ''amend[ed] the comment,'' and in fact the pricing was ''almost universal.'' Tr. 1147.

or what a pharmacy charges for a particular dispensed medication. Tr. 1151. Dr. Buffington testified that after reviewing the acquisition price and sales price on the pill stickers, there was no apparent evidence of inappropriate practice based on the fee structure for the cash paying patients. Tr. 1152.

Dr. Buffington testified that the analysis would not change if a person paid in cash, had a combination of drugs, and drove 30 to 50 miles. Tr. 1153. He testified that once a pharmacist finds the prescription to be fillable the first time based on certain factors, each time after that, there is no longer a red flag.[47] Dr. Buffington testified that pharmacists use their professional judgment in deciding whether to fill it, while complying with Florida Rule 64B17–831. Tr. 1155.

Based on his education, training, and experience, Dr. Buffington reviewed the information in this case and did not see any evidence that would support the inferences made by the Government. He testified that no formal metrics were used and he felt that DEA ''attempt[ed] to manifest or fabricate information from pharmacy records that are incomplete or descriptive of things that they're trying to infer.'' Tr. 1161. Dr. Buffington did not see any red flags, noted that there was other attainable information, and that all the prescriptions charged by the Government and issued by the Respondent are within the standard of care and the scope of professional practice of Florida law as to Florida pharmacies. Tr. 1162, 1241, 1277–78. In particular, Dr. Buffington noted that there were additional fields in the PioneerRx database referred to as Medication Therapy Management and that there were multiple other tabs and therefore further additional information that the investigator can request and consider as a factor. Tr. 1163–64.[48] [However, as discussed in more detail below, Respondent was served with three subpoenas that required the production of all documents that contained any discussion or resolution of red flags. Thus, Dr. Buffington's testimony that there might have been additional materials resolving red flags is not entitled to any weight. Further, there is no evidence that Dr. Buffington reviewed any additional tabs and thus his testimony as to whether there could be information on such other tabs is entirely speculative.] As to the legality, Dr. Buffington testified that there is a three-step process: (1) Presuming legality of a prescription absent evidence to the contrary, (2) the pharmacist validates that the order is valid based on data points and data elements, and (3) doing a Prospective Drug Review. Tr. 1278.

Dr. Buffington has also worked with the Florida Department of Health and Board of Pharmacy in developing regulations relating to pharmacy practice. Tr. 1164. At one point, Dr. Buffington served on the national association of the American Pharmacists Board of Trustees, where he had a dialogue with the DEA to express that healthcare professionals feel like they are part of the solution and although the term ''red flag'' has merit, flags are not metrics and are only things to consider. Tr. 1164–65. According to Dr. Buffington, despite pleas from healthcare professionals, no guidance material has been published for pharmacists since the 2010 Pharmacists Manual and in fact the term ''red flags'' is not even in the manual. 1165–66.

Dr. Buffington testified that there is no requirement that a pharmacist learn about DEA administrative decisions or be familiar with or read the **Federal Register** as the DEA does not have jurisdiction over pharmacy practice. Tr. 1168–69. Although Dr. Buffington testified that the DEA administrator's findings are binding upon DEA registrants, he believes that this does not include every pharmacist and such findings would relate to criminal issues rather than the scope of practice. Tr. 1237. Furthermore, he testified that the DEA is law enforcement and has jurisdiction over criminality, not medical decision-making and pharmacologic decision-making over the use of medications. Tr. 1245.

Dr. Buffington testified that the second aspect of the mandatory CE or assessment ''b'' is using the Prescription Drug Monitoring Database, which Dr. Buffington incorporates into his class. Tr. 1169. Dr. Buffington is familiar with the types of data that E–FORCSE maintains, serves as a consultant with the team that manages the E–FORCSE system in Florida, and covers the types of data that E–FORCSE includes in his continuing education course. Dr. Buffington testified that the third assessment, ''c'', is the assessment of prescriptions for therapeutic value, which requires the practitioners involved in dispensing the drug to use their professional judgment in assessing risk and reviewing a patient's historical response to a medication in deciding whether a drug should be dispensed. Tr. 1169–71, 1175. Dr. Buffington testified that unless there is a known drug allergy or an actual drug interaction, the pharmacist does not need to document his process in dispensing prescriptions. Tr. 1171. Furthermore, Dr. Buffington testified that a pharmacist does not always have the opportunity to speak directly with a patient because a caregiver or family member may bring the prescription, the prescription is called in and the patient is not present, or the prescription may be mailed to a patient. Tr. 1172. Dr. Buffington testified that in these instances, and especially with the current pandemic, such events do not minimize the opportunity to call and have a direct dialogue with a patient and practitioners should touch point to discuss concerns instead of just refusing a prescription. Tr. 1173.

Dr. Buffington testified that pharmacists must also learn how to detect whether a prescription is not based on a legitimate medical purpose, which can be done through communicating with a prescriber, evaluating and having a discussion with the patient, and putting down the patient's diagnosis[49] in the records. Tr. 1178. Dr. Buffington also noted that even if a prescription is outside of the FDA-approved list, pharmacologically, using such a prescription is fine as long as the pharmacist has supporting clinical rationale. Tr. 1174–75. Dr. Buffington testified that Florida Administrative Rule 64B16–27.831 is the law and rule related to prescribing and dispensing of controlled substances, which does not require that pharmacists be educated on DEA administrative decisions, because this would be based on criminal issues and not on something in terms of delivery of healthcare services, which is dictated on the a state level. Tr. 1176–77.[50]

Dr. Buffington testified that the next section is proper patient storage and disposal of controlled substances which discusses how a patient is supposed to store and dispose of controlled substances and requires healthcare professionals to record the receipts, the transfer, and the destruction of controlled substances. Tr. 1177. Dr. Buffington testified that the next section of Florida Administrative Rule 64B16–27.831 relates to protocols for addressing and resolving problems

[47] Furthermore, Dr. Buffington noted that there is no evidence in the record providing how often a pharmacist at Gulf Med did *not* fill a particular prescription. Tr. 1154.

[48] Dr. Buffington analogized his review of the record to that of a puzzle and the missing tabs equated to missing pieces of the puzzle. Tr. 1163–64.

[49] Dr. Buffington noted that in his review of the universe of prescriptions for this case, although it is not required, some of the prescribers routinely include diagnostic codes on the prescriptions. Tr. 1175–76.

[50] *See Gonzalez* v. *Oregon,* 546 U.S. 243, 270–72 (2006), for context.

recognized during the drug utilization review, including but not limited to, drug-drug interactions, side effects, high-dose and low-dose guidelines, which is new to the CE as of June 2018. Tr. 1177–78. Dr. Buffington testified that the mere presence of a dosage range is not a rate limiter for dispensing a prescription, but rather a pharmacist must use his professional judgment. Tr. 1178. Dr. Buffington does not advise pharmacies to document any resolution of these DUR-related issues because there is no requirement to do so and each pharmacy has a process within their own facility to convey from peer to peer. Tr. 1178–79.

Dr. Buffington testified that the protocol for addressing and resolving issues relating to drug utilization review are limited to drug-drug interactions, side effects, and high-dose and low-dose guidelines. Tr. 1179. He testified that such issues must rise to the level of needing resolution in a pharmacist's professional judgment, not that something just occurred. Dr. Buffington testified that Section H requires pharmacists to be educated on the availability of NARCAN or naloxone for overdose treatment. He testified that Section I relates to pharmacists initiating counseling with patients who have opioid prescriptions, which makes it imperative for there to be an open dialogue between the pharmacist and patient. He testified that Section J relates to available treatment resources for opioid physical dependence, addiction, misuse, or abuse. Tr. 1181. Dr. Buffington testified that Respondent pharmacists at Gulf Med were not providing copies of the CDC pamphlet to patients receiving opioid prescriptions, but there is no legislative mandate that the pharmacists give that particular document to patients. Tr. 1181–82. Dr. Buffington testified that there was a legislative change in 2019 that requires pharmacists to develop and/or produce or distribute a patient education pamphlet so the CDC's pamphlet would be an acceptable tool to satisfy that requirement. Tr. 1182.

Dr. Buffington testified that when a prescription is dispensed, a label is produced and given to the patient as an educational resource. Tr. 1182–83. He testified that this labeling is in response to an OBRA–90 mandate that serves as an additional trigger to see if a patient has any questions and leaves with information that improves their health outcomes and safety. Tr. 1185. He testified that the software also generates educational information about warning signs, side effects, drug interactions, and how to store and protect medication. At this point in the testimony, the Respondent's counsel discussed that there is a Critical Comments box in the lower right-hand corner on page 1 of Government's Exhibit 39 which includes a data field for pop-ups and went through several patients. Tr. 1185–1192; GX 39. Dr. Buffington testified that for patient J.R., among the critical comments listed for various dates, the signature or the directions for the use of the prescriptions were verified by the pharmacist with the prescriber. Tr. 1184. Dr. Buffington testified that on May 15, 2019, patient J.R. was also given the CDC pamphlet. On August 5, 2019, the pharmacist requested clarification or verification of the prescription with the provider. Tr. 1184–85; GX 39 at 5. Dr. Greshler prescribed Oxycodone acetaminophen, a combination tablet, and the pharmacist wrote a note saying ''per M.D. patient prior dose was ineffective. Need to start oxy/acet 10/325'' and ''Spoke to Rochelle. Patient was told to increase his dose to 10 milligrams per M.D.'' with the ten milligrams referring to the first active ingredient, Oxycodone. Tr. 1186; GX 39 at 5. There is also a prescription from Dr. Mikovic for morphine extended release, fifteen milligram tablet with a note saying ''new regimen is added to help, current therapy is not sufficient.'' Tr. 1178–92; GX at 7. Dr. Buffington testified that there is only a minimal requirement for a pharmacist so such a note would be an acceptable note. Tr. 1187; GX at 7. Dr. Buffington testified that continuity of care information is also available to pharmacies even in different pharmacies for particular patients. Tr. 1188.

There was also a prescription from a physician, Gilberto Acosta, for an Oxycodone and acetaminophen combination for five milligrams of Oxycodone and 325 milligrams of acetaminophen with a note that said ''doctor wants to add long-acting MS Contin with short Percocet 5.'' Tr. 1190. Based on the dispensing log, the patient also received diazepam, a benzodiazepine typically used for management of anxiety and muscle spasms as well as temazepam, another benzodiazepine, which is used as a sleep aid. Tr. 1191. Dr. Buffington testified that such a prescription is not uncommon, but would necessitate counseling of the patient to watch for over drowsiness in the morning from the temazepam and to limit the diazepam used during the day. Tr. 1191–92. Based on Dr. Buffington's review of the universe of prescriptions that were provided in this case, there were no prescriptions that caused him any concerns. Tr. 1192.

Dr. Buffington testified that there is nothing unusual or inappropriate in a patient using insurance to pay for one prescription and not another because the patient may have an access issue, scope of benefit and coverage issue, difference in out-of-pocket cost at one pharmacy, and other reasons. Tr. 1193. Furthermore, Dr. Buffington believes that the prices that Gulf Med charged for prescriptions such as Oxycodone or Hydromorphone were not surprising or astonishing numbers and even if there was a high value there would be no regulatory problem because that is the patient's prerogative. Tr. 1194. Furthermore, there was nothing that Dr. Buffington reviewed that caused him any concern about whether or not Gulf Med and its pharmacists were exercising their corresponding responsibility or violating the applicable standard of care based upon any of the dosing instructions included in any of the prescriptions. Tr. 1193–94, 1995–96.

Dr. Buffington disagreed with Dr. Schossow's testimony regarding driving under the influence of a benzodiazepine and an opiate as there was no way to determine whether or not the patient was the person who was driving and that there is no clinical expectation that combining these two drugs would in fact impair someone's ability to drive or impact their cognitive status. Tr. 1194–1195. Dr. Buffington testified that although it is possible, it would be disingenuous to infer that putting the two drugs together would be an incorrect behavior. Tr. 1195, 1241. In fact, he testified that the FDA does not say in the black box warning that both drugs cannot be used together and it is not inappropriate to prescribe them together. Tr. 1195, 1243. Dr. Buffington testified that once a prescription is dispensed, the pharmacist cannot control if a person is going to independently abuse something. Tr. 1277.

Dr. Ricard Fertil

Dr. Fertil is a licensed pharmacist in Florida. Tr. 1337. He attended FIU for undergraduate school. He attended and received his doctorate of pharmacy degree from Florida A&M in 2003. Tr. 1336–37. During his attendance at Florida A&M, he performed internships and externships at area hospitals including Jackson Hospital, Texas Hospital and Hollywood Memorial Hospital. Tr. 1337–38. He also trained at CVS and Publix pharmacies in Florida. Tr. 1338. All of his training and experience as a pharmacist has been in Florida. Tr. 1339.

Following his licensing, he worked at CVS and Publix Pharmacies, retail chain pharmacies. Tr. 1339. Later, he worked at independent pharmacies in Southwest Florida for eight or nine years. Tr. 1339–40. While at independent pharmacies, he was involved in setting the prices for medications dispensed to customers. Tr. 1340. He was also involved in negotiating contracts with pharmacy benefits managers in setting rates of reimbursement. Tr. 1341.

Dr. Fertil is the pharmacist in charge at Gulf Med Pharmacy. Gulf Med operates with a single pharmacist and a pharmacy technician. Tr. 1370–71. He was involved with software venders, and in setting up the PioneerRx software for Gulf Med, including setting the pricing formulas within the software. Tr. 1341–42.

Dr. Fertil described the layout of Gulf Med. Located within a building formerly housing a bank, Gulf Med has a drive-through window to service customers. It also has separate rooms for compounding medications, and a consultation room, where HIPAA-protected matters are discussed with the patient in private, and where the pharmacist exercises his professional judgement in determining whether to fill each separate prescription. Tr. 1334–35, 1367–68, 1397–98. Dr. Fertil is unfamiliar with the term, ''red flag.'' Tr. 1395. The pharmacist reviews the diagnosis and medical history with the customer. Distance traveled by the customer would only concern Dr. Fertil if they traveled from outside the County, although he was unaware of any law restricting the filling of a prescription on the basis of distance traveled. Tr. 1406–07. Dr. Fertil did not view payment by cash as a suspicious circumstance, nor would it cause him to decline filling a prescription. Tr. 1408–10. If the customer is opiate naïve, as determined by a review of the E–FORCSE, the pharmacy has a policy not to fill the prescription. Tr. 1346–47. The pharmacist determines if the prescription contains the statutorily required components. Tr. 1351–52. The PioneerRx software also prompts the pharmacist as to required components and alerts. Tr. 1352–56; RX 13–22. Review of the E–FORCSE database, which the pharmacist does for every controlled substance prescription presented, also reveals whether the customer is doctor-shopping. Tr. 1347–50, 1357–58; RX 1–11. When directed to review three controlled substance prescriptions for B.D.a., Dr. Fertil confirmed none contained any notations that the E–FORCSE had been referenced. Tr. 1418–21. Dr. Fertil explained that no documentation was necessary, and that his signature on the prescription was proof that he checked the E–FORCSE. When asked if he ever noted PDMP on the prescriptions, he confirmed that sometimes he wrote PDMP to confirm that he checked the PDMP, but that sometimes he simply signed the prescriptions, also confirming that he checked the PDMP. Tr. 1419–20. Ultimately, Dr. Fertil explained that there was no set way that he confirmed on the prescription that he checked the PDMP. Sometimes he would note ''verified E–FORCSE'', sometimes he put a check mark or initials. Tr. 1423. The pharmacist will also consult with the prescribing physicians as needed. Tr. 1349–50.

Dr. Fertil confirmed that he discussed with the charged patients, J.R. and L.V. their restrictions presented for their prescriptions for combinations of medications of opioids, benzodiazepine and a muscle relaxant, the risks of this combination, including the sedative effect. Tr. 1360–61. Further, the patients were questioned as to whether they were experiencing any of the noted side effects of the drug combinations, and were provided written warnings, including drug interactions, abuse and side effects, produced by the PioneerRx software system and stapled to their receipts. Tr. 1361–64. Dr. Fertil confirmed that he used his professional judgement in resolving some of the alerts of the PioneerRx software and in filling the subject prescriptions. Tr. 1362–63. Dr. Fertil explained that Gulf Med had a much smaller volume of prescriptions than the large chain pharmacies, permitting the pharmacist to spend more time and attention with patients than at the chain pharmacies. Tr. 1363.

Dr. Fertil was present when the Administrative Inspection Warrant was served on Gulf Med., on February 14, 2018. Tr. 1364–65, 1372. He also received the Administrative Subpoena requiring ''patient profile'' information. Tr. 1365, 1372–73. Dr. Fertil cooperated and worked with the DEA computer technician to retrieve the information DEA required. Tr. 1365, 1369, 1373–74, 1379. The DEA technician also worked with a representative of PioneerRx to obtain the information required. Tr. 1365. The DEA technician operated the PioneerRx software in obtaining the information sought, and printed the documents in question. Tr. 1367, 1377. The documents printed by the DEA Technician included ''screen shots'' of the first tab of the ''patient profiles.'' Tr. 1425–29; GX 5, 19, 20, 21, 22, 35, 36, 37, 38, 39, 40. Whereas, RX 13–22 represents an Excel spreadsheet reflecting information from all five tabs of the same document. Tr. 1428–29.

When the DEA made further requests for patient profile information, Dr. Fertil produced the same type of information as they retrieved during their first request. Tr. 1365–66, 1381–95. Dr. Fertil could not remember whether he read the May, 2019 subpoena, which required the ''patient profiles'' and patient medication records for the charged patients, so he could not confirm that the documents he provided in response to the subpoena were complete. Tr. 1388–89. Dr. Fertil had great difficulty recalling receiving the third subpoena in August, 2019. Tr. 1391. He could not recall reviewing the subpoena to determine what documents were being requested or what documents were provided in response to the subpoena, despite attempts to refresh his memory. Tr. 1390–95. Although Dr. Fertil could not remember what documents he provided in response to the second and third subpoenas, he was adamant the documents provided were the same type of documents the DEA seized during service of the first administrative subpoena. Tr. 1392–94.

The Facts

Stipulations of Fact

The Government and the Respondent did not agree to any stipulations of fact.

Findings of Fact

The factual findings below are based on a preponderance of the evidence, including the detailed, credible, and competent testimony of the aforementioned witnesses, the exhibits entered into evidence, and the record before me. The findings of fact are based primarily on those proposed by the Government in its post-hearing brief. I have also considered the findings of fact proposed by the Respondent and found that many of those proposed findings related to matters proposed by the Government or related to matters addressed elsewhere in this Recommended Decision. If a proposed finding of fact is not included in this section and is also not addressed elsewhere in this Decision, it is because that proposed finding was not relevant to deciding this case.

I. Background

1. Respondent is registered with the DEA to handle controlled substances in Schedules II through V under DEA COR No. FG6290061 at 4106 Del Prado Boulevard, South, Cape Coral, FL 33904. DEA COR No. FG6290061 will expire by

its own terms on September 30, 2022. GX 1

2. DEA lists Ambien (zolpidem tartrate) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(54).

3. DEA lists Ativan (lorazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(30).

4. DEA lists hydromorphone as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(vii).

5. DEA lists methadone as a Schedule II controlled substance under 21 CFR 1308.12(c)(15). DEA lists MS Contin (morphine sulfate extended release) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(ix).

6. DEA lists Klonopin (clonazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(11).

7. DEA lists Norco (hydrocodone-acetaminophen) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(vi).

8. DEA lists oxycodone as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(xiii).

9. DEA lists Percocet (oxycodone–acetaminophen) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(xiii).

10. DEA lists Restoril (temazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(50).

11. DEA lists Soma (carisoprodol) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(6).

12. DEA lists Valium (diazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(16).

13. DEA lists Xanax (alprazolam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(2).

II. DEA's Investigation Into Respondent

14. On February 14, 2018, DEA investigators executed an administrative inspection warrant (''AIW'') on the Respondent, pursuant to which DEA seized the hardcopies of controlled substance prescriptions that Respondent had dispensed from its opening through the date the AIW was executed. GX 2; Tr. at 34–35. On the same date, the DEA also served an administrative subpoena on Respondent seeking, (a) copies of Respondent's patient profiles for certain listed individuals; (b) copies of ''[a]ny and all other records . . . maintained pursuant to the requirements of Florida Statutes and Florida Administrative Code 64B16–27.800 documenting the steps taken to avoid or resolve any issues with the prescriptions presented by'' those same listed individuals; and (c) copies of ''[a]ny other documentation kept by'' the Respondent ''in connection with the filling of prescriptions or providing medical treatment'' for those named individuals, including dispensing logs or reports, for those listed individuals. GX. 3; Tr. at 45. Government Exhibits 2 and 3 are true and correct copies of the AIW and administrative subpoena, respectively, that DEA served on Respondent on February 14, 2018. Tr. at 35,41–42,64–65.

15. Government Exhibit 5 contains true and correct copies of the patient profiles for Patients J.B., T.G., and L.V. produced by Respondent pursuant to the administrative subpoena served on February 14, 2018. Tr. at 65–69. Government Exhibit 6 contains true and correct copies of the dispensing logs for Patients J.B., T.G., and L.V. produced by Respondent pursuant to the administrative subpoena served on February 14, 2018. Tr. at 69–71. Government Exhibits 7–15 contain true and correct copies of the prescriptions Respondent dispensed to Patients J.B., A.B., B.Da., R.D., B.Di., T.G., S.K., R.R., and L.V., respectively, that the DEA seized pursuant to the AIW served on February 14, 2018. Tr. at 76–103, 111–16. The DEA did not seize any other documents pertaining to Patients J.B., A.B., B.Da., R.D., B.Di., T.G., S.K., R.R., and L.V. pursuant to the AIW served on February 14, 2018, beyond those reflected in Government Exhibits 5–15; nor did Respondent produce any other documents pertaining to those same patients pursuant to the administrative subpoena served on February 14, 2018, beyond those reflected in Government Exhibits 5–15. Tr. at 117–18.

16. The DEA provided Respondent a receipt for the items that were seized by DEA during the execution of the AIW on February 14, 2018, or that were produced by the Respondent pursuant to the administrative subpoena served that same day. Government Exhibit 4 is a true and correct copy of the warrant return filed pursuant to the AIW served on February 14, 2018, and contains as an attachment a true and accurate copy of the receipt provided to the Respondent. Tr. at 52–59.

17. In May 2019, DI served a second administrative subpoena on Respondent seeking, *inter alia,* (a) hardcopies of controlled substance prescriptions that Respondent had dispensed from February 15, 2018, through May 3, 2019; (b) copies of Respondent's patient profiles for certain listed individuals; and (c) copies of ''[a]ny and all records . . . maintained pursuant to the requirements of Florida Statutes and Florida Administrative Code 64B16–27.800 for Patient Records, documenting the steps taken to avoid or resolve any issues with the prescriptions presented by'' those same listed individuals ''reflecting efforts by the pharmacist to exercise their corresponding responsibility to assess the validity'' of controlled substance prescriptions dispensed to those listed individuals. Gov't Ex. 16; Tr. at 119. Government Exhibit 16 is a true and correct copy of the administrative subpoena that DEA served on Respondent in May 2019. Tr. at 120–21.

18. DI has conducted approximately twelve (12) investigations while employed by DEA. Tr. 27–28.

19. With its production of documents in response to the May 2019 administrative subpoena, the Respondent also produced a signed certificate of authenticity of domestic business records. Tr. at 123–24. Government Exhibit 18 is a true and correct copy of the signed certificate of authenticity of domestic business records produced by the Respondent with its production of documents in response to the May 2019 administrative subpoena. Tr. at 124.

20. Government Exhibits 19–22 contain true and correct copies of the patient profiles for Patients R.D., T.G., S.K., and L.V., respectively, produced by Respondent pursuant to the administrative subpoena served in May 2019. Tr. at 129–38. Government Exhibits 23–32 contain true and correct copies of the prescriptions Respondent dispensed to Patients J.B., A.B., B.Da., R.D., B.Di., T.G., S.K., J.R., R.R., and L.V., respectively, that the Respondent produced pursuant to the administrative subpoena served in May 2019. Tr. at 143–77. The Respondent did not produce any other documents pertaining to Patients J.B., A.B., B.Da., R.D., B.Di., T.G., S.K., J.R., R.R., or L.V., pursuant to the administrative subpoena served in May 2019 beyond those reflected in Government Exhibits 19–32. Tr. at 178.

21. The DEA provided Respondent a receipt for the items that were produced by the Respondent pursuant to the administrative subpoena served in May 2019. Tr. at 126–27. Government Exhibit 17 is a true and correct copy of the receipt provided to the Respondent. Tr. at 127.

22. In August 2019, DI served a third administrative subpoena on Respondent seeking, with respect to Patients J.B., A.B., B.Da., B.Di., J.R., and R.R., (a) hardcopies of controlled substance prescriptions that Respondent had dispensed to those patients from May 3, 2019, through August 9, 2019; (b) copies of Respondent's patient profiles for those patients; and (c) copies of ''[a]ny and all records . . . maintained pursuant to the requirements of Florida Statutes and Florida Administrative

Code 64B16–27.800 for Patient Records, documenting the steps taken to avoid or resolve any issues with the prescriptions presented by'' those patients ''reflecting efforts by the pharmacist to exercise their corresponding responsibility to assess the validity'' of controlled substance prescriptions dispensed to those patients. Gov't Ex. 33; Tr. at 179.

23. Government Exhibit 33 is a true and correct copy of the administrative subpoena that DEA served on Respondent in August 2019. Tr. at 179–82.

24. With its production of documents in response to the August 2019 administrative subpoena, the Respondent also produced a signed certificate of authenticity of domestic business records. Tr. at 184. Government Exhibit 34 is a true and correct copy of the signed certificate of authenticity of domestic business records produced by the Respondent with its production of documents in response to the August 2019 administrative subpoena. Tr. at 184–85.

25. Government Exhibits 35–40 contains true and correct copies of the patient profiles, prescriptions, and other responsive documents for Patients J.B., A.B., B.Da., B.Di., J.R., and R.R., respectively, that Respondent produced pursuant to the administrative subpoena served in August 2019. Tr. at 186–201. The Respondent did not produce any other documents pertaining to Patients J.B., A.B., B.Da., B.Di., J.R., or R.R. pursuant to the administrative subpoena served in August 2019 beyond those reflected in Government Exhibits 35–40. Tr. at 187, 190–91, 193, 195, 197– 98, 200–01.

26. During the course of the investigation, DI queried the Florida Prescription Drug Monitoring Database (''E–FORCSE'') and obtained information regarding Respondent's dispensing of controlled substance as it was reported to the State of Florida. Tr. at 205–216. Government Exhibits 41–42 are true and correct copies of the data obtained from the E–FORSCE database for the dates listed. *Id.* There is no evidence in the record to indicate that the information reported by Respondent to the E–FORSCE database is inaccurate or unreliable.

27. Subsequent to Respondent's Second Supplement Prehearing Statement, which concerned information retrieved from the PioneerRx pharmacy management software used by the Respondent, DEA obtained a declaration from J.R., Vice President of PioneerRx, concerning the functioning of that software. Tr. at 238–40. Government Exhibit 48 is a true and correct copy of the declaration of J.R. Tr. at 242–48.

28. DI testified that use of cash to pay for a prescription for controlled substances and the willingness of a customer to pay a higher-than-market price to purchase said medications are ''red flags'' that a prescription may be illegitimate. Tr. 106–107; 109–110. However, he later testified that there is no DEA regulation prohibiting a pharmacy from accepting cash as payment for prescriptions for controlled substances. Tr. 373–374.

III. The Government's Expert

29. Tracey J. Schossow, a pharmacy expert retained by DEA, is a clinical pharmacist at Florida Blue Cross Blue Shield. In that capacity, she reviews medications prescribed to Blue Cross members to ensure, among other things, that the medications are being issued for a legitimate medical purpose, and to provide cost-effective alternatives for prescribed medications where appropriate. Dr. Schossow holds both a bachelor's degree in pharmacy and a doctorate in pharmacy. She is a licensed pharmacist in Florida and also holds an additional Florida license as a consultant pharmacist. Tr. at 403–04, 408; GX 43.

30. Dr. Schossow has 26 years of experience as a pharmacist, with 12-years' experience as a retail pharmacist and the remainder as a clinical pharmacist. Immediately prior to her current role, Dr. Schossow was a clinical pharmacist for ProcareRx, a hospice-centered pharmacy benefits manager (''PBM''). While at ProcareRx, Dr. Schossow worked with hospice patients and managed medications for those patients, including opioids, benzodiazepines, and muscle relaxants. Additionally, Dr. Schossow served on the committee that managed which medications were on the ProcareRx formulary based on cost and efficacy considerations, and she also managed the queue for high-cost claims submitted by the hospices and ran test claims for the PBM to determine costs at different pharmacies across the State of Florida. Tr. at 404–08; GX 43.

31. Through her education and experience, Dr. Schossow has gained specialized knowledge regarding the practice of pharmacy, including the costs charged by pharmacies for controlled substance medications, the standard of care for dispensing controlled substances in the State of Florida, the obligations of a retail pharmacist in the detection and prevention of abuse and diversion of controlled substances, and a pharmacist's corresponding responsibility under federal law. Tr. at 411–14.

32. Dr. Schossow has previously been accepted by this Agency as an expert witness on three occasions. Tr. at 412, 423–24.

33. Dr. Schossow was accepted by the Tribunal as an expert in in the field of pharmacy and the standard of care for the practice of pharmacy in the State of Florida. Tr. at 427.

34. Dr. Schossow was unfamiliar with any clarification issued by the Center for Disease Control (''CDC'') regarding its 2016 opiate guidelines.*[E] Tr. 992.

IV. The Standard of Care in the State of Florida

A. Generally

35. Florida law, like federal law, requires that a pharmacist exercise his or her corresponding responsibility to ensure, prior to dispensing controlled substances, that each prescription is valid and has been issued for a legitimate medical purpose by an individual practitioner in the usual course of professional practice. As part of this evaluation, the pharmacist must perform a drug use review (''DUR'') on each new and refill prescription. This DUR includes examination of, among other things, potential side effects of the medication, potential drug interactions, whether the medication is being clinically abused or misused, and whether the medication is being dosed appropriately. Tr. at 431–32, 438–40. Many of these issues are specifically enumerated in Fla. Admin. Code r. 64B16–27.810. Tr. at 437.

36. Florida law also requires that a pharmacy maintain a ''patient profile'' for its customers that includes a variety of information, such as the pharmacist's comments relevant to the patient's drug therapy. Tr. at 437–39; *see also* Fla. Admin. Code r. 64B16–27.800. The standard of care requires a pharmacist to document the steps that he took to resolve any areas of concern or potential problems in the patient records. Tr. at 437–42.

B. Red Flags

37. Dr. Schossow testified that a red flag is something ''about a prescription that causes the pharmacist to take pause'' when filling a prescription. Tr. at 446. Dr. Schossow testified that the red flag ''may be signs of diversion'' or

*[E] There was an attempt to clarify Dr. Schossow's testimony regarding the 2016 opiate guidelines, but it is difficult from the transcript to tell which documents are being referenced by counsel and the witness. Tr. 1060–1068. The RD states *infra* that Dr. Schossow clarified later that she was generally aware of the CDC's clarification regarding its 2016 opiate guidelines.

signs that the prescription ''may harm the patient,'' and that the pharmacist's examination of red flags was part of the prospective drug use review with respect to issues of clinical abuse or misuse of the prescribed substance. *Id.* Dr. Schossow testified that red flags are well known to pharmacists in the State of Florida. *Id.* at 452–60.

38. Dr. Schossow testified that the standard of care in the State of Florida requires a pharmacist who encounters a prescription with a red flag to address that red flag and to resolve it, if the red flag is in fact resolvable, and to record the issue by identifying the red flag and how the pharmacist resolved it. *Id.* at 462–63. Dr. Schossow further testified that a Florida pharmacist acting in the usual course of professional practice would likewise identify red flags and record the resolution of those red flags. *Id.* at 463.

39. Dr. Schossow testified that the combination of an opioid, a benzodiazepine, and the muscle relaxer carisoprodol—commonly known as the ''Trinity'' cocktail—is a red flag because that combination of controlled substances is dangerous to the patient and known by pharmacists to be sought after by drug abusers. *Id.* at 480–83.

40. Dr. Schossow testified that prescriptions for cocktail medications—specifically the combination of an opioid and a benzodiazepine—is a red flag for the pharmacist because both of those categories of drugs depress the patient's central nervous system. *Id.* at 499–500. Dr. Schossow testified that the CDC Guidelines for Prescribing Opioids for Chronic Pain and FDA black box warning for opioid medications both warn against the combination of opioids and benzodiazepines because that combination of medications, which both depress the patient's central nervous system, can lead to sedation, respiratory depression, overdose, and death. *Id.* at 455–56, 476, 500, 526.

41. Dr. Schossow testified that cash payment for controlled substance prescriptions is a red flag. *Id.* at 580–83. Dr. Schossow further testified that high cash payments for controlled substance prescriptions enhance the red flag for cash payments because ''a drug seeker is willing to pay more for a drug if they can get the drug'' and is ''willing to pay . . . whatever they need to pay to obtain the medication.'' *Id.* at 580–86.

42. Dr. Schossow testified that prescriptions for long-acting and short-acting opioids in a combination that does not make pharmacological sense are also a red flag for pharmacists. *Id.* at 599–600. Specifically, Dr. Schossow testified that long-acting opioids, like MS Contin, last in the body 8-to-12 hours, while a short acting opioid like hydromorphone lasts in the body only 2-to-4 hours, and the proper method of treatment for pain management was to give more of the patient's total daily MME dose of opioids in the form of long-acting opioids than short-acting opioids. Dr. Schossow testified that, in contrast, prescriptions that provide a patient with a greater MME of short-acting opioids than long-acting opioids do not make pharmacological sense and are a red flag. *Id.* at 603–06.

43. [Omitted for brevity and relevance.]

44. Dr. Schossow testified that abnormal travel distances on the part of a patient to obtain and fill controlled substance prescriptions are a red flag. *Id.* at 679. While I accept this concept, I did not find that the evidence supported 30–50 mile round trip distances as abnormal under the facts of this case.

45. Dr. Schossow testified that therapeutic duplication—which is the simultaneous prescription of two medications that are in the same drug class and act the same way—is a red flag because prescribing two medications that do the same thing is not necessary and is therapeutically inappropriate. *Id.* at 704–05. Dr. Schossow testified that therapeutic duplication of benzodiazepines can compound the side effects of those drugs, which depress the patient's central nervous system and can cause respiratory depression, sedation, overdose, and death. *Id.* at 705.

V. Patient J.B.

46. Between March 22, 2017, and August 8, 2019, Respondent filled at least 100 prescriptions for controlled substances for Patient J.B., including 26 prescriptions for 60 units of MS Contin 30 mg, 32 prescriptions for 108–120 units of oxycodone 30 mg, 33 prescriptions for 90 units of Xanax 1 mg, and 9 prescriptions for 30 units of Soma 350 mg. Information regarding the controlled substance prescriptions dispensed to Patient J.B. is accurately set forth in Government Exhibits 6–7, 23, 35, and 41–42.

47. All of the prescriptions filled by Patient J.B. at Respondent pharmacy from March 22, 2017, through September 7, 2018, were paid for in cash. GX 6–7, 23, 48 ¶ 7(b).

48. Dr. Schossow examined the prescriptions dispensed to Patient J.B. and identified multiple red flags with respect to those prescriptions, including prescriptions for the Trinity cocktail, prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, high prices paid for prescriptions for oxycodone 30 mg, and dosing of long- and short-acting opioids in a manner that did not make pharmacological sense. Tr. at 485– 91, 498–500, 503–04, 513–16, 520–28, 530–34, 851–57. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient J.B. are set forth in Appendix A at 1–3.

49. Dr. Schossow reviewed the patient profile maintained by Respondent for Patient J.B., and concluded that the red flags she had found with respect to the prescriptions filled for Patient J.B. were not mentioned, addressed, resolved or documented on the patient profile. GX 5 at 1; Gov't Ex. 35 at 1; Tr. at 857–59.

50. Dr. Schossow reviewed the medical records maintained by Respondent for Patient J.B. and concluded that those documents did not address, resolve, or document any of the red flags she had found with respect to the prescriptions filled for Patient J.B. GX 35 at 2–5; Tr. at 858.

51. Dr. Schossow reviewed the dispensing logs maintained by Respondent for Patient J.B. and concluded that those documents did not address, resolve, or document any of the red flags she had found with respect to the prescriptions filled for Patient J.B. GX 35 at 8–9; Tr. at 858.

52. Dr. Schossow testified that, based on her review of the prescriptions, patient profiles, and medical records that Respondent maintained for Patient J.B., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient J.B. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 859–60.

VI. Patient A.B.

53. At all times relevant to this matter, Patient A.B. resided at 12175 Harry Street, Bokeelia, Florida 33922. GX. 36 at 1; GX 41–42. Patient A.B.'s approximate roundtrip travel distance from his residence, to his physician, to Respondent, and returning to his residence, is 44 miles. ALJ Ex. 21 Attachs. A–B, Attach. C at 1–3; ALJ Ex. 23 at 3.

54. Between November 8, 2017, and July 17, 2017, Respondent filled at least 69 prescriptions for Patient A.B., including 23 prescriptions for 60 units of MS Contin 15 mg, 23 prescriptions for 120 units of hydromorphone 8 mg, and 23 prescriptions for 30–40 units of Valium 10 mg. Information regarding the controlled substance prescriptions dispensed to Patient A.B. is accurately set forth in Government Exhibits 8, 24, 36, and 41–42.

55. All of the prescriptions filled by Patient A.B. at Respondent were paid for in cash. GX 8, 24, 36, 48 ¶ 7(b).

56. Dr. Schossow examined the prescriptions dispensed to Patient A.B. and identified multiple red flags with respect to those prescriptions, including prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, high prices paid for prescriptions for hydromorphone 8 mg, dosing of long- and short-acting opioids in a manner that did not make pharmacological sense, and the distance traveled by Patient A.B. to obtain and fill prescriptions for controlled substances. Tr. at 535–42, 813–17, 819–50. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient A.B. are set forth in Appendix A at 4–7.

57. Dr. Schossow reviewed the patient profile maintained by Respondent for Patient A.B., and concluded that the red flags she had found with respect to the prescriptions filled for Patient A.B. were not mentioned, addressed, resolved or documented on the patient profile. GX 36 at 1; Tr. at 844–45.

58. Dr. Schossow reviewed the medical records maintained by Respondent for Patient A.B. and concluded that those documents did not address, resolve, or document any of the red flags she had found with respect to the prescriptions filled for Patient J.B. GX 36 at 2–11; Tr. at 845.

59. Dr. Schossow reviewed the dispensing logs maintained by Respondent for Patient A.B. and concluded that those documents did not address, resolve, or document any of the red flags she had found with respect to the prescriptions filled for Patient J.B. GX. 36 at 12; Tr. at 845.

60. Dr. Schossow testified that, based on her review of the prescriptions, patient profiles, and medical records that Respondent maintained for Patient A.B., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient A.B. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 850–51.

VII. Patient B.Da.

61. At all times relevant to this matter, Patient B.Da. resided at 5512 Avenue D, Bokeelia, Florida 33922. GX 37 at 1; GX 41–42. Patient B.Da.'s approximate roundtrip travel distance from his residence, to his physician, to Respondent, and returning to his residence, is 48.8 miles. ALJ Ex. 21 Attachs. A–B, Attach. C at 4–6; ALJ Ex. 23 at 3.

62. Between October 25, 2017, and August 5, 2019, Respondent filled at least 39 prescriptions for Patient B.Da., including 5 prescriptions for 90 units of methadone 10 mg, 8 prescriptions for 30 units of MS Contin 30 mg, 13 prescriptions for 120–150 units of hydromorphone 8 mg, and 13 prescriptions for 30 units of Xanax 2 mg. Information regarding the controlled substance prescriptions dispensed to Patient B.Da. is accurately set forth in Government Exhibits 9, 25, 37, and 41–42.

63. All of the prescriptions filled by Patient B.Da. at Respondent were paid for in cash. GX 9, 25, 37, 48 ¶ 7(b).

64. Dr. Schossow examined the prescriptions dispensed to Patient B.Da. and identified multiple red flags with respect to those prescriptions, including prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, high prices paid for prescriptions for hydromorphone 8 mg, dosing of long- and short-acting opioids in a manner that did not make pharmacological sense, and the distance traveled by Patient B.Da. to obtain and fill prescriptions for controlled substances. Tr. at 745–56. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient B.Da. are set forth in Appendix A at 8–10.

65. Dr. Schossow testified that a Florida pharmacist acting within the standard of care should have evaluated the red flags she noted and addressed them with the physician, care giver, or patient as appropriate and should have documented the resolution of those red flags if they could be resolved. Tr. at 757.

66. Dr. Schossow reviewed the patient profile and prescriptions maintained by Respondent for Patient B.Da., and concluded that the red flags she had found with respect to the prescriptions filled for Patient B.Da. were not mentioned, addressed, resolved or documented on the patient profile or prescriptions. GX 37 at 1; Tr. at 756–57.

67. Dr. Schossow reviewed the medical records maintained by Respondent for Patient B.Da. and concluded that those documents did not address, resolve, or document any of the red flags she had found with respect to the prescriptions filled for Patient B.Da. GX 37 at 4–8; Tr. at 757.

68. Dr. Schossow testified that, based on her review of the prescriptions, patient profiles, and medical records that Respondent maintained for Patient B.Da., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient B.Da. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 757.

VIII. Patient R.D.

69. At all times relevant to this matter, Patient R.D. resided at 5459 Thomas Street, Bokeelia, Florida 33922. Gov't Ex. 19 at 1; Gov't Exs. 41–42. Patient B.Da.'s approximate roundtrip travel distance from his residence, to his physician, to Respondent, and returning to his residence, is 40.6 miles. ALJ Ex. 21 Attachs. A–B, Attach. C at 2, 7–8; ALJ Ex. 23 at 3.

70. Between December 20, 2017, and April 10, 2019, Respondent filled at least 36 prescriptions for Patient R.D., including 18 prescriptions for 120–140 units of hydromorphone 8 mg, and 18 prescriptions for 30 units of Ativan 2 mg. Information regarding the controlled substance prescriptions dispensed to Patient R.D. is accurately set forth in Government Exhibits 10, 26, and 41–42.

71. All of the prescriptions filled by Patient R.D. at Respondent were paid for in cash. GX 10, 26, 48 ¶ 7(b).

72. Dr. Schossow examined the prescriptions dispensed to Patient R.D. and identified multiple red flags with respect to those prescriptions, including prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, high prices paid for prescriptions for hydromorphone 8 mg, and the distance traveled by Patient R.D. to obtain and fill prescriptions for controlled substances. Tr. at 675–701. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient R.D. are set forth in Appendix A at 11–13.

73. Dr. Schossow testified that a Florida pharmacist acting within the standard of care should have evaluated the red flags she noted and addressed them with the physician, care giver, or patient as appropriate and should have documented the resolution of those red flags if they could be resolved. Tr. at 701.

74. Dr. Schossow reviewed the patient profile and prescriptions maintained by Respondent for Patient R.D., and concluded that there was no evidence to suggest that the Respondent had investigated or assessed any of the red flags that she had identified with respect to the prescriptions filled by Patient R.D. GX 19 at 1; Tr. at 702.

75. Dr. Schossow testified that the Respondent's comments on the patient profile that Respondent maintained for Patient R.D. did not address any of the red flags that she had identified with respect to the prescriptions filled by Patient R.D. GX 19 at 1; Tr. at 702.

76. Dr. Schossow testified that, based on her review of the prescriptions, patient profiles, and medical records that Respondent maintained for Patient R.D., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient R.D. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 702.

IX. Patient B.Di.

77. Between April 21, 2017, and July 17, 2019, Respondent filled at least 85 prescriptions for Patient B.Di., including 28 prescriptions for 60 units of MS Contin 30 mg, 28 prescriptions for 120 units of hydromorphone 8 mg, 28 prescriptions for 60–90 units of Xanax 1 mg, and 1 prescription for 60 units of Adderall 20 mg. Information regarding the controlled substance prescriptions dispensed to Patient B.Di. is accurately set forth in Government Exhibits 11, 27, 38, and 41–42.

78. All of the prescriptions filled by Patient B.Di. at Respondent were paid for in cash. GX 11, 27, 38, 48 ¶ 7(b).

79. Dr. Schossow examined the prescriptions dispensed to Patient B.Di. and identified multiple red flags with respect to those prescriptions, including prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, high prices paid for prescriptions for hydromorphone 8 mg, and dosing of long- and short-acting opioids in a manner that did not make pharmacological sense. Tr. at 718–43. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient B.Di. are set forth in Appendix A at 14–17.

80. Dr. Schossow testified that a Florida pharmacist acting within the standard of care should have evaluated the red flags she noted and addressed them with the physician, care giver, or patient as appropriate and should have documented the resolution of those red flags if they could be resolved. Tr. at 743–44.

81. Dr. Schossow reviewed the patient profile and prescriptions maintained by Respondent for Patient B.Di., and concluded that there was no evidence to suggest that the Respondent had addressed, investigated, resolved, or documented the resolution of any of the red flags that she had identified with respect to the prescriptions filled by Patient B.Di. GX 38 at 1; Tr. at 744.

82. Dr. Schossow testified that, based on her review of the prescriptions and patient profile that Respondent maintained for Patient B.Di., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient B.Di. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 744.

X. Patient T.G.

83. Between April 5, 2017, and April 22, 2019, Respondent filled at least 32 prescriptions for Patient T.G., including 14 prescriptions for 60 units of MS Contin 60 mg, 1 prescription for 56 units of oxycodone 15 mg, and 17 prescriptions for 84–120 units of oxycodone 30 mg. Information regarding the controlled substance prescriptions dispensed to Patient T.G. is accurately set forth in Government Exhibits 12, 28, and 41–42.

84. All of the prescriptions filled by Patient T.G. at Respondent were paid for in cash. GX 12, 28, 48 ¶ 7(b).

85. Dr. Schossow examined the prescriptions dispensed to Patient T.G. and identified multiple red flags with respect to those prescriptions, including cash payment for controlled substances and high prices paid for prescriptions for oxycodone 30 mg. Tr. at 556–57, 563–64, 579–94. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient T.G. are set forth in Appendix A at 18–19.

86. Dr. Schossow reviewed the patient profiles and prescriptions maintained by Respondent for Patient T.G., and concluded that there was no evidence to suggest that the Respondent had investigated or assessed any of the red flags that she had identified with respect to the prescriptions filled by Patient T.G. GX 5 at 2; GX 20 at 1; Tr. at 595–96.

87. Dr. Schossow testified that, based on her review of the prescriptions and patient profiles that Respondent maintained for Patient T.G., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient T.G. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 596–97.

XI. Patient S.K.

88. Between March 8, 2017, and May 1, 2019, Respondent filled at least 79 prescriptions for Patient S.K., including 29 prescriptions for 60 units of MS Contin 15 mg, 29 prescriptions for 98–110 units of hydromorphone 8 mg, and 21 prescriptions for 28–60 units of Klonopin 1 mg. Information regarding the controlled substance prescriptions dispensed to Patient S.K. is accurately set forth in Government Exhibits 13, 29, and 41–42.

89. All of the prescriptions filled by Patient S.K. at Respondent were paid for in cash. GX 19, 29, 48 ¶ 7(b).

90. Dr. Schossow examined the prescriptions dispensed to Patient S.K. and identified multiple red flags with respect to those prescriptions, including prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, high prices paid for prescriptions for hydromorphone 8 mg, and dosing of long- and short-acting opioids in a manner that did not make pharmacological sense. Tr. at 597–624, 626–640. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient S.K. are set forth in Appendix A at 20–22.

91. Dr. Schossow testified that a Florida pharmacist acting within the standard of care should have evaluated the red flags she noted and addressed them with the physician, care giver, or patient as appropriate and should have documented the resolution of those red flags if they could be resolved. Tr. at 640–41.

92. Dr. Schossow reviewed the patient profile and prescriptions maintained by Respondent for Patient S.K., and concluded that there was no evidence to suggest that the Respondent had addressed, investigated, resolved, or documented the resolution of any of the red flags that she had identified with respect to the prescriptions filled by Patient S.K. GX 21 at 1; Tr. at 641.

93. Dr. Schossow testified that, based on her review of the prescriptions and patient profile that Respondent maintained for Patient S.K., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient S.K. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 641.

XII. Patient J.R.

94. Between February 27, 2019, and August 2, 2019, Respondent filled at least 23 prescriptions for Patient J.R., including 1 prescription for 60 units of MS Contin 15 mg, 1 prescription for 120 units of Norco 5–325 mg, 3 prescriptions for 120 units of Norco 7.5–325 mg, 1 prescription for 120 units of Percocet 5–325 mg, 2 prescriptions for 60 units of Valium 2 mg, 4 prescriptions for 30–60 units of Valium 5 mg, 5 prescriptions for 30 units of Restoril 30 mg, and 6 prescriptions for 120 units of Soma 350 mg. Information regarding the controlled substance prescriptions dispensed to Patient J.R. is accurately set forth in Government Exhibits 30, 39, and 41–42.

95. Dr. Schossow examined the prescriptions dispensed to Patient J.R. and identified multiple red flags with respect to those prescriptions, including

prescriptions for the Trinity cocktail and therapeutic duplication of benzodiazepine prescriptions. Tr. at 703–16. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient J.R. are set forth in Appendix A at 23.

96. Dr. Schossow testified that a Florida pharmacist acting within the standard of care should have evaluated the red flags she noted and addressed them with the physician, care giver, or patient as appropriate and should have documented the resolution of those red flags if they could be resolved. Tr. at 716–17.

97. Dr. Schossow reviewed the patient profile and prescriptions maintained by Respondent for Patient J.R., and concluded that there was no evidence to suggest that the Respondent had addressed, investigated, resolved, or documented the resolution of any of the red flags that she had identified with respect to the prescriptions filled by Patient J.R. GX 39 at 1; Tr. at 717.

98. Dr. Schossow testified that, based on her review of the prescriptions and patient profile that Respondent maintained for Patient J.R., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient J.R. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 717.

XIII. Patient R.R.

99. Between December 5, 2017, and August 6, 2019, Respondent filled at least 55 prescriptions for Patient R.R., including 15 prescriptions for 28–60 units of MS Contin 60 mg, 20 prescriptions for 120–168 units of hydromorphone 8 mg, 1 prescription for 60 units of Xanax 1 mg, and 19 prescriptions for 30 units of Xanax 2 mg. Information regarding the controlled substance prescriptions dispensed to Patient R.R. is accurately set forth in Government Exhibits 14, 31, 40, and 41–42. All of the prescriptions filled by Patient R.R. at Respondent were paid for in cash. GX 14, 31, 40, 48 ¶ 7(b).

100. Dr. Schossow examined the prescriptions dispensed to Patient R.R. and identified multiple red flags with respect to those prescriptions, including prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, high prices paid for prescriptions for hydromorphone 8 mg, dosing of long- and short-acting opioids in a manner that did not make pharmacological sense, and dosing of benzodiazepine medications in a manner that did not make pharmacological sense. Tr. at 642–72. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient R.R. are set forth in Appendix A at 24–26.

101. Dr. Schossow testified that a Florida pharmacist acting within the standard of care should have evaluated the red flags she noted and addressed them with the physician, care giver, or patient as appropriate and should have documented the resolution of those red flags if they could be resolved. Tr. at 673.

102. Dr. Schossow reviewed the patient profile and prescriptions maintained by Respondent for Patient R.R., and concluded that there was no evidence to suggest that the Respondent had addressed, investigated, resolved, or documented the resolution of any of the red flags that she had identified with respect to the prescriptions filled by Patient R.R. GX 40 at 1; Tr. at 672–73.

103. Dr. Schossow testified that the Respondent's comments on the patient profile that Respondent maintained for Patient R.R. did not address any of the red flags that she had identified with respect to the prescriptions filled by Patient R.R. GX 40 at 1; Tr. at 673–74.

104. Dr. Schossow reviewed the medical records and dispensing log maintained by Respondent for Patient R.R. and concluded that those documents did not address, resolve, or document any of the red flags she had found with respect to the prescriptions filled for Patient R.R. GX 40 at 2–7; Tr. at 674.

105. Dr. Schossow testified that, based on her review of the prescriptions, patient profile, dispensing log and medical records that Respondent maintained for Patient R.R., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient R.R. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 674.

XIV. Patient L.V.

106. Between March 2, 2017, and May 14, 2019, Respondent filled at least 93 prescriptions for Patient L.V., including 28 prescriptions for 14–60 units of MS Contin 60 mg, 1 prescription for 120 units of oxycodone 20 mg, 27 prescriptions for 90–140 units of oxycodone 30 mg, 16 prescriptions for 60–90 units of Xanax 1 mg, 8 prescriptions for 60 units of Xanax 2 mg, and 13 prescriptions for 30 units of Ambien 10 mg. Information regarding the controlled substance prescriptions dispensed to Patient L.V. is accurately set forth in Government Exhibits 6, 15, 32, and 41–42.

107. All of the prescriptions for oxycodone 20 mg or oxycodone 30 mg filled by Patient L.V. at Respondent were paid for in cash. GX 6, 15, 32, 48 ¶ 7(b). All of the prescriptions for MS Contin filled by Patient L.V. at Respondent, with the exceptions of the prescriptions filled on January 22, 2019; February 19, 2019; and April 15, 2019, were paid for in cash. GX 6, 15, 32, 48 ¶ 7(b). The prescriptions for 60 units of Xanax 1 mg filled by Patient L.V. at Respondent on March 2, 2017; March 30, 2017; and April 27, 2017, were also paid for in cash. GX 6, 15, 48 ¶ 7(b).

108. Dr. Schossow examined the prescriptions dispensed to Patient L.V. and identified multiple red flags with respect to those prescriptions, including prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, and high prices paid for prescriptions for oxycodone 30 mg. Tr. at 510–11, 758–59, 767–79, 791–808. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient L.V. are set forth in Appendix A at 27–30.

109. Dr. Schossow reviewed the patient profiles maintained by Respondent for Patient L.V., and concluded that there was no evidence to suggest that the Respondent had addressed, investigated, resolved, or documented the resolution of any of the red flags that she had identified with respect to the prescriptions filled by Patient L.V. GX 5 at 3; GX 22 at 1; Tr. at 808–09, 812.

110. Dr. Schossow reviewed the dispensing log maintained by Respondent for Patient L.V. and concluded that those documents did not address, resolve, or document any of the red flags she had found with respect to the prescriptions filled for Patient L.V. GX 6 at 5–6; Tr. at 809.

111. Dr. Schossow testified that, based on her review of the prescriptions, patient profile, and dispensing log that Respondent maintained for Patient L.V., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient L.V. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 812–13.

The Respondent's Expert

112. Dr. Buffington received his Doctor of Pharmacy (PharmD) degree and a Master of Business Administration degree from Mercer University in Atlanta, Georgia. RX 12; Tr. 1078–79.

113. Dr. Buffington completed his clinical practice residency and clinical pharmacology research fellowship at

Emory University Hospital in Atlanta, Georgia. RX 12; Tr. 1078–79.

114. Dr. Buffington represents clinical pharmacists on the American Medical Association (''AMA'') Current Procedural Terminology (''CPT'') Panel, and has served as a medication safety expert for the United States Department of Health and Human Services, Center for Medicare and Medicaid Services (''CMS''). Tr. 1078–79.

115. Dr. Buffington is also a Clinical Associate Professor in both the College of Medicine, since 1991, and the College of Pharmacy, since 2011, at the University of South Florida, in which settings he teaches clinical pharmacology, toxicology, pharmacy law, and a variety of aspects of healthcare administration and practice management. Tr. 1079.

116. Dr. Buffington possesses over thirty (30) years of experience in clinical pharmacology, toxicology, pharmacy and medical malpractice, substance use disorders, and long-term care. Tr. 1079.

117. The patients referred to Dr. Buffington's practice typically have high-risk medications for evaluation from a medication profile, but also a therapeutic and outcomes perspective. Tr. 1080.

118. Additionally, Dr. Buffington's practice designs and manages, as a principle investigator, clinical pharmacology trials involving investigations of newly developed medications or comparison of existing prevailing medications, all for the purpose of improving patient safety and outcomes. Tr. 1080–81.

119. Dr. Buffington's practice also provides a drug information service and forensic consulting services to both public and private clients in the healthcare sector. Tr. 1081. Dr. Buffington's consulting service clients include pharmacists, medical practitioners, healthcare facilities and organizations, and law enforcement agencies. Tr. 1081.

120. Dr. Buffington has worked as a retail pharmacist for an independent pharmacy within the past year, including in the roles of practitioner and auditor. Tr. 1090–91.

121. As a teacher of pharmacy law at various colleges and universities in Florida, Dr. Buffington's instruction includes review of Florida statutes and administrative code provisions. Tr. 1098. These provisions include §§ 64B16–27.800, 810, and 831 of the Florida Administrative Code, the discussion of which is part of the pharmacy law curriculum Dr. Buffington teaches, and with which he is familiar. Tr. 1098.

122. Dr. Buffington was engaged by the Respondent to serve as an expert witness in approximately February of 2020. Tr. 1076–77.

123. Dr. Buffington was provided with all of Respondent's documents that were seized by or produced to the DEA in connection with the Government's investigation into the Respondent. Tr. 1077.

124. Dr. Buffington has served as an expert witness and has been accepted as an expert in state and federal courts. Tr. 1078. He has also previously testified as an expert in administrative proceedings. Tr. 1078.

125. Dr. Buffington is familiar with a wide variety of pharmacy business software platforms used by retail pharmacies to track the dispensing process. Tr. 1113–14.

126. Dr. Buffington is familiar with the alert systems included in pharmacy business software platforms and has, in fact, served as an author of many of them. Tr. 1113–14.

127. Dr. Buffington testified that individuals residing in the Fort Myers/Cape Coral area may often be required to travel inland toward the city center from their home on a barrier island to patronize retail or clinical support services because the services available on the quiet, non-commercial barrier islands are often sparce. Tr. 1141–1142.

128. Dr. Buffington believes that there are many logical explanations for why a person may elect to patronize a pharmacy other than the one that is located nearest their home. Tr. 1142–44. For example, Dr. Buffington testified that they may elect to patronize a pharmacy near their place of employment or near their prescribing physician. *Id.*

129. Dr. Buffington testified that there is no prohibition against a patient paying for a controlled substance prescription using cash or a cash equivalent. Tr. 1144.

130. In forming his opinions in this proceeding, Dr. Buffington drew upon his experience, training and conducting drug diversion investigations with state and federal agencies, including law enforcement agencies. Tr. 1159–1160.

131. Based on Dr. Buffington's review of the Government's exhibits, he believed that there were other relevant data fields within the PioneerRx software that DEA did not obtain. Tr. 1163–1164.

132. In 2015 and 2016, Dr. Buffington participated in helping create a national stakeholders' statement or request to DEA seeking guidance on ''red flag'' issues. Tr. 1164–1165.

Expert Opinion

[Omitted for brevity.] Drs. Schossow and Buffington were qualified as experts in the field of pharmacy and the professional standards for the practice of pharmacy in the State of Florida. They gave their opinions regarding the relevant standards in Florida for the practice of pharmacy, including the existence of red flags, or from Dr. Buffington's perspective, ''yellow lights.'' The relevant professional standards may be established by an expert witness through his experience in the field, and through his reliance upon and application of state and federal professional standards.

[Omitted for brevity.] [51]

As far as expert opinion, Dr. Schossow demonstrated a commanding grasp of pharmacy practice and the standard for pharmacists in addressing ''red flags.'' However, there were several matters for which she had diminished credibility. For one, she was apparently unaware of the CDC Press Release clarifying the 2016 Guidelines for Prescribing Controlled Substances. It clarified that the Guidelines were not intended to apply to patients who had been on high MME on a long term basis. She later explained that she was generally aware of it, however, this clearly diminished her credibility regarding issues related to high MME of long-term patients. [Omitted.]*[F] Finally, her assertion that all pharmacies were fungible and dismissing the reality that a patient may have a preference for one pharmacy over another, all other factors being equal, was not credible.

[Omitted.]

The Respondent made the point in his brief that Dr. Schossow did not confer with the subject patients or with their prescribing physicians. Dr. Schossow conceded that a diligent pharmacist would, as circumstances require, attempt to resolve any red flags by discussing them with the patient and with the prescribing physician. The Respondent infers that the fact Dr. Schossow did not discuss any red flags with the patients or with the prescribers renders Dr. Schossow's conclusions regarding red flags questionable as Dr.

[51] [Footnote omitted.]

*[F] I have omitted the RD's assertion that Dr. Schossow offered inconsistent testimony regarding the dosing of alprazolam for Patient R.R. Patient R.R. received a prescription to take half of a two-milligram tablet of alprazolam every twelve hours. Dr. Schossow testified that in general it is not unusual for a physician to advise a patient to take half of a pill, but it is a red flag when the prescription involves two-milligram tablets of alprazolam, which are highly abused and highly sought after on the street. Tr. 642–44. Dr. Schossow testified that she has never seen these directions on an alprazolam prescription. *Id.*

Schossow did not attempt to determine if the subject red flags were resolvable.

Although certainly the extent of Dr. Schossow's review of relevant material is critical to the conclusions she draws, the focus of Dr. Schossow's opinions relate to whether the Respondent complied with his corresponding responsibility to resolve red flags prior to dispensing the subject medications, and to documenting any resolution within the file. It is neither here nor there that Dr. Schossow could have resolved her own concerns regarding the subject red flags by speaking to the patients and prescribers years later. Nor is it dispositive that Dr. Schossow could have determined that the subject red flags were resolvable at the time they were dispensed, if the Respondent failed to satisfy its corresponding responsibility to resolve them. So, I do not view the fact that Dr. Schossow did not speak with the subject patients or prescribers as diminishing the probity of her relevant opinions as to the Respondent's acts or omissions at all.

Dr. Buffington

Dr. Buffington had very impressive credentials and experience. He seemed to know the Florida statutes and regulations, chapter and verse. [However, I find that Dr. Buffington's credibility was greatly diminished by his combative tone, his evasive and confusing descriptions of a pharmacist's professional obligations, his repeated criticism of the Government's investigation, and his attempts to argue the Respondent's case. For example, on cross examination, Dr. Buffington repeatedly stated that Government counsel's questions were irrelevant to the case.*[G] I also find that Dr. Buffington's conclusion that Respondent dispensed prescriptions within the usual course of professional practice was entitled to little weight, because it does not appear to be based on a meaningful review of the evidence in this case. Although there is little-to-no documentation showing that Respondent addressed or resolved the red flags that Dr. Schossow identified, Dr. Buffington appears to believe that the fact that Respondent filled these prescriptions is proof that it exercised its professional responsibility. Dr. Buffington testified that ''the profound value that a pharmacist brings is their clinical oversight and interaction with the patient,'' but given the lack of documentation, it is unclear how Dr. Buffington was able to reach any conclusions about whether Respondent exercised any clinical oversight or had any meaningful interactions with the patients. Dr. Buffington seemed to believe that the fact that nobody showed him evidence that Respondent knew that the prescriptions Respondent filling were unlawful was proof that Respondent had exercised its corresponding responsibility. *See, e.g.,* Tr. 1163 (''[N]othing I saw [ ] demonstrated an inability to evaluate as the professional judgment takes place.''). Dr. Buffington's credibility was diminished for the following additional reasons.]

Dr. Buffington Misunderstands DEA's Jurisdiction

Despite having testified at a number of DEA administrative hearings, being a consultant for federal agencies, and teaching pharmacy law, Dr. Buffington repeatedly demonstrated a surprising misconception that the DEA and the subject administrative hearings involved only criminal matters. Despite testifying at a hearing in which DEA was obviously evaluating, in part, the Respondent's controlled substance dispensing practices, he maintained that although the DEA administrator's findings are binding upon DEA registrants, this does not include every pharmacist, and such findings would relate to criminal issues rather than the scope of practice. Tr. 1237. Furthermore, he maintained that DEA is a law enforcement agency and determines criminality, not medical decision-making or pharmacologic decision-making over the use of medications. Tr. 1245. Accordingly, he argued, there is no requirement that a pharmacist *[H] learn about DEA administrative decisions or be familiar with or read the Federal Register as the DEA does not have jurisdiction over pharmacy practice. Tr. 1168–69, 1176–77. The Respondent is not herein involved with the criminal arm of the DEA, it is involved with its regulatory arm. And in fact, the DEA [publishes final orders in administrative proceedings involving doctors, pharmacies, and other DEA registrants, which provide final adjudications on the public record of DEA's expectations for current and prospective members of the registrant community regarding their obligations under the CSA, in particular how the provisions of the CSA are adjudicated in enforcement actions.] [52] [Omitted for clarity.] [53]

The ''Standard of Care'' Applied by Dr. Buffington Was Less Credible Than Dr. Schossow's

Similarly, Dr. Buffington suffered diminished credibility in that he relied on the reasonable, prudent pharmacist [54] ''standard of care'' applicable to medical malpractice negligence suits (Fla. Stat. § 766.102) rather than on the pharmacist's professional standards, *i.e.,* ''in the course of his professional practice.'' [55] As the Government noted in its post-hearing brief, the medical malpractice standard of care under § 766.102 is not wholly consistent with [the usual course of professional practice].[56] *See* Fl. Admin. Code Ann. r. 64B16–27.800, .810, and .831; Fl. St. §§ 465.103(6)(14), 465.016, 465.023, 893.04(1). [Furthermore, § 766.102 does not even apply to pharmacists. It applies to ''healthcare providers,'' which is defined to exclude pharmacists.*[I]]

[Omitted.] [57] [58] [Dr. Schossow's testimony on the standard of care and

*[G] *See, e.g.,* Tr. 1240 (claiming that the length of time that Respondent's pharmacists spent responding to alerts within PioneerRX that notify the pharmacist of potential problems was ''irrelevant to the case given there is not a single requirement for documentation formatting and the documentation may not have transpired during that pathway''); *id.* at 1253 (''The question was did I think there is not an increased risk when you combine the three medications. My answer was no, there is, and this is what we're faced with every day when you combine a wide variety of medications. That's not relevant to this discussion.''); *id.* at 1255 (testifying, in response to a question about whether consuming the ''trinity'' cocktail could produce a high in illicit drug users: ''Yes. And made worse with alcohol but so can their base medications on their individual basis. That's irrelevant to the case'').

*[H] DEA regulates pharmacies, not pharmacists. Because the pharmacy is the registrant, it is incumbent on the pharmacy to be familiar with DEA decisions and create pharmacy policies that ensure that pharmacists are fulfilling their corresponding responsibility. *See Suntree Pharmacy and Suntree Medical Equipment, LLC,* 85 FR 73,753, 73,770 (2020); *see also S&S Pharmacy, Inc.,* 46 FR 13,051, 13,052 (1981).

[52] [Omitted for clarity.]

[53] [Omitted for clarity.]

[54] [Omitted for clarity.]

[55] [Omitted for clarity.]

[56] The ''prevailing professional standard of care,'' which under Florida law is defined as ''that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate for reasonably prudent similar heath care providers.'' § 766.102, Fla. Stat. (emphasis added).

*[I] Florida Statute § 766.102 defines ''healthcare providers'' as:

. . . any hospital or ambulatory surgical center as defined and licensed under chapter 395; a birth center licensed under chapter 383; any person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, part I of chapter 464, chapter 466, chapter 467, part XIV of chapter 468, or chapter 486; a health maintenance organization certificated under part I of chapter 641; a blood bank; a plasma center; an industrial clinic; a renal dialysis facility; or a professional association partnership, corporation, joint venture, or other association for professional activity by health care providers.

Pharmacists are administered under chapter 465.

[57] [Omitted.]

the usual course of professional practice was informed by numerous materials, such as federal regulations, expert testimony from past DEA administrative decisions, relevant Florida statutes and regulations, Florida mandatory continuing education, on-the-job training, materials promulgated by the CDC and FDA, and accepted practices within the profession. Tr. 408–09, 434–36, 451–55, 476, 888–94, 912–16, 927–28. On the other hand, Dr. Buffington's testimony about the standard of care and the usual course of professional practice did not appear to be informed by all of these materials and appeared to rely in part on an inapplicable Florida Statute.] Thus, Dr. Buffington's conclusory opinions that the various red flags identified by Dr. Schossow were unfounded are accordingly diminished in credibility. Similarly, Dr. Buffington's refutation of Dr. Schossow's opinions regarding the standard of care, based upon a disjointed source, such as a single Florida regulation, have diminished credibility.

Dr. Buffington's Testimony Regarding Documentation Was Not Credible

Dr. Buffington was not always clear in his testimony. He typically dismissed the requirement to document the resolution of red flags as not required by Florida regulation. However, he also testified that the standard of care for a pharmacist in Florida is based on the level of care that a reasonable pharmacist would use in like circumstances and reasonable pharmacists could disagree about what the requirements are for documentation of the resolution of red flags in the State of Florida. Tr. 1101, 1249. This nebulous standard leaves the requirement for documentation of the resolution of red flags apparently debatable among reasonable pharmacists—hardly a workable standard.

Dr. Buffington's Testimony About ''Red Flags'' Was Inconsistent and Not Credible

Dr. Buffington expressed disdain for the use of the term ''red flags,'' [59] but his understanding of the term was not always clear. He sometimes noted that a red flag was something which a pharmacist needed to consider, consistent with Dr. Schossow's testimony. However, he more frequently referred to it as a hard stop, precluding the filling of the prescription, which is inconsistent with Dr. Schossow's testimony.[60] Tr. 1173. This was surprising, as his CV reveals he had officially conferred with the DEA over the use of the term red flags, but to no avail. He suggested ''yellow light'' as a more appropriate term for matters which required investigation. He also observed that any confusion was partly due to DEA's failure to provide meaningful guidance to the regulated community as to red flags.[61] Later, as noted above, Dr. Buffington advised that the Florida professional standards did not require documentation of findings by the pharmacist. Tr. 1135, 1171. He counseled that reasonable pharmacists could disagree whether documentation was required by the pharmacist, a nebulous and unworkable standard. Yet Dr. Buffington testified that the Respondent complied with his obligation to document red flags, even though no documentation resolving the subject red flags appear in the records. Tr. 1109, 1112.

I credit Dr. Schossow's testimony over Dr. Buffington's regarding the requirement of documentation of red flags (yellow lights in Dr. Buffington's vernacular) within the applicable standard of care and Florida course of professional practice in pharmacy. Dr. Schossow's testimony in that regard was logical and internally consistent. [Dr. Schossow emphasized that documentation is important for patient safety and continuity of care. Tr. 441–42, 479–80, 640–41.]

Although Dr. Buffington often noted that the Respondent complied with the regulatory requirements set out in the Florida statutes and regulations in defending his opinion that the Respondent acted appropriately as to the allegations (Tr. 1110–13, 1118, 1135, 1141, 1144, 1171), it is important to note that compliance with the letter of the Florida statutes and regulations is no defense to a finding that the Respondent violated the standard of professional practice. *Cohn* v. *Department of Professional Regulation,* 477 So.2d 1039, 1042–43, District Court of Appeal of Florida, Third District (1985).

[Omitted for brevity.]

Dr. Buffington's Testimony About a Pharmacist's Corresponding Responsibility Was Not Credible

Dr. Buffington also applied a series of presumptions, which [are inconsistent with a pharmacist's] corresponding responsibility. He indicated that the presumption was to fill a prescription, unless evidence revealed that it should not be filled. However, the pharmacist has an affirmative, not passive, corresponding obligation to investigate each prescription. *See* 21 CFR 1306.04(a); *see also* Fla. Stat. § 893.04(2)(a) (''[a] pharmacist may not dispense a controlled substance listed in Schedule II, Schedule III, or Schedule IV to any patient or patient's agent without first determining, in the exercise of her or his professional judgment, that the prescription is valid'') (emphasis added).*[J] The onus is on the pharmacist to confirm the validity of each controlled prescription. Under federal law, a [pharmacy has a corresponding responsibility to ensure that a prescription for a controlled substance ''be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a).] [62]

Dr. Buffington's Testimony on the ''Trinity'' Cocktail and Other Drug Combinations Was Inconsistent and Confusing

Dr. Buffington's [testimony about a pharmacist's obligations when customers present prescriptions for potentially dangerous drug combinations, such as the ''trinity'' cocktail or the opioid/benzodiazepine combination, was inconsistent and confusing. Although Dr. Buffington acknowledged that pharmacists need to consider the potential adverse effects of certain drug combinations,*[K] at other

[58] [Omitted.]

[59] [Omitted for clarity.]

[60] [Dr. Schossow defined ''red flags'' as circumstances surrounding a prescription that cause a pharmacist to take pause, including signs of diversion or the potential for patient harm. Tr. 446. Omitted remainder of footnote.]

[61] Whether suspicious circumstances are referred to as ''red flags'' or ''yellow lights'', or whether the Agency updated its Pharmacist's Manual, the Agency has consistently [credited the testimony of pharmacy experts] in published decisions out of Florida that suspicious circumstances must be investigated and resolved, with such resolution documented.

*[J] I am not finding a violation of this statute because it was not referenced in the OSC.

[62] *See JM Pharmacy Grp., Inc., d/b/a Farmacia Nueva & Best Pharma Corp.,* 80 FR 28667, 28669 (2015). Thus, the Government can prove a violation by showing either that the pharmacist filled a prescription (1) notwithstanding his/her actual knowledge that the prescription lacked a legitimate medical purpose, or (2) being willfully blind to (or deliberately ignorant of) the fact that the prescription lacked a legitimate medical purpose. *See id.* at 28,671–72. [Omitted for clarity.]).

*[K] *See, e.g.,* Tr. 1116 (Dr. Buffington's testimony that a pharmacist would be expected to ''look at the impact'' of a patient taking an opioid and a benzodiazepine concurrently, but that there is no default presumption that they cannot be prescribed together), *id.* at 1118 (testifying that the FDA's black box warning informs practitioners of ''potential complications,'' but that it does not mean a pharmacist cannot dispense these two drugs together), *id.* at 1119 (testifying that a pharmacist should conduct an evaluation when a patient

Continued

times he insisted that prescriptions for the ''trinity'' cocktail were always appropriate. For example, Dr. Buffington testified:

> The three together is always okay. The decision to not fill based on another variable may absolutely be the final decision of the pharmacist. It doesn't make the fact that you can't do three together so the only thing would be is if you determined that it was for an inappropriate use. It's not that the three were used together. If you became knowing that it was for an inappropriate use, not that the three were prescribed together. If even the colloquial term and the slang of red flags is an inference to things that you should look at and evaluate, not these are something we count and you are in trouble if your count hits a threshold. That's a disingenuous attempt at an investigation.

Tr. 1254. When asked whether he would document his decision to fill the ''trinity'' cocktail, Dr. Buffington testified that the act of filling the prescription was all the documentation that was needed:

> No, sir. I would document by the assessment and filling of the prescription. If it didn't get filled then it didn't get filled and that is documentation in and of itself. If it is filled then that's documentation that was filled. If you would only record additional notations—if you felt there was an issue to reconcile. The three together are not an issue to not be filled.

Tr. 1261. Dr. Buffington's testimony on drug cocktails was sometimes confusing and his attempts to advocate for Respondent colored his responses. However, I find that Dr. Buffington's testimony was generally consistent with Dr. Schossow's testimony that drug cocktails are a red flag (or yellow flag) that must be considered by the pharmacist prior to dispensing. Dr. Schossow testified that it is a red flag if opioids and benzodiazepines are prescribed together because they are both central nervous system depressants, which can cause sedation, respiratory depression, overdose, coma, and death. *See, e.g.* Tr. 530–34. Dr. Buffington also acknowledged that this drug combination can cause adverse effects (*see, e.g.,* Tr. 1116, 1118–19), although he attempted to minimize the apparent danger posed by the combination of opioid, benzodiazepine and muscle relaxant, by highlighting that other even non-controlled medications, and alcohol, can produce dangerous reactions. Tr. 1243, 1255. Thus, while I find that Dr. Buffington's testimony on this issue is entitled to minimal weight because of its inconsistency, I find that it is generally supportive of my conclusion that prescriptions for the ''trinity'' cocktail or the opioid/benzodiazepine combination are a red flag that a pharmacist must address and resolve before dispensing.] [Omitted.] *[L] [63] [64] [65]

presents a prescription for an opioid, a benzodiazepine, and a muscle relaxant, and should have discussions with the patient).

Dr. Buffington's Testimony on Tallying Red Flags Was Argumentative and Not Credible

Dr. Buffington's position that it was improper to ''count'' red flags to increase the suspicion of improper behavior is contrary to [Dr. Schossow's credible testimony that a pharmacist must consider the combination of red flags presented by each prescription. *See, e.g.,* Tr. 956–57 (testifying that each prescription ''is its own individual entity'' and the distance red flag should be assessed along with the other red flags with the prescriptions). Dr. Buffington's testimony seemed to be aimed at criticizing DEA rather than offering a measured opinion about a pharmacist's obligations in the usual course of professional practice in Florida.].[66]

Partiality

Finally, Dr. Buffington displayed signs of partiality. The credibility of expert witnesses, and thus their value to the factfinder, is based first upon their evident impartiality. An expert witness's hiring by a party contestant presents the obvious profit consideration and potential motivation to appease his employer. Beyond the ubiquitous profit motivation, evidence of overt partiality can be telling. Indications of partiality may arise when an expert appears to argue its employer's case in his responses. Another may be where the expert is more amenable or solicitous to his employer's questions than of those posed by the party opponent, or is even contentious with properly posed inquiries by the opposing party. Dr. Buffington exhibited all of those features.

Dr. Buffington exceeded the scope of his qualified expertise by commenting on the efficacy of the investigation, and, in his view, the ill motives of the investigators, despite being cautioned not to do so.[67] Dr. Buffington exhibited other indications of partiality. He invaded the province of the factfinder. He concluded there was no intent on the part of the Respondent to violate his subject professional responsibilities.[68] *See, e.g.,* 1131–32, 1134–35. He volunteered that the Government presented insufficient evidence to prove their case. He was openly advocating the Respondent's case. His subjectivity and partiality were well exposed.

[The ALJ does not make an explicit credibility finding on Dr. Buffington's testimony, although he identifies multiple inconsistencies and highlights Dr. Buffington's partiality. Based on the RD's criticisms of Dr. Buffington's testimony, and based on the fact that the RD generally gave greater weight to Dr. Schossow's expert testimony than to Dr.

*[L] Dr. Buffington offered confusing testimony about how a pharmacist might react differently to prescriptions for opioids and benzodiazepines based on whether the patient was receiving multiple benzodiazepines and multiple opioids and based on whether these drugs were prescribed by different practitioners. Tr. 1117. In its Exceptions, Respondent argued that the RD mischaracterized this testimony. Resp Exceptions, at 16. I find that this testimony is irrelevant to my Decision and I have omitted the RD's references to it. Based on Dr. Schossow's credible expert testimony (supported by portions of Dr. Buffington's testimony), I find that concurrent prescriptions for an opioid and a benzodiazepine are a red flag that must be addressed, resolved, and documented, prior to dispensing. Dr. Buffington's contested testimony addresses what factors a pharmacist might consider in determining whether the drug cocktail red flag can be resolved in a particular situation. Dr. Buffington did not testify that any of these factors were relevant to any of Respondent's customers in this case, nor did he point to any documentation in Respondent's files indicating that these factors impacted Respondent's decision to fill any prescriptions. Therefore, this testimony does not impact my determination of whether Respondent's dispensing of controlled substances was within the usual course of professional practice in Florida.

[63] [Omitted for clarity.]

[64] [Omitted for clarity.]

[65] [Omitted for clarity.]

[66] [Prior Agency decisions have noted, based on credible expert testimony, that a] pharmacy's filling of multiple prescriptions containing a variety of red flags can support the conclusion that the pharmacy violated its corresponding responsibility under 21 CFR 1306.04 due to the pharmacy's actual knowledge or its willful blindness of the prescriptions' illegitimate nature. *Pharmacy Doctors Enters. d/b/a Zion Clinic Pharmacy,* 83 FR at 10,896–97 (citing *Hills Pharmacy, L.L.C.,* 81 FR at 49836–39; *The Medicine Shoppe,* 79 FR 59,504, 59,512–13 (2014); *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195,* 77 FR at 62,317–22; and *E. Main St. Pharmacy,* 75 FR 66,149, 66,163–65 (2010).

[67] The Tribunal advised Dr. Buffington not to give his opinion about whether the investigation was appropriate. Tr. 1254. The Tribunal reiterated that this not a criminal matter, but rather an administrative proceeding and directed Dr. Buffington to focus on his expertise as it relates to pharmacy law, etc. Tr. 1254–55.

[68] Specifically, Dr. Buffington testified that there was no evidence presented in this case that a pharmacist in the State of Florida at Gulf Med Pharmacy was knowingly aware. Tr. 1134. He believed that Gulf Med also did not ''turn a blind eye'' or ''bur[y] their head in the sand'' when Gulf Med pharmacists were presented with issues due to red flags because the Florida pharmacy statutes, and administrative rules require a pharmacist use professional judgment and there is no requirement that this needs to be documented. Tr. 1135. He testified that there were no breaches of the pharmacist's responsibilities or that the pharmacist had breached a duty. Tr. 1131–32.

Buffington's in his legal analysis, it is evident that the ALJ found Dr. Buffington's opinions to be generally inconsistent, unreliable, and lacking in credibility. I agree with that conclusion. Regarding Dr. Schossow's credibility, I agree with the ALJ that she demonstrated a commanding grasp of pharmacy practice and the standard for pharmacists in addressing ''red flags.'' I also find that Dr. Schossow's opinions were consistent and credible and entitled to significant weight in my Decision.]

Credibility of Non-Expert Witnesses

I found DI to be credible, despite several peripheral matters in which his memory failed him. I found both patient witnesses to be fully credible. However, L.V.'s anecdotal opinion that the Respondent's medication pricing she found reasonable does not diminish the credibility of Dr. Schossow's studied conclusion that the subject prices were exorbitant. I also found Dr. N. to be fully credible. Dr. Fertil's credibility will be discussed in the Analysis section.

Analysis

Findings as to Allegations

The Government alleges that the Respondent's COR should be revoked because the Respondent failed to ensure that it only filled prescriptions issued for legitimate medical purposes, and within the course of professional practice, in violation of its corresponding responsibility, and repeatedly filled prescriptions in the face of obvious red flags of diversion without documenting the resolution of those red flags, in violation of state law under the Florida Administrative Code, and state requirements for the minimum standard of care, and that its continued registration would be inconsistent with the public interest, as provided in 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f). ALJ Ex. 1.

In the adjudication of a revocation or suspension of a DEA COR, the DEA has the burden of proving that the requirements for such revocation or suspension are satisfied. 21 CFR 1301.44(e). Where the Government has sustained its burden and made its *prima facie* case, a respondent must both accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *Patrick W. Stodola, M.D.,* 74 FR 20727, 20734 (2009). Acceptance of responsibility and remedial measures are assessed in the context of the ''egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.'' *David A. Ruben, M.D.,* 78 FR 38363, 38364 (2013). Where the Government has sustained its burden, the registrant must present sufficient mitigating evidence to assure the Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008).

The Agency's conclusion that ''past performance is the best predictor of future performance'' has been sustained on review in the courts, *Alra Labs., Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). *See also Ronald Lynch, M.D.,* 75 FR 78745, 78754 (2010) (holding that the Respondent's attempts to minimize misconduct undermined acceptance of responsibility); *George C. Aycock, M.D.,* 74 FR 17529, 17543 (2009) (finding that much of the respondent's testimony undermined his initial acceptance that he was ''probably at fault'' for some misconduct); *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 463 (2009) (noting, on remand, that despite the respondent having undertaken measures to reform her practice, revocation had been appropriate because the respondent had refused to acknowledge her responsibility under the law); *Med. Shoppe-Jonesborough,* 73 FR at 387 (noting that the respondent did not acknowledge recordkeeping problems, let alone more serious violations of federal law, and concluding that revocation was warranted).

The burden of proof at this administrative hearing is a preponderance-of-the-evidence standard. *Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981). The Administrator's factual findings will be sustained on review to the extent they are supported by ''substantial evidence.'' *Hoxie,* 419 F.3d at 481. The Supreme Court has defined ''substantial evidence'' as such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. *Consol. Edison Co. of New York* v. *NLRB,* 305 U.S. 197, 229 (1938). While ''the possibility of drawing two inconsistent conclusions from the evidence'' does not limit the Administrator's ability to find facts on either side of the contested issues in the case, *Shatz* v. *U.S. Dep't of Justice,* 873 F.2d 1089, 1092 (8th Cir. 1989); *Trawick,* 861 F.2d at 77, all ''important aspect[s] of the problem,'' such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Village Pharm.* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007); *Humphreys* v. *DEA,* 96 F.3d 658, 663 (3rd Cir. 1996). The ultimate disposition of the case must be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. *Steadman,* 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall* v. *DEA,* 412 F.3d 165, 183 (D.C. Cir. 2005), but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz* v. *Glover Livestock Comm'n Co.,* 411 U.S. 182, 188 (1973)). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this Recommended Decision are entitled to significant deference, *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this Recommended Decision constitutes an important part of the record that must be considered in the Administrator's decision. *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Administrator and do not limit the exercise of his discretion. 5 U.S.C. 557(b) (2006); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* § 8 (1947).

Analysis of Dispensing Allegations

Failure To Resolve and To Document Red Flags

The Government alleges that the Respondent filled numerous prescriptions for ten patients that raised red flags of drug abuse and/or diversion, to include drug cocktails; dangerous combinations; traveling long distances; prescriptions for the highest commercially available strength; paying in cash; paying unusually high prices in cash; and therapeutic duplication. ALJ Ex. 1. The Government further alleges that the Respondent failed to resolve these red flags, or failed to document

their resolution. *Id.* The Government claims that by filling these ten patients' controlled substance prescriptions and failing to resolve the red flags they presented, the Respondent violated its corresponding responsibility under 21 CFR 1306.04(a) and dispensed controlled substances outside the usual course of pharmacy practice in violation of 21 CFR 1306.06, in addition to Florida Administrative Code r. 64B16–27.831. *Id.* Furthermore, the Government claims that by failing to resolve red flags and to document that resolution in the patients' profiles, the Respondent violated Florida Administrative Rule 64B16–27.800 and 27.810. *Id.*

With respect to each patient, the Government presented documentary evidence and testimony from its pharmacy expert, Dr. Schossow, that the Respondent filled numerous controlled substance prescriptions that raised red flags, including drug cocktails, dangerous combinations, patients traveling long distances, prescriptions for the highest commercially available strength, patients paying in cash, and patients paying unusually high prices in cash. The Government further presented evidence that the Respondent failed to document any resolution of these red flags in the patients' profiles.

The Government's expert conceded that each of the red flags that she identified were resolvable. Therefore, the question becomes, whether the Respondent resolved them prior to dispensing the controlled substance. The Government's expert testified that documentation of the resolution of red flags is required by the pharmacists' standard of professional responsibilities. The Respondent and his expert testified that no such documentation is required under Florida law or in the course of professional practice. Alternately, Dr. Buffington mused that reasonable pharmacists could differ whether documentation was required. However, despite believing that he had no professional responsibility to do so, the Respondent testified that he fully resolved all red flags and filled the subject prescriptions consistent with his professional judgment and with Florida law. Tr. 1360–64. The Respondent's expert testified that he observed no red flags within the record. Tr. 1162, 1241, 1277–78. Furthermore, he testified that even if there were red flags, there was no requirement to document red flags, but the Respondent resolved all red flags and documented their resolution. However, there is little-to-no documentary resolution of the red flags credibly identified by Dr. Schossow (or yellow lights in Dr. Buffington's vernacular) in evidence, as far as I could discern.[69] The evidentiary record consists of the relevant PDMP records; subject physical prescriptions; the subject patient profiles, including comments by the pharmacist in the comments section; dispensing logs; and any medical records which were part of the pharmacy records, all obtained through a series of administrative subpoenas. Tr. 466–67.

The Government suggests that the factfinder should infer the absence of the subject documentation resolving red flags demonstrates a failure to resolve the red flags. *Superior Pharmacy,* 81 FR 31,309, 31,314 (2016). However, the Respondent's expert, who reported experience with the PioneerRx computer program testified that there were additional fields in the PioneerRx database referred to as Medication Therapy Management and that there were multiple other tabs and therefore [there might have been] additional information that the investigators failed to obtain from the Respondent. Tr. 1163–64. [However, as discussed in more detail below, Respondent was served with three subpoenas that required the production of all documents that contained any discussion or resolution of red flags. Thus, Dr. Buffington's testimony that there might have been additional materials resolving red flags appeared to be speculative and is not entitled to any weight.] Furthermore, Dr. Schossow testified that the few examples of the pharmacist's comments highlighted at the hearing did not resolve the subject red flags.

Administrative Subpoenas

The Government's attempts to obtain documents from the Respondent began with the service of the AIW and administrative subpoena requesting various records from the Respondent on February 14, 2018. It should be noted that subpoenas are not requests, which can summarily be ignored by the recipient. They are duly authorized commands by the Attorney General and enforceable by the U.S. District Court. *See* 21 U.S.C. 875, 876, 880.

The first administrative subpoena was highly detailed and specific in its commands. It required, in part, copies of Respondent's patient profiles for certain listed patients, copies of ''[a]ny and all other records . . . maintained pursuant to the requirements of Florida Statutes and Florida Administrative Rule 64B16–27.800 documenting the steps taken to avoid or resolve any issues with the prescriptions presented by'' those same listed individuals; and copies of ''[a]ny other documentation kept by'' the Respondent ''in connection with the filling of prescriptions or providing medical treatment'' for those named individuals, including dispensing logs or reports, for those listed individuals. GX 3; Tr. 35, 41–42, 45, 64–65. Although, as Dr. Buffington noted, the term red flags does not appear in Florida regulations, the documents required by the subpoena would plainly include the type of documentation generated to resolve red flags.[70]

At the February 14, 2018 visit and search of the Respondent pharmacy, the Government's team of investigators included a computer technician. By all accounts, Dr. Fertil was cooperative and assisted the investigators in locating pharmacy and patient records. He helped connect the Government personnel with a technician from PioneerRx in order for the investigators to retrieve information from the PioneerRx record system. Other than that, the evidence discloses that Dr. Fertil did not actively collect any documents in response to the warrant and first administrative subpoena. Rather, he left it to the investigators to collect the required documents, assisting them with access to records and to the PioneerRx system, as they required. He placed them in touch with personnel from PioneerRx, who apparently walked them through the process of downloading the required material from the PioneerRx system. I cannot fault Dr. Fertil's actions on February 14, 2018. I think he did everything the law required and that the Agency would expect. The Government left after apparently retrieving all the documents they required. On February 14, 2018, the investigators did not retrieve all of the information stored on the PioneerRx system. In relevant part, they apparently only obtained screen shots of the first of multiple tabs of the PioneerRx system, by printing those.

In May of 2019, the Government served a second subpoena on the Respondent pharmacy. It required production of hardcopies of controlled substance prescriptions that Respondent had dispensed from February 15, 2018, through May 3, 2019, copies of the Respondent's patient profiles for certain listed individuals, and, like the first subpoena, copies of ''[a]ny and all records . . . maintained pursuant to the

[69] The Respondent submitted an excel spreadsheet encompassing the information contained in the subject patient profiles within the PioneerRx program. I could [not discern any relevance to the spreadsheet in terms of documenting Respondent's attempts to address and resolve the red flags that Dr. Schossow identified].

[70] [Footnote omitted.]

requirements of Florida Statutes and Florida Administrative Rule 64B16–27.800 for Patient Records, documenting the steps taken to avoid or resolve any issues with the prescriptions presented by'' those same listed individuals ''reflecting efforts by the pharmacist to exercise their corresponding responsibility to assess the validity'' of controlled substance prescriptions dispensed to those listed individuals. Tr. at 119–21; GX 16.

In August 2019, DI served a third administrative subpoena on Respondent seeking, with respect to Patients J.B., A.B., B.Da., B.Di., J.R., and R.R., hardcopies of controlled substance prescriptions that Respondent had dispensed to those patients from May 3, 2019, through August 9, 2019, copies of the Respondent's patient profiles for those patients, and copies of ''[a]ny and all records . . . maintained pursuant to the requirements of Florida Statutes and Florida Administrative Code 64B16–27.800 for Patient Records, documenting the steps taken to avoid or resolve any issues with the prescriptions presented by'' those patients ''reflecting efforts by the pharmacist to exercise their corresponding responsibility to assess the validity'' of controlled substance prescriptions dispensed to those patients. Tr. at 179–82; GX 33.

Adverse Inference

The Respondent, through Dr. Fertil, responded to the second and third subpoenas by providing records specific to the patients identified and dates included. However, the Respondent did not recall if he read the subpoenas, or if he supplied everything requested in the subpoenas. He only remembered that he supplied the same type of information that the Government seized during the service of the search warrant and first administrative subpoena on February 14, 2018.

I can safely conclude that he read the second and third subpoenas, as he supplied highly specific information and documents required. Regarding the aspect of the May and August subpoenas relating to documents required by Florida Administrative Rule 64B16–27.800 for Patient Records, he testified he only supplied the same type of records the government seized on February 14, 2018, believing that those same type of records were what the Government wanted. It was unusual that Dr. Fertil could describe his deliberative process in gathering or screening records in response to the second and third subpoenas, when he could not remember whether he read the subpoenas, nor if he supplied everything requested in the subpoenas. The record is also unclear how, in May and in August, 2019, he knew exactly what records were retrieved by the Government on February 14, 2018, as he testified he left the investigators to retrieve the documents they required with the assistance of a PioneerRx technician, and the receipt provided him for those documents does not disclose that only the first tab of the PioneerRx system was copied and seized.[71] His selective memory loss is not credible. If he did not remember even reading the subpoenas, his rationale for including and withholding records is not credible.

Either there were no [records documenting the resolution of red flags] in the Respondent's records, or Dr. Fertil ignored the subpoena requirements surrounding this [type of] documentation. In either case, we can infer that his failure to provide such highly exculpatory documentation suggests it does not exist. He testified that he was not obligated to resolve red flags and to document their resolution by the Florida regulations, but that he did resolve them and document them. However, he has not identified or presented any such documentation in evidence.[72] Based on his failure to provide the required documentation to the Government in May and August 2019, we can fairly infer that no such documentation exists. [Omitted for clarity.]

Failure To Resolve Red Flags

The Government argues that I should apply the adverse inference that the absence of the subject documentation as to the resolution of red flags suggests no resolution occurred. [I find that such an inference is appropriate in this case.] *M [Omitted.] [73]

Dr. Schossow testified that in evaluating a pharmacist's performance in the course of professional practice, the failure to document the resolution of red flags demonstrated the red flags were not resolved. Tr. 465–66. [Based on this testimony, the adverse inference, and the inconsistent and not credible testimony of the Pharmacist's PIC,] I will conclude [ ] that the failure to document the resolution of red flags establishes that the red flags were not resolved.

Specific Red Flags

Unusual Distance Traveled

[Omitted.] *N [74]

Payment in Cash

The Government argues that, in the context of this case, payment in cash for

[71] In relevant part, the receipt for documents seized on February 14, 2018, only references ''profiles printouts'' for GI 18–351298. GX 4.

[72] Where respondent testified that he had exculpatory inventories in his office, but failed to produce them at his hearing, the Administrator gave no credit to the testimony ''[i]n view of the level of professional exposure attendant upon the potential loss of his DEA registration. . . .'' *Lesly Pompy, M.D.,* 84 FR 57,749, 57,758 (2019). A physician may not expect to vindicate himself through oral representations at the hearing about his compliance with the standard of care that were not documented in appropriately maintained patient records. *Lesly Pompy, M.D.,* 84 FR 57,749, 57,760 (2019). Pharmacist's testimony that she resolved various red flags merited no weight because she failed to produce documentary evidence to corroborate her claim. *Pharmacy Doctors Enters. d/b/a Zion Clinic Pharmacy,* 83 FR at 10,887.

*M The ALJ declined to draw an adverse inference that Respondent failed to resolve red flags based on Respondent's failure to document the resolution of the red flags, citing to the Agency's decision in *Hills Pharmacy* as support. *See* RD, at 127–28 (citing *Hills Pharmacy, L.L.C.,* 81 FR 49,816, 49,835–36 (2016). However, in *Hills Pharmacy,* a former Acting Administrator declined to draw an adverse inference based solely on the respondent's failure to document red flags on the prescriptions themselves, when other materials (such as patient profiles) were not in evidence. The Acting Administrator noted that because there was no state or federal law that required red flags to be documented on the prescriptions themselves, the respondent may have documented the resolution elsewhere. *Id.* In this case, however, the Government admitted patient profiles, prescriptions, and other pharmacy records into evidence. Additionally, the Government admitted into evidence all documents that DEA obtained from Respondent in response to a subpoena requesting: (1) All documentation showing the steps taken to resolve red flags, and (2) all documentation reflecting efforts by Respondent's pharmacists to exercise their corresponding responsibility. Thus, I find that it is appropriate in this case to infer that Respondent failed to address and resolve red flags based on the absence of documentation evidencing attempts to address and resolve red flags. Therefore, I apply here, the ''adverse inference rule.'' As the D.C. Circuit explained, ''the rule provides that when a party has relevant evidence within his control which he fails to produce, that failure gives rise to an inference that the evidence is unfavorable to him.'' *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. (UAW)* v. *Nat'l Labor Relations Bd.,* 459 F.2d 1329, 1336 (D.C. Cir. 1972). The Court reiterated this rule in *Huthnance* v. *District of Columbia,* 722 F.3d 371, 378 (D.C. Cir. 2013). According to this legal principle, Respondent Pharmacy's decision not to provide evidence within its control gives rise to an inference that any such evidence is unfavorable to Respondent Pharmacy.

[73] [Omitted for clarity.]

*N The ALJ determined that the Government failed to prove that the distances that Respondent's customers traveled to fill their prescriptions, which ranged from approximately thirty to fifty miles, represented a red flag in this case. I find that it is unnecessary for me to determine whether the distances traveled were a red flag in this case because the Government has proven that these prescriptions presented several additional red flags that Respondent did not resolve. I thus conclude

Continued

controlled substances is a red flag, as it may represent an attempt by the patient to avoid scrutiny of an insurance carrier, who may investigate the propriety of the controlled prescription.[75] [Dr. Schossow testified that cash payments are a red flag because ''drug seeker[s] [are] willing to pay more for a drug if they can get the drug. They're willing to pay whatever they want, you know, whatever they need to pay to obtain the medication.'' Tr. 585–86.] [Omitted.] *O

Unusually High Cash Payments

The Government argues that the payment of inflated prices for controlled substances creates a red flag of diversion or abuse. [Omitted.] *P The Government offered the expert opinion of Dr. Schossow, who, although she has not served a customer in seven years, has had extensive and recent experience in the average pricing of the subject medications in Florida. Tr. 405, 564–65. She managed a rejection que, and more recently reviews ''High Dollar Reports'' for Blue Cross/Blue Shield of Florida. Tr. 403–04. She testified that pharmacies throughout Florida charge twenty to twenty five percent over acquisitions costs, while the Respondent's prices were in excess of that, sometimes more than triple the market rate. Tr. 565–66. Dr. Schossow testified that the excessive prices charged by the Respondent represented a red flag, which were not resolved by the Respondent. Her subject opinion is credible and consistent with Agency [decisions that have credited expert testimony that cash payments at high prices for a large quantity of controlled substances are suspicious.[76] I find based on Dr. Schossow's credible expert testimony that it was a red flag that Respondent's customers were willing to pay very high prices in cash for controlled substances.]

Dangerous Combinations

The Government highlighted two medication combinations the Respondent dispensed. They argued these combinations represented red flags, which were not resolved by the Respondent. They were the combination of an opioid and a benzodiazepine, which has a ''black box'' warning from the FDA. This combination has the risk of respiratory suppression and overdose. Although it may ultimately be justified as therapeutic depending on the circumstances, it requires investigation, resolution and documentation by the pharmacist.

The Respondent also filled numerous prescriptions of an opioid, a benzodiazepine, and a muscle relaxant, that raised multiple red flags of drug abuse and/or diversion. Not only did Dr. Schossow opine that these red flags are recognized by Florida's standard of pharmacy practice, but all of these red flags [have been recognized by DEA as indicators] of drug abuse and/or diversion.[77]

Furthermore, the Government's evidence shows that the Respondent failed to document sufficient resolution of these red flags. Although the Respondent testified that he resolved all red flags or suspicious circumstances, there's no documentary evidence to corroborate his claim. *Pharmacy Doctors Enters. d/b/a Zion Clinic Pharmacy,* 83 FR 10876, 10887 (2018).

Dispensing Immediate Release Opioids in Combination With Long-Acting Opioids

Dr. Schossow testified that dispensing immediate release opioids in combination with long-acting opioids, in which the MME of the immediate release is greater than the MME of the long-term opioids does not make pharmacologic sense and creates a dangerous risk of overdose. Tr. 599–600. She explained that the long-acting opioids had a long half-life and remained in the patient's system for a long period, relieving pain. This would reduce the need for large amounts of immediate release opioids. Although Dr. Buffington defended the use of long-acting opioids in combination with immediate release opioids, he did not directly address Dr. Schossow's point relating to the comparative MME levels of the two. Tr. 1121–22, 1129–30. I credit Dr. Schossow's testimony that this combination of opioids represented a red flag and that the red flag went unresolved by the Respondent.

[Omitted for clarity and brevity.*Q As discussed in more detail below, I find

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that Respondent dispensed prescriptions outside the usual course of professional practice in Florida based on its failure to resolve these red flags, and I find it unnecessary to determine whether the distances traveled represented yet another red flag that Respondent failed to resolve.

[74] [Omitted.]

[75] Payment in cash actually refers to payment in currency, credit card, or even by check. It does not include payment through an insurance carrier or government program payer.

*O I agree with the ALJ's ultimate conclusion that cash payments were a red flag in this case, but I disagree with his statement that cash payments were not ''a huge red flag.'' RD, at 130. I give minimal weight to Dr. Buffington's testimony about the red flag of cash payments because it was not grounded in a discussion of the Florida usual course of professional practice. Dr. Buffington testified that the prices he saw ''were not surprising or astonishing,'' but even if they were high, it is ''the patient's prerogative'' to pay those prices. Tr. 1193. Dr. Buffington also testified that there are many reasons that a patient may pay in cash, which is something that the pharmacist can discuss with the patient. *Id.* However, Dr. Buffington did not adequately address the concern that cash payments are a red flag because drug seekers are willing to pay high prices for a drug. Tr. 585–86. Although I agree with Dr. Buffington that there are legitimate reasons that a patient may pay in cash, I find based on Dr. Schossow's credible expert testimony that cash payments were a red flag in this case, and it was outside the usual course of professional practice for Respondent to fail to address, resolve, and document this red flag, particularly in combination with the other red flags.

*P I have omitted, for brevity, the RD's discussion of his decision to exclude the Government's evidence of national average costs of drugs, which was intended to show that Respondent charged high prices for controlled substances. There is other evidence on the record that shows that Respondent charged high prices for controlled substances—specifically, Dr. Schossow's testimony (which is also discussed in this section) that Respondent's prices greatly exceeded its acquisition costs. Therefore, the Government adequately supported its contention that Respondent charged high prices even without evidence of national average drug costs. Thus, I need not resolve whether the ALJ properly excluded the evidence of national average costs of drugs.

[76] ''[A]ny reasonable pharmacist knows that a patient that . . . wants to pay cash for a large quantity of controlled substances is immediately suspect.' '' *Jones Total Health Care Pharmacy, L.L.C.,* 81 FR 79,188, 79,194 (2016), *pet. for rev. denied,* 881 F.3d 823 (11th Cir. 2018) (quoting *East Main Street Pharmacy,* 75 FR 66149, 66158 (2010)). Where a pharmacy's prices for controlled substances far exceed prices charged by other pharmacies, it may be inferred that the pharmacy knows that those purchasing those high-priced controlled substances are either abusing or diverting them. *Jones Total Health Care Pharmacy, L.L.C.,* 81 FR 79,188, 79,199–200 (2016), *pet. for rev. denied,* 881 F.3d 823 (11th Cir. 2018) (citing *United States* v. *Leal,* 75 F.3d 219, 223 (6th Cir. 1996)).

[77] Oxycodone, carisoprodol, and alprazolam are a combination of drugs that the DEA has encountered in investigations of registrants ''engaged in blatant drug dealing.'' *Sigrid Sanchez, M.D.,* 78 FR at 39,332 n.2 (2013) (citing *Paul H. Volkman, M.D.,* 73 FR 30,630 (2008)). ''The combination of a benzodiazepine, a narcotic and carisoprodol is 'well known in the pharmacy profession' as being used 'by patients abusing prescription drugs.' '' *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.,* 81 FR 79,188, 79,194 (2016), *aff'd,* 881 F.3d 823 (11th Cir. 2018) (quoting *E. Main St. Pharmacy,* 75 FR 66149, 66163 (2010)). Several DEA decisions have discussed the abuse of the ''trinity'' cocktail, which typically consists of carisoprodol, oxycodone, and alprazolam. *Holiday CVS,* 77 FR at 62,321 n.22 (citing *East Main Street Pharmacy,* 75 FR 66,149, 66,158 (2010) (noting expert's testimony that ''[i]t is well known in the pharmacy profession [that] the combination of a benzodiazepine, narcotic pain killer, and Soma [the branded version of carisoprodol] [is] being used by patients abusing prescriptions drugs'') and *Paul J. Volkman, M.D.,* 73 FR at 30,637–38, *aff'd, Volkman* v. *DEA,* 567 F.3d 215 (6th Cir. 2009) (discussing expert's testimony regarding abuse of drug cocktails of oxycodone, alprazolam, and carisoprodol)).

*Q The ALJ concluded that Florida law requires pharmacists to document in the patient profile the steps that they take to resolve red flags. *See, e.g.,* RD, at 134–35 (citing Fla. Admin. Code r. 64B16–27.800). The Respondent takes Exception to this conclusion, arguing that there is no Florida law or regulation that mandates pharmacists to document the resolution of red flags. Resp Posthearing, at 5–12. I need not address whether Florida law requires pharmacists to document red flag resolution, however, because Dr. Schossow offered credible expert testimony that failing to document red flag

that Respondent acted outside the usual course of professional practice by repeatedly filling prescriptions without addressing and resolving red flags, and without documenting the resolution. *See* 21 CFR 1306.06. I further find that Respondent violated its corresponding responsibility by filling prescriptions that Respondent knew were not prescribed for a legitimate medical purpose, or was willfully blind to such. *See* 21 CFR 1306.04.] [78]

Government's Burden of Proof and Establishment of a Prima Facie Case

[In order to make a *prima facie* case that a ground for revocation of Respondent's registration exists, the Government must demonstrate that Respondent's continued registration is inconsistent with the public interest]. [Text omitted for clarity].

Public Interest Determination: The Standard

Pursuant to 21 U.S.C. 823(a)(4) (2006 & Supp. III 2010), the Administrator [79] may revoke a DEA Certificate of Registration if the registrant has committed such acts as would render its registration inconsistent with the public interest. Evaluation of the following factors have been mandated by Congress in determining whether maintaining such registration would be inconsistent with ''the public interest'':

1. The recommendation of the appropriate State licensing board or professional disciplinary authority.

2. The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

3. The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

4. Compliance with applicable State, Federal, or local laws relating to controlled substances.

5. Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

''These factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Agency may properly give each factor whatever weight it deems appropriate in determining whether a registrant's registration should be revoked. *Id.* (citation omitted); *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *see also Morall,* 412 F.3d at 173–74 (D.C. Cir. 2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16422, 16424 (1989). Moreover, the Agency is ''not required to make findings as to all of the factors,'' *Hoxie,* 419 F.3d at 482; *see also Morall,* 412 F.3d at 173, and is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (holding that the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors, and that remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest.'' *Krishna-Iyer,* 74 FR at 462.

Factors Two and Four: Experience in Dispensing, and Compliance With Applicable State, Federal, or Local Laws Relating to Controlled Substances

The Government seeks the revocation of the Respondent's COR based primarily on conduct most appropriately considered under Public Interest Factors Two and Four.[80]

The DEA often analyzes Factor Two and Factor Four together. See, *e.g.,* Fred Samimi, M.D., 79 FR 18,698, 18,709 (2014); John V. Scalera, M.D., 78 FR 12,092, 12,098 (2013). Under Factor Two, the DEA analyzes a registrant's ''experience in dispensing controlled substances.'' 21 U.S.C. 823(f)(2); *Id.* This analysis focuses on the registrant's acts that are inconsistent with the public interest, rather than on a registrant's neutral or positive acts and experience. Kansky J. Delisma, M.D., 85 FR 23,845, 23,852 (2020) (citing Randall L. Wolff, M.D., 77 FR 5106, 5121 n.25 (2012). The Agency has acknowledged that even a considerable level of benign or even commendable experience could be easily outweighed by evidence demonstrating that continued registration was inconsistent with the public interest.[81]

Likewise, under Factor Four, the DEA analyzes an applicant's compliance with Federal and state controlled substance laws with the analysis focusing on violations of state and Federal laws and regulations concerning controlled substances. Delisma, 85 FR at 852 (citing *Volkman* v. *DEA*, 567 F.3d 215, 223–24 (6th Cir. 2009)) (citations omitted). As DEA has held in the past, a registrant's ''ignorance of the law is no excuse'' for actions that are inconsistent with responsibilities attendant upon a registration. *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,809 (2015) (quoting *Sigrid Sanchez, M.D.,* 78 FR 39,331, 39,336 (2013) (citing *Patrick W. Stodola,* 74 FR 20,727, 20,735 (2009) and *Hageseth* v. *Superior Ct.,* 59 Cal. Rptr. 3d 385, 403 (Ct. App. 2007) (a ''licensed health care provider cannot 'reasonably claim ignorance' of state provisions regulating medical practice'')). Under Agency precedent, ''[a]ll registrants are charged with knowledge of the CSA, its implementing regulations, as well as applicable state laws and rules.'' *Id.* at 74809 (internal citations omitted).

[Omitted.] *[R]

resolution is outside the usual course of professional practice in Florida. Although Dr. Buffington offered conflicting testimony that documentation is not required in the usual course of professional practice, I agree with the ALJ that Dr. Schossow's testimony regarding documentation requirements was more credible.

[78] [Footnote omitted.]

[79] This authority has been delegated pursuant to 28 CFR 0.100(b) and 0.104 (2008).

[80] 21 U.S.C. 823(f)(2), (4). There is nothing in the record to suggest that a state licensing board made any recommendation regarding the disposition of the Respondent's DEA COR (Factor One). Likewise, the record contains no evidence that the Respondent has been convicted of (or charged with) a crime related to controlled substances (Factor Three).

[81] *See, e.g., Paul J. Caragine, Jr.,* 63 FR 51,592, 51,560 (1998) (''[E]ven though the patients at issue are only a small portion of Respondent Pharmacy's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future.''); *Med. Shoppe-Jonesborough,* 73 FR at 386 (finding that the misconduct outweighed the fact that only a relatively small portion of the respondent's patient population was involved).

*[R] I disagree with the ALJ's assertion that the testimony of J.R. and L.V. constitutes positive dispensing experience under Factor Two, and I disagree with the ALJ's conclusion that Factor Two weighs in Respondent's favor based on this testimony. Dr. Schossow identified several red flags with J.R.'s and L.V.'s prescriptions. Dr. Schossow testified that L.V. presented prescriptions for the potentially dangerous combination of opioids and benzodiazepines, she paid for some prescriptions in cash and others with insurance, and she made unusually high cash payments. Tr. 510–28, 758, 767–68, 772–74, 776, 778. Dr. Schossow reviewed Respondent's records for L.V. and did not find any indication that Respondent addressed or resolved these red flags. Tr. 529. Respondent did not successfully rebut these conclusions. Dr. Fertil testified briefly about his interactions with L.V. Respondent's counsel asked him whether he ''ha[d] any occasion to discuss with patients like J.R. and L.V. their restrictions presented for combinations that included a benzodiazepine, an opioid, and, in some cases, Soma or carisoprodol.'' Tr. 1360. Dr. Fertil confirmed that he had, and he also confirmed that he had provided those customers with information regarding potential side effects of the combination and discussed with them the potential sedative effects. *Id.* at 1361. Dr. Fertil, however, did not testify that he addressed or resolved the red flag that the patient was receiving this potentially dangerous drug combination, or that he resolved the red flags of unusually high cash payments and

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*[S] *Standard of Care as to Charged Violations*

[According to the CSA's implementing regulations, ''[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice.'' 21 CFR 1306.06. Further, a controlled substance prescription must be ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). While the ''responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription.'' *Id.* The regulations establish the parameters of the pharmacy's corresponding responsibility.

An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of . . . 21 U.S.C. 829 . . . and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Id. ''The language in 21 CFR 1306.04 and caselaw could not be more explicit. A pharmacist has his own responsibility to ensure that controlled substances are not dispensed for non-medical reasons.'' *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy,* 55 FR 4729, 4730 (1990) (citing United *States* v. *Hayes,* 595 F.2d 258 (5th Cir. 1979), *cert. denied,* 444 U.S. 866 (1979); *United States* v. *Henry,* 727 F.2d 1373 (5th Cir. 1984) (reversed on other grounds)). As the Supreme Court explained in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

To prove a pharmacist violated his or her corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See* 21 CFR 1306.04(a) (''[T]he person *knowingly* filling [a prescription issued not in the usual course of professional treatment] . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'') (emphasis added). DEA has also consistently interpreted the corresponding responsibility regulation such that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.'' *Bertolino,* 55 FR at 4730 (citations omitted); *see also JM Pharmacy Group, Inc. d/b/a Pharmacia Nueva and Best Pharmacy Corp.,* 80 FR 28,667, 28,670–72 (2015) (applying the standard of willful blindness in assessing whether a pharmacist acted with the requisite scienter). Pursuant to their corresponding responsibility, pharmacists must exercise ''common sense and professional judgment'' when filling a prescription issued by a physician. *Bertolino,* 55 FR at 4730. When a pharmacist's suspicions are aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription. *Id.; Medicine Shoppe-Jonesborough,* 300 F. App'x 409, 412 (6th Cir. 2008) (''When pharmacists' suspicions are aroused as reasonable professionals, they must at least verify the prescription's propriety, and if not satisfied by the answer they must refuse to dispense.'').

Finally, ''[t]he corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself.'' *Holiday CVS,* 77 FR at 62,341 (citing *Med. Shoppe—Jonesborough,* 73 FR at 384; *United Prescription Servs., Inc.,* 72 FR 50,397, 50,407–08 (2007); *EZRX, L.L.C.,* 69 FR 63,178, 63,181 (2004); *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies,* 75 FR 61,613, 61,617 (2010); *Issuance of Multiple Prescriptions for Schedule II Controlled Substances,* 72 FR 64,921, 64,924 (2007) (other citations omitted)). The DEA has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employee. *EZRX, L.L.C.,* 69 FR at 63,181; *Plaza Pharmacy,* 53 FR 36,910, 36,911 (1988). Similarly, ''[k]nowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself.'' *Holiday CVS,* 77 FR at 62,341.]

[Text omitted.] *[T]

In the case before me, the Government presented no evidence that the Respondent's pharmacists filled a prescription with actual knowledge that the prescriptions were not legitimate. Absent actual knowledge, the Government can establish scienter by showing that a pharmacist was ''willfully blind (or deliberately ignorant) to the fact that the prescription lacked a legitimate medical purpose.'' *Id.* To establish willful blindness, it is necessary to show that a pharmacist subjectively believed that there was a high probability that the prescription lacked a legitimate medical purpose and that the pharmacist deliberately avoided learning the truth. *Id.* Here, the Government argues that the Respondent's failure to document the resolution of numerous red flags when it filled many prescriptions establishes that the Respondent was willfully blind as to the medical legitimacy of those prescriptions. Gov Posthearing, at 34–35.

alternating cash and insurance payments. L.V.'s testimony also did not shed light on whether Respondent made any attempts to address or resolve these red flags. L.V. testified that she was rejected by other pharmacies, and she chose Gulf Med because they filled her prescriptions in a timely manner and at a reasonable price. Tr. 1303. L.V.'s belief that the prices were reasonable is not sufficient to rebut Dr. Schossow's credible expert testimony that the prices were high, and that it was a red flag for L.V. to pay those prices in cash.

Likewise, Respondent did not offer testimony or evidence that suggested that Respondent made adequate attempts to address or resolve the red flags that Dr. Schossow identified with J.R.'s prescriptions. Dr. Schossow testified that J.R. presented prescriptions for the potentially dangerous ''trinity'' cocktail and for multiple benzodiazepines. Although J.R. testified that he discussed his many medical problems with Respondent's pharmacists, and they answered his questions and provided him with instructional material, there is not sufficient evidence on the record that Respondent addressed and resolved the red flags with J.R.'s prescriptions. Dr. Buffington testified that Respondent made some notations in J.R.'s records about conversations with J.R.'s physicians and J.R.'s treatment, but he did not point to any notations that indicated that Respondent adequately addressed the red flags that Dr. Schossow identified. Therefore, I credit Dr. Schossow's testimony that Respondent failed to address and resolve red flags with J.R.'s and L.V.'s prescriptions prior to dispensing, and that Respondent dispensed controlled substances to these customers outside the usual course of professional practice in Florida and in violation of its corresponding responsibility.

*[S] I am replacing portions of the Standard of Care section in the RD with preferred language regarding prior Agency decisions; however, the substance is primarily the same.

*[T] I have omitted, for brevity, text regarding the legal standard requiring a nexus between the state laws that have been violated and the CSA's purpose of preventing drug abuse and diversion. I find that the Florida laws in this case are sufficiently related to controlled substances to be considered in my public interest analysis, and that my consideration of these state law violations bears a rational relationship to the core purpose of the CSA. *See Salman Akbar, M.D.,* 86 FR 52,181, 52,194–95 (2021) (citing 21 U.S.C. 823(a)(4); *Judulang* v. *Holder,* 556 U.S. 42, 63 (2011)).

The Government has introduced a preponderance of evidence to prove that the Respondent dispensed numerous controlled substance prescriptions for at least ten patients. Those prescriptions raised classic red flags of drug abuse and/or diversion, to include paying in cash, paying high prices in cash, dangerous drug cocktails, and combining extended release and immediate release opioids, highest strength of the medication, among others.*U The Government also introduced the supplied patient profiles for each of these ten patients, as well as hardcopy prescriptions, dispensing reports and PDMP information. The profiles contain insufficient information, and in some cases no information, that [indicates that Respondent took adequate steps to address or resolve the red flags raised by each prescription]. The evidence reveals a concerning pattern of a pharmacy that repeatedly [acted outside the usual course of professional practice by failing] to document information needed to resolve red flags. This concerning pattern demonstrates that regardless of the obvious signs of drug abuse and diversion that are well-known to the pharmacy community, the Respondent repeatedly dispensed controlled substances and rarely, if ever, documented any information in response to those red flags in the patient records. And when the Respondent documented information, it was always insufficient to resolve all the concerns raised by the prescription.

With respect to the prescriptions in evidence, the Government has further demonstrated a violation of the Respondent's corresponding responsibility under 21 CFR 1306.04(a). The Government has proven this violation through documentary evidence and testimony from its expert witness.*V

Furthermore, the Respondent failed to rebut or meaningfully discredit the Government's case. For the reasons discussed, the Respondent and Respondent's expert had diminished credibility. In light of the record as to this factor, I find that the Government has proven that the Respondent failed to comply with federal law [and the usual course of professional practice in Florida] with respect to resolving and documenting resolution of red flags of drug abuse and/or diversion, and with respect to its corresponding responsibility for the prescriptions in evidence.

The totality of this evidence demonstrates a concerning lack of compliance with applicable federal law [and state professional practice standards] that poses a significant risk of diversion and threatens public health and safety. This evidence further demonstrates a lack of commitment on the Respondent's part with respect to its federal and state controlled substance obligations. Therefore, I find that Factors Two and Four significantly favor revoking the Respondent's registration. [The record evidence establishes that Respondent filled controlled substance prescriptions in violation of its corresponding responsibility and outside the usual course of professional practice. Thus, I conclude that Respondent has engaged in misconduct which supports the revocation of its registration. I therefore find that the Government has established a *prima facie* case that Respondents' continued registrations ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).]

Acceptance of Responsibility

With the Government's *prima facie* burden having been met, the Respondent must present sufficient mitigating evidence to assure the Administrator that it can be entrusted with the responsibility incumbent with such registration. *Medicine Shoppe-Jonesborough,* 73 FR at 387 (2008); *Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007). As past performance is the best predictor of future performance, DEA has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for its actions and demonstrate that it will not engage in future misconduct. *ALRA Labs, Inc.,* 54 F.3d at 452; *Medicine Shoppe,* 73 FR at 387; *see also Hoxie,* 419 F.3d at 483 (reasoning that ''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[ ]'' in the public interest determination). Likewise, in making the public interest determination, ''this Agency places great weight on a registrant's candor, both during an investigation and in [a] subsequent proceeding.'' *Robert F. Hunt,* 75 FR 49,995, 50,004 (2010); *Hoxie,* 419 F.3d at 483.

Although correcting improper behavior and practices is very important to establish acceptance of responsibility, conceding wrongdoing is critical to reestablishing trust with the Agency. *Holiday CVS, L.L.C.,* 77 FR at 62,346; *Daniel A. Glick, D.D.S.,* 80 FR at 74,801.

The Respondent has not unequivocally accepted responsibility for the proven violations. In fact, the Respondent has not tendered any acceptance of responsibility at all, whether equivocal or unequivocal. The Respondent's pharmacist-in-charge testified at the hearing, but denied all wrongdoing. The Respondent's post-hearing brief is silent on this issue.

*U Agency decisions have consistently found that prescriptions with similar red flags were so suspicious as to support a finding that the pharmacists who filled them violated their corresponding responsibility because they had actual knowledge of, or were willfully blind to, the prescriptions' illegitimacy. *See, e.g., Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR 10,876, 10,898, *pet. for rev. denied,* 789 F. App'x 724 (11th Cir. 2019) (long distances; pattern prescribing; customers with the same street address presenting the same prescriptions on the same day; drug cocktails; cash payments; early refills); *Hills Pharmacy,* 81 FR 49,816, 49,836–39 (2016) (multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting similar prescriptions on the same day; long distances; drug cocktails); *The Medicine Shoppe,* 79 FR 59,504, 59,507, 59,512–13 (2014) (unusually large quantity of a controlled substance; pattern prescribing; irregular dosing instructions; drug cocktails); *Holiday CVS,* 77 FR 62,316, 62,317–22 (2012) (long distances; multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting virtually the same prescriptions within a short time span; payment by cash); *East Main Street Pharmacy,* 75 FR 66,149, 66,163–65 (2010) (long distances; lack of individualized therapy or dosing; drug cocktails; early fills/refills; other pharmacies' refusals to fill the prescriptions).

*V Further, the Government introduced evidence that is consistent with violations of Florida law. Florida law and the Florida standard of care require a pharmacist to conduct a prospective drug use review before dispensing a controlled substance. Tr. 211, 227–28; Fla. Admin. Code r. 64B16–27.810. This includes ''review[ing] the patient record and each new and refill prescription presented for dispensing'' to identify, among other things, ''[o]ver-utilization or under-utilization,'' ''[t]herapeutic duplication,'' ''drug-drug interactions,'' and ''[c]linical abuse/misuse.'' Fla. Admin. Code r. 64B16–27.810. After conducting this review, the pharmacist must ''take appropriate steps to avoid or resolve the potential problems.'' *Id.* The purpose of the prospective drug use review is to identify red flags that require resolution before dispensing a controlled substance. Tr. 207–08, 211. Additionally, Florida law requires pharmacists to ''exercise[] sound professional judgment,'' review each prescription ''with each patient's unique situation in mind,'' and ''attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.'' Fla. Admin. Code r. 64B16–27.831.

I find that the evidence on the record is consistent with violations of Florida law, based on Respondent's repeated filling of prescriptions without documenting any attempts to address or resolve red flags. However, I find that it is unnecessary for me to determine whether Respondent violated Florida law, because Respondent's repeated violations of federal law are sufficient for me to conclude that Respondent's registration is inconsistent with the public interest. I do find, however, that the Florida laws in this case bolster Dr. Schossow's credible expert testimony that pharmacists must conduct a drug utilization review on every prescription.

Resp't Posthearing Br. 29, ¶ (i); 32, ¶ (ii); 36, ¶ (iii).

The Respondent took the similar approach in its opening statement, arguing that the Government has failed to satisfy its burden; accusing the DEA of never intending to clearly or objectively evaluate the evidence; attacking the credentials of the Government's expert; claiming that the Respondent exercised appropriate judgment when dispensing the relevant controlled substance prescriptions in compliance with Florida law; and complaining about the standard the DEA is imposing on its conduct. Tr. 503–05. In other words, the message from the Respondent's post-hearing brief and its opening statement is that it has done nothing wrong. These sentiments are inconsistent with a registrant that is remorseful for misconduct and determined to regain the Agency's trust. By failing to accept responsibility, the Respondent has failed to overcome the Government's *prima facie* case. In addition to failing to accept responsibility, the Respondent has also failed to offer any evidence of remediation.

Egregiousness and Deterrence

[Omitted for brevity.] The egregiousness and extent of an applicant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19,386, 19,387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman,* 73 FR 30,630, 30,644 (2008); *see also Gregory D. Owens,* 74 FR 36,751, 36,757 n.22 (2009). [Likewise, DEA considers its interest in deterring future misconduct by both the registrant as well as other registrants. *David A. Ruben, M.D.,* 78 FR 38,363, 38,364 (2013).]

I find that the proven misconduct is egregious and that deterrence considerations weigh in favor of revocation. The proven misconduct involves repeated instances of dispensing high-strength schedule II controlled substances despite the presence of well-known signs of drug abuse and diversion. The proven misconduct also involves repeat instances of failing to follow state standards of practice with respect to documenting red flag resolution. Continuously dispensing high-strength schedule II opioids, sometimes dangerously combined with high-strength benzodiazepines, and failing to document any investigation into those red flags, constitutes egregious misconduct because it allowed for the potential of unchecked diversion of controlled substances into illegitimate channels.

[Omitted for brevity.] *[W]

I further find that general deterrence considerations weigh in favor of revocation. Allowing the Respondent to retain its COR despite the proven misconduct would send the wrong message to the regulated community. Imposing a sanction less than revocation would create the impression that registrants can maintain DEA registration despite repeatedly failing to resolve and document the resolution of red flags in accordance with [the usual course of professional practice]. Revoking the Respondent's COR communicates to registrants that the DEA takes all failings under the CSA seriously and that severe violations will result in severe sanctions.

Loss of Trust

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Acting Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008).

There is no evidence that suggests the Respondent has learned any lessons from its misconduct and in fact, as discussed *supra,* the Respondent does not appear to believe it has done anything wrong. [Omitted for clarity.] The Respondent's failure to accept responsibly and present remediation evidence has convinced this Tribunal that the DEA cannot trust Respondent with the obligations of a DEA registration.

Recommendation

Considering the entire record before me, the conduct of the hearing, and observation of the testimony of the witnesses presented, I find that the Government has met its burden of proof and has established a *prima facie* case for revocation. Furthermore, I find that the Respondent has not accepted responsibility, or presented sufficient evidence demonstrating that the Agency can entrust it with a COR.

Therefore, I recommend that the Respondent's DEA COR No. FG6290061 should be REVOKED, and that any pending applications for modification or renewal of the existing registration, and any applications for additional registrations, be DENIED.

Signed: November 25, 2020
MARK M. DOWD
U.S. Administrative Law Judge

The Respondent's Exceptions

On December 15, 2020, Respondent filed its Exceptions to the RD. I find that Respondent's seven Exceptions are either without merit or irrelevant to my Decision. Therefore, I reject Respondent's Exceptions and affirm the RD's conclusion that Respondent's continued registration is inconsistent with the public interest, and that revocation is the appropriate sanction.

Exception 1

In the first Exception, Respondent argues that the RD's conclusion that Florida law and the Florida standard of care require pharmacists to document the resolution of red flags ''was based upon a clear error of law, and thus arbitrary and capricious.'' Resp Exceptions, at 5–11. Respondent argues that the provisions of the Florida Administrative Code that the RD cites to do not support this conclusion. *Id.*

I do not need to address Respondent's arguments about the Florida Administrative Code, because I have concluded, based on Dr. Schossow's credible expert testimony, that a pharmacist operating in the usual course of professional practice in Florida must address, resolve, and document red flags prior to dispensing a controlled substance. Dr. Schossow testified that such documentation is necessary to ensure patient safety and continuity of care. I have thus concluded that, by repeatedly filling prescriptions without adequately addressing, resolving, or documenting red flags, Respondent violated its corresponding responsibility because the pharmacists knew these controlled substances were not prescribed for legitimate medical purposes, or were willfully blind to such, in violation of their corresponding responsibility under 21 CFR 1306.04(a), and Respondent dispensed controlled substances outside the usual course of professional practice, in violation of 21 CFR 1306.04(a) and 1306.06. Because documentation of red flags is required in the usual course of professional practice in Florida, I find that it is irrelevant whether Respondent took

*[W] I have omitted, for brevity, the RD's statements that revocation is the appropriate remedy notwithstanding the lack of evidence related to Factors One, Three, and Five. As discussed in more detail above, the Agency is ''not required to make findings as to all of the factors,'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall,* 412 F.3d at 173, and is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988).

adequate steps under Florida law to document any attempts to resolve the red flags.

Exceptions 2 and 6

Respondent next argues that the ALJ's conclusion that Respondent failed to document the resolution of red flags was ''unsupported by substantial evidence and otherwise arbitrary and capricious,'' because the government failed to offer complete copies of the relevant patient profiles. Resp Exceptions, at 12. Respondent similarly argues that the ALJ arbitrarily and capriciously concluded that the absence of documentation resolving red flags supports the inference that no such documentation exists. *Id.* at 16–17 (Exception 6). These Exceptions are disingenuous and lend further support for my conclusion that Respondent cannot be entrusted with a DEA registration.

The Government served three administrative subpoenas on Respondent throughout the course of the investigation, each of which required Respondent to produce ''[a]ny and all records . . . maintained pursuant to the requirements of Florida Statutes and Florida Administrative Rule 64B16–27.800 for Patient Records, documenting the steps taken to avoid or resolve any issues with the prescriptions presented by'' the listed patients. Gov't Exs. 3, 16, 33; RD, at 125. The second and third subpoenas further specified that Respondent was required to produce all documentation ''reflecting efforts by the pharmacist to exercise their corresponding responsibility to assess the validity'' of controlled substance prescriptions dispensed to those listed patients. Gov't Exs. 16, 33. At the hearing, the Government admitted into evidence all records that it obtained from Respondent pursuant to these subpoenas. *See* RD, at 84–87. Thus, if the record is devoid of relevant records documenting the resolution of red flags, then Respondent is at fault for failing to comply with the subpoenas.*[X] If Respondent realized during the course of the administrative litigation that there were additional materials that it had omitted from its subpoena response, then Respondent should have produced those materials immediately. As discussed in more detail above, I find that it is appropriate in this case to infer that no additional documentation of red flags exists based on Respondent's failure to produce this potentially exculpatory evidence.

Exception 3

I declined to rule on whether the distances that Respondent's customers traveled in this case were a red flag, because there was sufficient evidence on the record that the prescriptions presented several additional red flags that should have been addressed, resolved, and documented. Therefore, I need not address Respondent's third Exception, which addresses the adequacy of Respondent's evidence regarding the distance red flag.

Exception 4

Respondent argues that the ALJ erred in discrediting Dr. Buffington's testimony that there is no presumption in pharmacy practice that concurrent prescriptions for opioids and benzodiazepines cannot be issued or filled. Resp Exceptions, at 15. Respondent believes that the ALJ gave too much weight to the FDA's ''black box'' warning over Dr. Buffington's expert testimony. However, my conclusion regarding the opioid/benzodiazepine combination is not that this drug combination should never be prescribed or dispensed, but rather that it is a red flag that a pharmacist must address, resolve, and document. As stated above, this conclusion was supported by Dr. Schossow's credible testimony and by portions of Dr. Buffington's testimony. This conclusion is further supported by Respondent's Exceptions, which acknowledge that the opioid/benzodiazepine combination poses potential complications. *Id.* (''Dr. Buffington . . . credibly testified that the ['black box''] warning exists to alert healthcare professionals as to potential complications with a particular drug combination.'').

Exception 7[Y]

Finally, Respondent argues that the ALJ arbitrarily and capriciously concluded that Dr. Buffington suffered diminished credibility based on the ALJ's erroneous conclusion that Dr. Buffington ''conflated the reasonable, prudent pharmacist 'standard of care' applicable to medical malpractice negligence suits with a pharmacist's professional standards, *i.e.,* 'in the usual course of professional practice.' '' Resp Exceptions, at 17. Respondent cites to a 2001 case from the Florida District Court of Appeals to support its argument that Dr. Buffington's articulation of the standard care—which relied in part on a medical malpractice statute, Fla. Stat. § 766.102, that applies to ''health care providers,''—was in fact correct. However, as discussed in more detail above, the definition of ''health care providers'' specifically excludes pharmacists. *See supra* n.*I. Thus, I agree with the ALJ's conclusion that Dr. Buffington suffered diminished credibility based on his inaccurate reliance on an inapplicable statute, and based on a number of additional factors, such as his overt partiality and his inconsistent testimony. Overall, I agree with the ALJ's assessment of Dr. Buffington's credibility.

Accordingly, I reject Respondent's Exceptions and affirm the RD's conclusion that Respondent's registration should be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I hereby revoke DEA Certificate of Registration No. FG6290061 issued to Gulf Med Pharmacy. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I further hereby deny any pending applications for renewal or modification of this registration, as well as any other pending application of Gulf Med Pharmacy for registration in Florida. Pursuant to the authority vested in me by 21 U.S.C. 824(f), as well as 28 CFR 0.100(b), I further order that any controlled substances seized pursuant to the Order of Immediate Suspension of Registration are forfeited to the United States. This Order is effective January 21, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2021–27718 Filed 12–21–21; 8:45 am]

BILLING CODE 4410–09–P

*[X] One of the three subpoenas was served in conjunction with an administrative inspection warrant, during which DEA obtained certain materials, such as patient profiles, directly from Respondent's computer system. Respondent faults DEA for failing to obtain complete patient profiles from the computer. Resp Exceptions, at 12. However, as the Government points out in its response to Respondent's Exceptions, only three of the named patients in the OSC were included in the initial warrant and subpoena. *See* Gov't Response, at 5. The remaining seven patients were listed in the subsequent two subpoenas, meaning that all of the documents that DEA obtained for those patients were produced by Respondent.

*[Y] I addressed Respondent's fifth Exception above. *See supra* n.*L.

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Part III

Department of Energy

10 CFR Part 430
Energy Conservation Program: Test Procedure for Dishwashers; Proposed Rule

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2016–BT–TP–0012]

RIN 1904–AD96

Energy Conservation Program: Test Procedure for Dishwashers

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of proposed rulemaking and request for comment.

SUMMARY: The U.S. Department of Energy (''DOE'') proposes to amend the current test procedures appendix for dishwashers, adopt a new test procedureappendix, incorporate by reference newly published Association of Home Appliance Manufacturers (''AHAM'') standards—AHAM DW–1–2020 and DW–2–2020—and apply certain provisions of the industry standards to to the test procedures appendices. The proposed amendments to the current procedure would establish requirements for water hardness, relative humidity, and loading pattern; update requirements for ambient temperature, detergent dosage, and standby power measurement; include testing approaches from recently published waivers for dishwashers; and include provisions for a minimum cleaning index threshold to validate the selected test cycle. The proposed new test procedure appendix would additionally include updated annual number of cycles and low-power mode hours for the calculation of energy consumption. DOE is seeking comments from interested parties on the proposal.

DATES:

Meeting: DOE will hold a webinar on Thursday, February 3, 2022, from 12:30 p.m. to 4:30 p.m. See Section V, ''Public Participation,'' for webinar registration information, participant instructions, and information about the capabilities available to webinar participants. If no participants register for the webinar, it will be cancelled.

Comments: DOE will accept comments, data, and information regarding this proposal no later than February 22, 2022. See Section V, ''Public Participation,'' for details.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2016–BT–TP–0012, by any of the following methods:

1. Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.

2. Email: ResDishwasher2016TP0012@ee.doe.gov. Include docket number EERE–2016–BT–TP–0012 and/or RIN number 1904–AD96 in the subject line of the message.

No telefacsimilies (''faxes'') will be accepted. For detailed instructions on submitting comments and additional information on the rulemaking process, see Section V of this document.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including the Federal eRulemaking Portal, email, postal mail, or hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing COVID–19 pandemic. DOE is currently suspending receipt of public comments via postal mail and hand delivery/courier. If a commenter finds that this change poses an undue hardship, please contact Appliance Standards Program staff at (202) 586–1445 to discuss the need for alternative arrangements. Once the COVID–19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

Docket: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts (if a public meeting is held), comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at *www.regulations.gov/docket?D=EERE-2016--BT-TP-0012.* The docket web page contains instructions on how to access all documents, including public comments, in the docket. See Section V of this document for information on how to submit comments through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Mr. Bryan Berringer, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–0371. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Ms. Amelia Whiting, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–2588. Email: *Amelia.Whiting@hq.doe.gov.*

For further information on how to submit a comment, review other public comments and the docket, or participate in a public meeting (if one is held), contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE proposes to maintain a previously approved incorporation by reference and to incorporate by reference the following additional industry standards into part 430:

ANSI/AHAM DW–1–2020 (''AHAM DW–1–2020''), ''Uniform Test Method for Measuring the Energy Consumption of Dishwashers,'' approved October 2020.

AHAM DW–2–2020, ''Household Electric Dishwashers,'' approved 2020.

Copies of AHAM DW–1–2020 and AHAM DW–2–2020 can be obtained from AHAM at 1111 19th Street NW, Suite 402, Washington, DC 20036; or by going to AHAM's online store at *www.aham.org/AHAM/AuxStore.*

IEC 62301 (''IEC 62301 Ed. 2.0''), Household electrical appliances—Measurement of standby power, (Edition 2.0, 2011–01).

A copy of IEC 62301 Ed. 2.0 can be obtained from the International Electrotechnical Commission, available from the American National Standards Institute, 25 W 43rd Street, 4th Floor, New York, NY 10036, (212) 642–4900, or go to *webstore.ansi.org.*

For a further discussion of these standards, see Section IV.M of this document.

Table of Contents

I. Authority and Background

Dishwashers are included in the list of ''covered products'' for which DOE is authorized to establish and amend energy conservation standards and test procedures. (42 U.S.C. 6292(a)(6)) DOE's test procedures for dishwashers are currently prescribed at 10 CFR 430.23(c) and appendix C1 to subpart B of part 430 (''appendix C1''). The following sections discuss DOE's authority to establish test procedures for dishwashers and relevant background information regarding DOE's consideration of test procedures for this product.

A. Authority

The Energy Policy and Conservation Act, as amended (''EPCA''),[1] authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part B [2] of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency. These products include dishwashers, the subject of this document. (42 U.S.C. 6292(a)(6))

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA specifically include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

The Federal testing requirements consist of test procedures that manufacturers of covered products must use as the basis for: (1) Certifying to DOE that their products comply with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6295(s)), and (2) making representations about the efficiency of those consumer products (42 U.S.C. 6293(c)). Similarly, DOE must use these test procedures to determine whether the products comply with relevant standards promulgated under EPCA. (42 U.S.C. 6295(s))

Federal energy efficiency requirements for covered products established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions of EPCA. (42 U.S.C. 6297(d))

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section be reasonably designed to produce test results which measure energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use and not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

EPCA also requires that, at least once every 7 years, DOE evaluate test procedures for each type of covered product, including dishwashers, to determine whether amended test procedures would more accurately or fully comply with the requirements for the test procedures to not be unduly burdensome to conduct and be reasonably designed to produce test results that reflect energy efficiency, energy use, and estimated operating costs during a representative average use cycle or period of use. (42 U.S.C. 6293(b)(1)(A))

If the Secretary determines, on her own behalf or in response to a petition by any interested person, that a test procedure should be prescribed or amended, the Secretary shall promptly publish in the **Federal Register** proposed test procedures and afford interested persons an opportunity to present oral and written data, views, and arguments with respect to such procedures. The comment period on a proposed rule to amend a test procedure shall be at least 60 days and may not exceed 270 days. In prescribing or amending a test procedure, the Secretary shall take into account such information as the Secretary determines relevant to such procedure, including technological developments relating to energy use or energy efficiency of the type (or class) of covered products involved. (42 U.S.C. 6293(b)(2)) If DOE determines that test procedure revisions are not appropriate, DOE must publish its determination not to amend the test procedures. DOE is publishing this notice of proposed rulemaking (''NOPR'') in satisfaction of its requirements under EPCA. (42 U.S.C. 6293(b)(1)(A))

In addition, EPCA requires that DOE amend its test procedures for all covered products to integrate measures of standby mode and off mode energy consumption. (42 U.S.C. 6295(gg)(2)(A)) Standby mode and off mode energy consumption must be incorporated into the overall energy efficiency, energy consumption, or other energy descriptor for each covered product unless the current test procedures already account for and incorporate standby and off mode energy consumption or such integration is technically infeasible. If an integrated test procedure is technically infeasible, DOE must prescribe a separate standby mode and off mode energy use test procedure for

[1] All references to EPCA in this NOPR refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020).

[2] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

the covered product, if technically feasible. (42 U.S.C. 6295(gg)(2)(A)(ii)) Any such amendment must consider the most current versions of the International Electrotechnical Commission (''IEC'') Standard 62301 [3] and IEC Standard 62087 [4] as applicable. (42 U.S.C. 6295(gg)(2)(A))

B. Background

DOE most recently amended its dishwasher test procedures in a final rule published October 31, 2012 that established a new test procedure at appendix C1. 77 FR 65942 (''October 2012 final rule''). (For additional information on the history of test procedure rulemaking for dishwashers, please see the October 2012 final rule.) Appendix C1 follows the same general procedures as those included in the previously established appendix (*i.e.,* ''appendix C''), with updates to: (1) Revise the provisions for measuring energy consumption in standby mode or off mode; (2) add requirements for dishwashers with water softeners to account for regeneration cycles; (3) require an additional preconditioning cycle; (4) include clarifications regarding certain definitions, test conditions, and test setup; and (5) replace obsolete test load items and soils. 77 FR 65942, 65982–65987. Appendix C1 is currently required to demonstrate compliance with DOE's energy conservation standards for dishwashers at 10 CFR 430.32(f).

The current version of the DOE test procedure includes provisions for determining estimated annual energy use (''EAEU'') in kilowatt-hours per year (''kWh/year''), estimated annual operating cost (''EAOC'') in dollars per year, and water consumption in gallons per cycle (''gal/cycle''). (10 CFR 430.23(c)) On December 13, 2016, DOE published a final determination (''December 2016 Final Determination'') regarding the energy conservation standards for dishwashers in which DOE removed appendix C, which was applicable only to dishwashers manufactured before May 30, 2013. *See* 81 FR 90072, 90073.

On August 20, 2019, DOE published a request for information (''August 2019 RFI'') seeking comments on the existing test procedure for dishwashers. 84 FR 43071. In the August 2019 RFI, DOE requested comments, information, and data about a number of issues, including: Cycle selections, cycle options, test load items, soils, annual number of cycles, loading pattern, detergent, rinse aid, water hardness, standby testing, room ambient conditions, incorporating requirements from existing waivers for testing dishwashers, repeatability and reproducibility of the test procedure, and efficiency metrics. *Id.*

DOE received comments in response to the August 2019 RFI from the interested parties listed in Table I–1.[5]

TABLE I–1—AUGUST 2019 RFI WRITTEN COMMENTS

Commenter(s)	Reference in this NOPR	Commenter type
Appliance Standards Awareness Project, American Council for an Energy-Efficient Economy, Alliance to Save Energy, and Natural Resources Defense Council, Northwest Energy Efficiency Alliance, Consumer Federation of America, National Consumer Law Center on behalf of its low-income clients.	Joint Commenters	Efficiency Organizations.
Association of Home Appliance Manufacturers [6]	AHAM	Trade Association.
California Energy Commission (''CEC'')	CEC	State Agency.
GE Appliances, a Haier company (''GEA'')	GEA	Manufacturer.
Pacific Gas and Electric Company (''PG&E''), San Diego Gas and Electric, and Southern California Edison.	California Investor Owned Utilities (''CAIOUs'').	Utility Association.
Samsung Electronics America	Samsung	Manufacturer.
Whirlpool Corporation	Whirlpool	Manufacturer.
Anonymous	Anonymous	Individual.

On October 30, 2020, DOE published a final rule (''October 2020 Final Rule'') establishing a separate product class for standard size dishwashers with a cycle time for the ''normal'' cycle of less than one hour (*i.e.,* 60 minutes) from washing through drying. 85 FR 68723. The definition for the new product class of standard size dishwashers with a ''normal'' cycle time of 60 minutes or less defines ''normal'' cycle time by reference to Section 1.12 of appendix C1. 10 CFR 430.32(f)(1)(iii). On August 11, 2021, DOE published a NOPR (''August 2021 NOPR'') proposing to revoke the final rule that established the new product class for dishwashers. 86 FR 43970. The new product class definition, as well as the previously established definitions for standard size dishwasher and compact dishwasher, incorporate by reference American National Standards Institute (''ANSI'') ANSI/AHAM DW–1–2010 for specifying the place settings used to distinguish between ''standard'' and ''compact.'' 10 CFR 430.32(f)(1)(i)–(iii).

II. Synopsis of the Notice of Proposed Rulemaking

Currently, DOE incorporates by reference into 10 CFR part 430 the 2010 edition of AHAM DW–1, ''Household Electric Dishwashers'' (''ANSI/AHAM DW–1–2010'') and applies certain provisions of the standard to appendix C1. AHAM most recently updated AHAM DW–1 with the release of the 2020 edition and also renumbered the standard as AHAM DW–2 (''AHAM DW–2–2020''). AHAM also published the new standard AHAM DW–1–2020, ''Uniform Test Method for Measuring the Energy Consumption of Dishwashers'' (''AHAM DW–1–2020''), which is consistent with the existing DOE test procedure in appendix C1, including referencing AHAM DW–2–2020 for the provisions where appendix C1 currently references ANSI/AHAM DW–1–2010. Several provisions in AHAM DW–1–2020 provide updates and additions as compared to the existing requirements in appendix C1.

[3] IEC 62301, *Household electrical appliances—Measurement of standby power* (Edition 2.0, 2011–01).

[4] IEC 62087, *Methods of measurement for the power consumption of audio, video, and related equipment* (Edition 3.0, 2011–04).

[5] The parenthetical reference provides a reference for information located in the docket of DOE's rulemaking to develop test procedures for dishwashers (Docket NO. EERE–2016–BT–TP–0012, which is maintained at *www.regulations.gov*). The references are arranged as follows: (Commenter name, comment docket ID number, page of that document).

[6] DOE notes that AHAM submitted an additional comment following close of the comment period in which it encouraged DOE to adopt the updated AHAM test procedure for dishwashers. (AHAM, No. 11)

In this NOPR, DOE proposes to incorporate by reference into 10 CFR part 430 the new industry standard, AHAM DW–1–2020, and update the industry standard incorporated by reference in 10 CFR part 430 from ANSI/AHAM DW–1–2010 to AHAM DW–2–2020. Specifically, DOE proposes to:

(1) Incorporate by reference AHAM DW–1–2020 into 10 CFR part 430 and apply certain provisions of the industry standards to appendix C1, including the following:

a. Add the water hardness specification in Section 2.11 of AHAM DW–1–2020;

b. Add the relative humidity specification in Section 2.5.1 of AHAM DW–1–2020 and the associated tolerance for the measurement instrument in Section 3.7 of AHAM DW–1–2020;

c. Update the active mode ambient temperature as specified in Section 2.5.1 of AHAM DW–1–2020;

d. Update the loading pattern requirement by applying the direction specified in Section 2.6 of AHAM DW–1–2020;

e. Update the specifications for detergent usage consistent with Section 2.10 of AHAM DW–1–2020. This includes changing the type of detergent used, and the calculation of detergent dosage to be used for the pre-wash and main-wash cycles of dishwashers other than water re-use system dishwashers;

f. Add specific dishwasher door configuration requirements during standby mode testing, by incorporating the specifications in Section 4.2 of AHAM DW–1–2020 and update the annual combined low-power mode hours based on cycle duration; and,

g. Incorporate the requirements from AHAM DW–1–2020 for the test methods pertaining to two granted waivers for dishwashers with specific design features.

(2) Establish new appendix C2, which would generally require testing as in appendix C1, with the following additional update:

a. Updated number of annual cycles and low-power mode hours used for calculating the estimated annual energy use as specified in Section 5 of AHAM DW–1–2020.

For both appendix C1 and proposed new appendix C2, DOE additionally proposes to:

(1) Specify provisions for scoring the test load and calculating a per-cycle cleaning index metric as specified in AHAM DW–2–2020 and establish a minimum cleaning index threshold of 65 as a condition for a test cycle to be valid.

(2) Incorporate the test methods specified in a waiver for testing a basic model of dishwashers that does not hook up to a water supply line, but has a manually filled, built-in water tank. Additionally, incorporate the test methods specified in a waiver for basic models of dishwashers that are installed in-sink (as opposed to built-in to the cabinetry or placed on countertops).

DOE's proposed actions are summarized in Table II–1 compared to the current test procedure, as well as the reason for the proposed change.

TABLE II–1—SUMMARY OF CHANGES IN PROPOSED TEST PROCEDURE RELATIVE TO CURRENT TEST PROCEDURE

Current DOE test procedure	Proposed test procedure	Applicable test procedure	Attribution
References provisions of ANSI/AHAM DW–1–2010 for some aspects of the test procedure.	References provisions of AHAM DW–1–2020 newly incorporated into 10 CFR part 430, with limited modifications.	Appendix C1 and appendix C2.	Harmonize with industry standard and practice.
Does not specify a water hardness requirement	Adds water hardness requirement to be consistent with AHAM DW–1–2020, which is 0 to 85 parts per million of calcium carbonate.	Appendix C1 and appendix C2.	Harmonize with industry standard and practice.
Does not specify any range for relative humidity	Specifies the relative humidity (''RH'') requirement from AHAM DW–1–2020, which is 35 percent ±15 percent.	Appendix C1 and appendix C2.	Harmonize with industry standard and practice.
Does not specify any instrumentation for measuring relative humidity.	References the instrumentation requirements for measuring relative humidity from AHAM DW–1–2020.	Appendix C1 and appendix C2.	Harmonize with industry standard and practice.
Specifies that the ambient temperature must be maintained at 75° ±5° F.	References the ambient temperature requirement from AHAM DW–1–2020, including maintaining it at a target temperature of 75° F.	Appendix C1 and appendix C2.	Harmonize with industry standard and practice
Does not specify a loading pattern.	References the loading pattern from AHAM DW–1–2020, which specifies the same loading requirements as the ENERGY STAR Cleaning Performance Test Method.	Appendix C1 and appendix C2.	Harmonize with industry standard and practice.
References the detergent type and detergent dosing requirements from ANSI/AHAM DW–1–2010, which specifies Cascade with the Grease Fighting Power of Dawn as the detergent and dosing requirements based on water volumes in the prewash and main wash cycles.	References the detergent type and detergent dosing requirements from AHAM DW–1–2020, which specifies Cascade Complete Powder detergent and dosing requirements based on number of place settings.	Appendix C1 and appendix C2.	Harmonize with industry standard and practice.
Uses 215 annual cycles for calculating annual energy use.	Reduces the annual number of cycles to 184 for calculating annual energy use.	Appendix C2	Harmonize with industry standard and practice.
Does not specify whether the dishwasher door should be open or closed during standby mode testing.	References the requirement from AHAM DW–1–2020, which specifies that the door must be opened at the end of an active cycle and closed immediately prior to standby power measurement.	Appendix C1 and appendix C2.	Harmonize with industry standard and practice.
Uses 8,465 hours to calculate combined low-power mode energy consumption for dishwashers that do not have a fan-only mode.	References the requirement from AHAM DW–1–2020 to use the measured cycle duration to calculate combined low-power mode hours.	Appendix C2	Harmonize with industry standard and practice.
Does not include a method to test dishwashers operating on 208-volt power supply.	Includes a method to test dishwashers intended for a 208-volt power supply, which is also included in AHAM DW–1–2020.	Appendix C1 and appendix C2.	Response to waiver and harmonize with industry standard and practice.
Does not include a method to test dishwashers with a water re-use system that uses water recovered from prior use.	Specifies the test method for dishwashers with a water re-use system from AHAM DW–1–2020.	Appendix C1 and appendix C2.	Response to waiver and harmonize with industry standard and practice.
Specifies installation instructions and test provisions only for dishwashers that connect to a water supply line.	Specifies installation instructions and test provisions for dishwashers that do not connect to a water supply line but instead have a built-in water tank.	Appendix C1 and appendix C2.	Response to waiver.
Specifies installation instructions only for under-counter and under-sink dishwashers.	Specifies installation instructions for ''in-sink'' dishwashers.	Appendix C1 and appendix C2.	Response to waiver.

TABLE II–1—SUMMARY OF CHANGES IN PROPOSED TEST PROCEDURE RELATIVE TO CURRENT TEST PROCEDURE—Continued

Current DOE test procedure	Proposed test procedure	Applicable test procedure	Attribution
Requires placing detergent within a main wash detergent compartment.	Specifies detergent placement instructions for dishwashers that do not have a main wash detergent compartment.	Appendix C1 and appendix C2.	Response to waiver.
Does not specify measurement of the normal cycle time specifically for determining whether a standard size dishwasher has a normal cycle time of 60 minutes or less.	Specifies measurement of the duration of the ''normal'' cycle for the purpose of product class determination.	Appendix C1 and appendix C2.	Update in response to new product class.
Does not specify a minimum cleaning index threshold to valid a test cycle.	References AHAM DW–2–2020 to specify measurement of a per-cycle cleaning index, with a threshold value of 65 as a condition for a test cycle to be valid.	Appendix C1 and appendix C2.	Ensure the test procedure produces test results which measure energy and water use during a representative average use cycle.

DOE has tentatively determined that the proposed amendments to the test procedure described in Section III of this document for appendix C1 would not require DOE to amend the energy and water conservation standards for dishwashers.

The additional proposed amendments for the newly proposed appendix C2 would alter the reported energy and water consumption of dishwashers, as discussed in each relevant section of this NOPR. However, as proposed, testing in accordance with these specific proposed changes would not be required until such time as compliance is required with any amended energy conservation standards based on appendix C2.

Discussion of DOE's proposed actions are addressed in detail in Section III of this document.

III. Discussion

In the August 2019 RFI, DOE requested stakeholder feedback on several topics including test setup, dishwasher cycle-related specifications, potential inclusion of additional cycle features, representative test load with soiling levels, and whether further clarification is needed for the prescribed test procedure. 84 FR 43071.

While DOE received specific comments pertaining to each topic on which it requested comments, DOE also received some general comments in response to the August 2019 RFI. An anonymous commenter stated that the Federal government should refrain from rulemakings on products. (Anonymous, No. 3 at p. 1) AHAM stated that the current test procedure produces representative results, is not unduly burdensome, and is consistent with the DOE Appliance Standard Program's goals. However, AHAM commented that there is inherent variation for soil-sensing dishwashers that could not be eliminated during testing, and that the test procedure should provide additional clarity and minimize variation, but there will always be some inconsistent soil responses in the test. (AHAM, No. 5 at pp. 2, 8) AHAM further stated that adding cycles or options, or changing the load or soils, would add significant test burden and decrease repeatability and reproducibility in some cases. However, AHAM stated, minor clarifications to the test procedure could improve it and suggested a number of clarifications in its comments, which DOE addresses in the relevant sections of this NOPR. (AHAM, No. 5 at p. 2) GEA and Whirlpool expressed support of AHAM's comments. (GEA, No. 10 at p. 1; Whirlpool, No. 4 at p. 1)

In the following sections, DOE addresses the topics on which it requested feedback in the August 2019 RFI, summarizes stakeholder comments received, responds to these comments, and proposes updates to the test procedure based on comments and DOE's analyses.

A. Scope of Applicability

This rulemaking applies to dishwashers, which are cabinet-like appliances which with the aid of water and detergent, wash, rinse, and dry (when a drying process is included) dishware, glassware, eating utensils, and most cooking utensils by chemical, mechanical and/or electrical means and discharge to the plumbing drainage system. 10 CFR 430.2. DOE is not proposing to amend the scope of the current dishwasher test procedure.

B. Updates to Industry Standards

The current dishwasher test procedure at appendix C1 references the AHAM industry standard, ANSI/AHAM DW–1–2010, for certain provisions of the DOE test procedure. In the August 2019 RFI, DOE requested comments in reference to this industry standard. 84 FR 43071, 43078. At the time of the August 2019 RFI, AHAM DW–1–2019, ''Household Electric Dishwashers'' (''AHAM DW–1–2019'') was the most recent version of the industry standard.

In response to the August 2019 RFI, stakeholders commented on the potential incorporation by reference of AHAM DW–1–2019, the then-current version of the industry standard. This NOPR refers to ANSI/AHAM DW–1–2010 and AHAM DW–1–2019, when discussing the August 2019 RFI and stakeholder comments, respectively.

Since the publication of the August 2019 RFI, AHAM published AHAM DW–1–2020 and AHAM DW–2–2020.

AHAM DW–1–2020 provides an industry test procedure for determining the energy and water consumption of dishwashers, updating the relevant test procedure provisions that were previously in ANSI/AHAM DW–1–2010.[7] AHAM DW–1–2020 specifies definitions, testing conditions, instrumentation, test cycle and measurements, and calculations for energy and water consumption of dishwashers. AHAM DW–1–2020 also references the IEC Standard 62301, ''Household electrical appliances—Measurement of standby power'', Edition 2.0, 2011–01 (''IEC 62301 Ed. 2.0'') for measuring standby mode and off mode power consumption. AHAM DW–1–2020 was developed by AHAM based upon the current appendix C1 and references, as applicable, AHAM DW–2–2020 in each instance where appendix C1 currently references ANSI/AHAM DW–1–2010.[8] AHAM DW–1–2020 also includes updates that reflect AHAM's comments in response to the August 2019 RFI. Additionally, AHAM included requirements pertaining to the

[7] As noted previously, AHAM DW–1–2019 included the measurement of cleaning performance but not energy or water consumption.

[8] The current references to ANSI/AHAM DW–1–2010 specify place settings, serving pieces, soiling procedures, loading procedures, and detergent specifications—all of which are now specified in AHAM DW–2–2020.

two dishwasher test procedure waivers that were in effect as of July 2020. DOE participated in the AHAM DW–1–2020 development process and provided feedback and comments for the task group's consideration on various topics.

AHAM DW–2–2020 supersedes the AHAM DW–1–2019 industry standard.[9] AHAM included minor changes and illustrations to improve consistency throughout the document, to reflect the latest representative items used for testing, and to eliminate ambiguity in test preparation. DOE proposes to reference relevant sections of AHAM DW–2–2020, which includes setup, measurement, and calculation instructions for evaluating dishwasher cleaning performance, for its proposal to specify a per-cycle cleaning index threshold as a condition for a valid test cycle.

Because ANSI/AHAM DW–1–2010 and AHAM DW–1–2019 have been superseded, the updates proposed in this NOPR are consistent with AHAM DW–1–2020 and AHAM DW–2–2020, as appropriate. Where the requirements differ between succeeding documents, the implications of these differences are discussed in more detail in the respective sections of this NOPR.

DOE is proposing to incorporate by reference into 10 CFR part 430 the currently applicable industry test procedure for dishwashers, AHAM DW–1–2020. Simultaneously, DOE is also proposing to update the industry standard incorporated by reference in 10 CFR part 430 from ANSI/AHAM DW–1–2010 to AHAM DW–2–2020. In addition, DOE is proposing to reference in appendix C1 and newly proposed appendix C2 specific provisions of AHAM DW–1–2020 and AHAM DW–2–2020, with modifications, to clarify provisions where the applicable industry consensus standards would not produce test results that are representative of the energy and water use of certain products.

DOE requests comment on its proposal to incorporate by reference into 10 CFR part 430 the most recent version of the industry standard for dishwasher energy and water use measurement, AHAM DW–1–2020, as well as the industry performance standard, AHAM DW–2–2020, both with modifications. DOE seeks comment on its preliminary conclusion that the proposed modifications to the industry standards are necessary so that the DOE test method satisfies the requirements of EPCA.

C. Metrics

DOE's dishwasher test procedures in 10 CFR 430.23(c) and appendix C1 provide results for dishwasher energy consumption in kWh/year and water consumption in gal/cycle. In the August 2019 RFI, DOE requested feedback on an energy and water use metric on a per-place setting basis, including any data characterizing how the energy use of dishwashers on the market in the United States could be impacted by it. 84 FR 43071, 43078.

DOE received comments regarding potential per-place setting energy and water use metrics. AHAM opposed such metrics and recommended that DOE maintain the number of place settings and metrics currently in appendix C1. AHAM stated that per-place setting energy and water use metrics could be confusing, whereas the current method is a less complex way to compare products. Also, AHAM expressed concern that a per-place setting metric would be too reliant on a claimed value of the number of place settings. (AHAM, No. 5 at p. 9) GEA expressed its support of AHAM's comments, stating that a per-place setting measurement would encourage manufacturers to increase the listed number of place settings to allow a higher maximum annual energy use, and that a uniform metric ensures appropriate comparison of ratings among models. (GEA, No. 10 at p. 2) The Joint Commenters also opposed the incorporation of per-place setting metrics for energy and water usage and provided data that they stated demonstrates that there is no correlation between place-setting capacity and energy or water use. (Joint Commenters, No. 8 at pp. 2–3) The CAIOUs also did not support per-place setting energy and water metrics, commenting that they have found no correlation between capacity and energy or water use, and that such metrics would cause confusion in the market. (CAIOUs, No. 7 at p. 3)

In this NOPR, DOE does not propose changing the efficiency metrics to a per-place setting basis. At this time, DOE does not have data to support the adoption of such a metric. The data submitted by the Joint Commenters demonstrates a wide range of certified annual energy and per-cycle water use values among units available on the market listed in DOE's Compliance Certification Database.

DOE agrees with the Joint Commenters' assertion that currently available data demonstrates no consistent correlation between place-setting capacity and either energy or water use. Additionally, such a metric would also likely require development of an additional method to determine capacity based on place settings. At this time, DOE proposes to maintain the current efficiency metrics in appendix C1 and the new appendix C2.

D. Test Setup

1. Water Hardness

Appendix C1 does not currently specify any water hardness requirement for testing. In the August 2019 RFI, DOE requested information on how water hardness may impact consumer dishwasher energy and water performance, and on the burden associated with including a water hardness requirement in the DOE test procedure. 84 FR 43071, 43077. DOE also requested information on the hardness level of water used in current testing as compared to the water hardness level specified in ANSI/AHAM DW–1–2010, and the degree to which the water hardness level impacts whether the test procedure is reasonably designed to measure energy or water use during a representative use cycle or period of use. *Id.*

AHAM, GEA, Joint Commenters, CAIOUs, and CEC expressed concern over the potential variability caused by the lack of a water hardness condition and recommended that DOE implement a water hardness requirement between 0 and 85 parts per million (''ppm'') of calcium carbonate (''$CaCO_3$''), consistent with ANSI/AHAM DW–1–2010. (AHAM, No. 5 at p. 7; GEA, No. 10 at p. 2; Joint Commenters, No. 8 at p. 1; CAIOUs, No. 7 at p. 2; CEC, No. 6 at p. 2) AHAM further stated that the water hardness specifications in AHAM DW–1–2019, which are the same as the water hardness specifications in ANSI/AHAM DW–1–2010, are consistent with laboratory practice. Further, AHAM expects that laboratories already have this capability and that including the requirement in DOE's test procedure would not increase test burden and would add clarity to the test. (AHAM, No. 5 at p. 7).

These comments from interested parties suggest that varying levels of water hardness may impact measured energy and water usage during testing. To reduce potential variability across testing facilities and to support reproducibility of results, DOE proposes incorporating the water hardness requirements in Section 2.11 of AHAM DW–1–2020, which specifies a maximum water hardness of 85 ppm of $CaCO_3$. This water hardness specification is the same as the water

[9] AHAM updated its numbering scheme for dishwasher standards, wherein DW–2 measures cleaning performance, whereas DW–1 measures energy and water consumption.

hardness specification in ANSI/AHAM DW–1–2010, AHAM DW–1–2019, and AHAM DW–2–2020, indicating on-going industry practice. Additionally, in the October 2012 final rule, AHAM and Whirlpool commented that the American Water Works Association found a water hardness range of 0 to 85 ppm to be the normal range occurring in municipal water supplies, and Whirlpool stated that the water hardness specification was intended to reduce lab-to-lab test variation. 77 FR 65942, 65967. Although DOE did not adopt a water hardness specification in the October 2012 final rule due to a lack of data, it acknowledged that it had proposed to include such a water hardness requirement in the ENERGY STAR test method for evaluating dishwasher cleaning performance that was under development at that time, and that DOE might consider the topic again in a future rulemaking if such data became available. *Id.* DOE finalized the ENERGY STAR ''Test Method for Determining Residential Dishwasher Cleaning Performance'' (''ENERGY STAR Cleaning Performance Test Method'') in 2014, which includes such a water hardness specification and which manufacturers have the option to use to report cleaning performance data. As such, certain manufacturers may already be testing their dishwashers according to these water hardness specifications. DOE notes that nine dishwasher brands are included in ENERGY STAR's Most Efficient database,[10] and that manufacturers of these models must report cleaning performance as measured by the ENERGY STAR Cleaning Performance Test Method. Furthermore, AHAM stated that it expects laboratories already have the capability to control water hardness to within these specifications. As such, DOE does not expect this proposal to be unduly burdensome or impact the rated energy and water use of dishwashers.

Additionally, as described further in Section III.G of this document, DOE is proposing to specify a minimum cleaning index threshold as a condition for a valid test cycle, which may also be impacted by water hardness.

DOE requests comment on its proposal to require use of the water hardness requirements from Section 2.11 of AHAM DW–1–2020.

[10] ENERGY STAR Most Efficient database available at *www.energystar.gov/most-efficient/me-certified-dishwashers.* Last accessed October 23, 2020.

2. Relative Humidity

Currently, appendix C1 does not specify an ambient relative humidity for testing. In the August 2019 RFI, DOE requested comment on whether ambient relative humidity affects energy or water consumption, and whether test facilities already maintain an ambient relative humidity of 20 to 50 percent, as specified in ANSI/AHAM DW–1–2010. Additionally, DOE requested information on what, if any, test burden would result from a relative humidity specification and the extent of any such burden. 84 FR 43071, 43077.

AHAM supported amending appendix C1 to specify relative humidity test conditions, stating that relative humidity is a potential source of variation. AHAM recommended specifying relative humidity consistent with the requirements in AHAM DW–1–2019, which according to AHAM, would entail minimal test burden since testing facilities already have such capability. AHAM further commented that imposing a relative humidity requirement would add clarity to the test procedure and reduce variation among testing laboratories. (AHAM, No. 5 at p. 8) GEA also expressed support for establishing a relative humidity requirement consistent with AHAM DW–1–2019. (GEA, No. 10 at p. 2).

DOE proposes amending appendix C1 to include the relative humidity requirement of AHAM DW–1–2020, which specifies in Section 2.5.1 that an ambient relative humidity condition of 35 percent ±15 percent must be maintained in the testing room throughout the soiling application and 2-hour air dry period. DOE also proposes to include this same requirement in the new appendix C2. The proposed ambient relative humidity level is the same requirement specified in ANSI/AHAM DW–1–2010, which DOE referred to in its August 2019 RFI, and AHAM DW–1–2019, which stakeholders referenced in their comments.

DOE's testing experience suggests that ambient relative humidity could potentially impact the adherence of the applied soils to the test load during the 2-hour air-dry period specified in AHAM DW–2–2020 (which is the same as that specified in ANSI/AHAM DW–1–2010 and AHAM DW–1–2019). The adherence of the applied soil loads to the dishware could impact the amount of energy and water required to remove those soils for soil-sensing dishwashers, which constitute a significant percentage of dishwashers on the market. Further, adherence of the applied soil loads could impact cleaning performance, which in turn could impact the determination of the validity of each test cycle (see Section III.G of this document for more details). Establishing a relative humidity requirement would limit any such potential variation and increase repeatability and reproducibility of test results. As discussed, the proposed relative humidity requirement is the same as the requirement in AHAM dishwasher standards, indicating that this reflects current industry practice. Additionally, AHAM stated that it expects laboratories already have the capability to control relative humidity to within these specifications. As such, DOE does not expect this proposal to increase test burden as compared to current industry practice.

In conjunction with this proposed relative humidity test condition, DOE also proposes to include the relative humidity measuring device requirement specified in Section 3.7 of AHAM DW–1–2020, which states that relative humidity measurement equipment must have a resolution of at least 1 percent relative humidity, and an accuracy of at least ±6 percent relative humidity over the temperature range of 75 degrees Fahrenheit (''°F'') ±5 °F.

DOE has compared this proposed requirement to the relative humidity measuring device requirements currently specified in other DOE test procedures. The Uniform Test Method for Measuring the Energy Consumption of Clothes Dryers at 10 CFR part 430, subpart B, appendix D1 and appendix D2; appendix E (Water Heaters); appendix H (Television Sets); appendix M and appendix M1 (Central Air Conditioners and Heat Pumps); appendix O (Vented Home Heating Equipment); appendix U (Ceiling Fans); appendix X1 (Dehumidifiers); and appendix AA (Furnace Fans) all require the use of a measuring device with a specified error tolerance to measure relative humidity. These appendices specify tolerances for the relative humidity measuring device ranging from 0.7 percent to 5 percent relative humidity. Therefore, DOE's proposal specifying a maximum error of no greater than ±6 percent relative humidity to ensure accurate measurement of relative humidity while testing should not cause undue burden, since testing facilities that test other covered consumer products or equipment that require control of the ambient relative humidity already have the capability to meet the proposed requirement.

DOE requests comment on its proposal to reference AHAM DW–1–2020 for the relative humidity and

associated instrumentation requirements, which specifies a relative humidity test condition of 35 percent ±15 percent, and a resolution of at least 1 percent relative humidity and an accuracy of at least ±6 percent relative humidity over the temperature range of 75 °F ±5 °F for the relative humidity measuring device. To the extent that stakeholder have additional information, DOE requests data regarding the impact of relative humidity on dishwasher energy and water usage.

3. Ambient Temperature

Section 2.5.1 of appendix C1 currently specifies an ambient temperature of 75 °F ±5 °F for active mode testing. In the August 2019 RFI, DOE requested comment regarding the impacts of narrowing the allowable ambient temperature range on dishwasher energy and water consumption, and whether this change would represent a burden for test facilities. 84 FR 43071, 43077.

In response, AHAM requested that DOE maintain the same room ambient temperature range of 75 ±5 °F, but that the test procedure should specify that 75 °F is the nominal target temperature. AHAM stated that the DOE clothes washer test procedure at 10 CFR part 430, subpart B, appendix J2 uses the same approach of establishing both a tolerance range and a target temperature. (AHAM, No. 5 at p. 8) GEA and Whirlpool additionally recommended specifying a target temperature of 75 °F in accordance with AHAM's suggestion. (GEA, No. 10 at p. 2; Whirlpool, No. 4 at p. 3) Whirlpool further stated that the temperature range is potentially a large source of variation in the test, and suggested reducing the allowable temperature tolerance from a range of 10 °F, providing confidential data to support its position. (Whirlpool, No. 4 at p. 3)

DOE notes that Section 2.5.1 of AHAM DW–1–2020 specifies an ambient temperature of 75 °F ±5 °F and further specifies a target temperature of 75 °F. DOE is proposing to reference these ambient temperature requirements in AHAM DW–1–2020 in appendix C1 and the new appendix C2. This proposed amendment would improve repeatability and reproducibility of results while minimizing additional test burden. As the proposed amendment is consistent with the industry standard, it reflects current industry practice. Additionally, as commented by AHAM, this amendment is consistent with the approach used to specify ambient temperature in the clothes washer test procedure at appendix J2.

DOE requests input on its proposal to specify a target nominal ambient temperature of 75 °F for active mode testing, as referenced from AHAM DW–1–2020.

4. 208-Volt Power

On April 10, 2017, DOE published a Decision and Order granting Miele, Inc. (''Miele'') a test procedure waiver (''Miele waiver'') for testing a specified basic model intended for a 208-volt power supply rather than the 115 volts or 240 volts specified in appendix C1. 82 FR 17227 (Case No. DW–12).[11] Miele is required to test the basic model specified in the Miele waiver using appendix C1, except that it must maintain the electrical supply to the dishwasher at 208 volts ±2 percent and within 1 percent of its nameplate frequency as specified by the manufacturer; and maintain a continuous electrical supply to the unit throughout testing, including the preconditioning cycles, specified in Section 2.9 of appendix C1, and in between all test cycles. 82 FR 17227, 17228–17229.

In the August 2019 RFI, DOE requested feedback on whether the test procedure waiver provisions were generally appropriate for testing basic models with the same attributes as those subject to the Miele waiver. 84 FR 43071, 43078.

In response, both GEA and AHAM supported incorporating the provisions of the Miele waiver into appendix C1. (AHAM, No. 5 at p. 9; GE, No. 10 at p. 2) Subsequently, AHAM published the AHAM DW–1–2020 standard, which includes provisions in Section 2.2.2 for testing dishwashers that operate with an electrical supply of 208 volts.

As soon as practicable after the granting of any waiver, DOE is required to publish in the **Federal Register** a notice of proposed rulemaking to amend its regulations so as to eliminate any need for the continuation of such waiver. 10 CFR 430.27(l). As soon thereafter as practicable, DOE will publish in the **Federal Register** a final rule. *Id.* Since AHAM DW–1–2020 includes the language from the Miele waiver, DOE proposes to reference these requirements in appendix C1 and the new appendix C2 for dishwashers that operate at 208-volts.

DOE requests comment on its proposal to reference in appendix C1 and the new appendix C2 the testing provisions from AHAM DW–1–2020 to address the Miele waiver for dishwashers that operate at 208-volts.

5. Built-In Water Reservoir

DOE published a Decision and Order on December 9, 2020 (''December 2020 Decision and Order''), granting CNA International Inc. (''CNA'') a test procedure waiver (''CNA waiver'') for a basic model of a compact dishwasher that does not connect to a water supply line and instead has a built-in reservoir that must be manually filled with water. 85 FR 79171 (Case No. 2020–008).[12] This NOPR proposes amendments regarding the specific design characteristics addressed in the CNA waiver, generalized to be applicable to any future dishwasher models with this design characteristic, so as to eliminate any need for the continuation of this waiver.

On September 4, 2020, DOE published a notice that announced its receipt of the petition for waiver and granted CNA an interim waiver. 85 FR 55268 (''CNA Notice of Petition for Waiver''). In its petition for waiver and petition for interim waiver, CNA requested that DOE waive sections of the dishwasher test procedure requiring water inflow and water pressure criteria pertaining to a water hookup that allows automatic water inflow into the machine during the test cycle. 85 FR 55268, 55270 Instead, CNA suggested an alternate test procedure in which the water tank is manually filled before the test is run and water consumption is stipulated. (*Id.*) In the CNA Notice of Petition for Waiver, DOE granted CNA an interim waiver that specified an alternate test procedure that would be appropriate for testing the subject basic model and solicited comments from interested parties on all aspects of the petition and the specified alternate test procedure. *Id.* at 85 FR 55270–55271. DOE received two comments in response to the Notice of Petition for Waiver, and an additional comment response on behalf of CNA.

Based on review of these comments, DOE determined in the December 2020 Decision and Order that the alternate test procedure granted in the interim waiver, with additional clarifying modifications, will allow for the accurate measurement of the energy and water use of the product while alleviating the problems CNA identified regarding testing the specified basic model according to DOE's applicable dishwashers test procedure. 85 FR 79171, 79171. In particular, the alternate

[11] All materials regarding the Miele waiver are available in docket EERE–2016–BT–WAV–0039 at *www.regulations.gov.*

[12] All materials regarding the CNA waiver are available in docket EERE–2020–BT–WAV–0024 at *www.regulations.gov.*

test procedure specified in the December 2020 Decision and Order included the following provisions:

(1) The water pressure, water meter, and water pressure gauge specifications do not apply because the water is added manually to the reservoir;

(2) Instructions to manually fill the built-in water reservoir to the full 5-liter reservoir capacity stated by the manufacturer;

(3) The water temperature is in accordance with Section 2.3.3 of appendix C1 (*i.e.,* 50° ±2 °F)

(3) Instructions regarding the required sequence of events as specified in the manufacturer instructions: Power on the dishwasher, then manually fill the built-in water reservoir, then begin the test cycle within 2 minutes after powering on the dishwasher;

(4) For each preconditioning cycle, the built-in reservoir is manually filled before each cycle, and measurement of the prewash fill water volume (if any) and main wash fill water volume are not taken; instead, main wash fill water volume is specified as 0.396 gallons (1.5 liters);

(6) Water consumption measurements are not performed; instead, water consumption is specified as 4.8 liters.

85 FR 79171, 79174.

DOE proposes to incorporate each of these provisions into both appendix C1 and proposed new appendix C2, generalizing those provisions that were specific to the basic model subject to the CNA waiver to be applicable for a dishwasher of any capacity with a manually filled built-in water reservoir. Specifically:

(1) Refer to the full reservoir capacity as reported by the manufacturer (rather than specifying the full capacity as 5 liters);

(2) Require following any sequence of events specified in the manufacturer instructions (rather than specifying the particular sequence of events required for the basic model subject to the CNA waiver);

(3) Use the prewash fill water volume (if any) and main wash water fill volume as reported by the manufacturer (rather than specifying a main wash fill water volume of 1.5 liters);

(4) Water consumption for each test cycle is the value reported by the manufacturer (rather than specifying water consumption as 4.8 liters).

DOE requests comment on its proposal to incorporate the requirements of the CNA waiver for any dishwasher with a built-in reservoir. In particular, DOE requests stakeholder feedback on using the detergent dosage requirement based on number of place settings rather than main wash water volume in the new appendix C2, for dishwashers with built-in reservoirs.

6. In-Sink Installation

On October 15, 2020, FOTILE Kitchen Ware Co. Ltd. (''FOTILE'') filed a petition for waiver and interim waiver seeking a waiver from the installation requirements specified in appendix C1, which pertain to under-counter or under-sink dishwashers. 86 FR 26712, 26713.

In granting FOTILE an interim waiver on February 8, 2021, DOE noted that FOTILE's alternate test procedure specified a test enclosure that differed from the installation instructions provided in the operation manual. 86 FR 8548, 8549. Specifically, the alternate test procedure retained a requirement that the enclosure be brought into the closest contact with the appliance that the configuration of the dishwasher allows. In the case of FOTILE's basic models, this would include close contact between the bottom of the enclosure and the underside of the in-sink dishwasher. In the FOTILE interim waiver notice, DOE noted that because the height of the product is $2^{15}/_{16}$ inches (541 millimeters (mm)), placing the bottom part of the enclosure as close as possible to the bottom of the compact in-sink dishwasher would conflict with the installation instructions in the operation manual, which specify a minimum enclosure height of $35^{7}/_{16}$ inches (900 mm). *Id.* This may potentially result in differing heat losses from the dishwasher that could impact energy consumption during the cycle. *Id.* In the interim waiver notice, DOE further noted that specifying the enclosure would be consistent with the manufacturer installation instructions and would provide results that are more representative of average use and requested comment on this topic. 86 FR 8548, 8551. DOE did not receive any comments in response to the FOTILE interim waiver.

On May 17, 2021, DOE published a Decision and Order granting FOTILE the waiver (''FOTILE waiver''). 86 FR 26712, 26715–26716 (Case No. 2020–020).[13] Specifically, according to the published FOTILE waiver, FOTILE is required to test compact in-sink dishwashers using appendix C1 with modifications to install these dishwasher basic models from the top of a rectangular enclosure (as opposed to the front). 86 FR 26712, 26713. DOE also specified the use of the installation requirements that were proposed in the alternate test procedure in the FOTILE interim waiver, with modifications to the provisions pertaining to the enclosure in which the dishwasher is tested. 86 FR 26712, 26714–26715.

[13] All materials regarding the FOTILE waiver are available in docket EERE–2020–BT–WAV–0035 at *www.regulations.gov.*

On July 22, 2021, DOE published a notification of extension of waiver granting a waiver to additional in-sink FOTILE basic model dishwashers. 86 FR 38700 (Case No. 2021–005).

DOE proposes to incorporate into appendix C1 and the new appendix C2 the alternate test procedures in the FOTILE waiver, such that the installation requirements would be applicable for any in-sink dishwasher. Specifically, DOE proposes that the requirements pertaining to the rectangular enclosure for under-counter or under-sink dishwashers that are specified in Section 2.1 of AHAM DW–1–2020 would not be applicable to in-sink dishwashers. For such dishwashers, DOE proposes that the rectangular enclosure must consist of a front, a back, two sides, and a bottom. The front, back, and sides of the enclosure must be brought into the closest contact with the appliance that the dishwasher configuration allows. DOE additionally proposes that the height of the enclosure must be as specified in the manufacturer's instructions for installation height. If no instructions are provided, DOE proposes that the enclosure height must be 36 inches, since this is the typical height of kitchen cabinetry with counters attached, which is where such a dishwasher would be installed. DOE also proposes that the dishwasher must be installed from the top and mounted to the edges of the enclosure.

DOE requests comment on its proposal to incorporate into appendix C1 and the new appendix C2 the installation requirements for in-sink dishwashers from the FOTILE waiver.

7. Absence of Main Detergent Compartment

In addition to seeking a waiver for the installation requirements for in-sink dishwashers, the basic models for which FOTILE sought a waiver do not have a main detergent compartment. 86 FR 26712, 26713. Specifically, according to the published FOTILE waiver, FOTILE is required to test compact in-sink dishwashers placing the detergent directly into the washing chamber. 86 FR 26712, 26715.

In this NOPR, DOE proposes to incorporate the provisions for detergent placement specified in the FOTILE waiver into both appendix C1 and proposed new appendix C2, generalizing this provision such that it would be applicable to any dishwasher that does not have a detergent compartment.

DOE requests comment on its proposal that the detergent must be placed directly into the dishwasher

chamber for any dishwasher that does not have a prewash or main wash detergent compartment.

E. Test Cycle Amendments

1. Cycle Selections

In the August 2019 RFI, DOE requested feedback on certain aspects regarding dishwasher testing cycle selection. DOE requested information on consumers' selection frequency of normal cycles and other cycle types, in addition to the data gathered in the U.S. Energy Information Agency's (''EIA'') 2015 *Residential Energy Consumption Survey* (''RECS''). DOE also sought information on whether cycle selection varies based on a specific product's energy and water consumption; if additional cycle options are available with the normal cycle, including any temperature or drying options other than those recommended by the manufacturer, the means for consumers to select additional cycle options; and the frequency with which consumers select the options. 84 FR 43071, 43074.

AHAM commented that consumers still most frequently select the normal cycle, and when consumers decide on a cycle selection, they typically use it for most of their cycles. Therefore, AHAM opposed any changes to the currently tested normal cycle. (AHAM, No. 5 at p. 3) AHAM asserted that EPCA does not require every possible cycle, combination of options, or use pattern to be tested, as such testing would be unduly burdensome to conduct and not representative of an average use cycle or period of use. AHAM commented that all potential use conditions need not be tested for representative results. According to AHAM, to establish or amend representative average use cycles, DOE must demonstrate national, statistically average consumer behavior that would warrant changing the current test procedure, based on consumer usage data. AHAM concludes there is no basis for extrapolating regional consumer data. (AHAM, No. 5 at p. 2) AHAM opposed adding more cycle options to the test because it asserts that there are not sufficient data, and the test could be unduly burdensome to conduct. (AHAM, No. 5 at p. 3).

Conversely, CEC commented that although it does not have information indicating frequent selection of other cycle types in addition to the normal cycle, if DOE has information indicating frequent consumer selection of other cycle types, then DOE is obligated to include measurement of the energy consumption of those other cycle types in the test procedure. (CEC, No. 6 at pp. 1–2).

Both GEA and Whirlpool supported AHAM's comment that the normal cycle should remain the tested cycle. (GEA, No. 10 at p. 2; Whirlpool, No. 4 at p. 2) Both manufacturers submitted confidential data that supported the position that the manufacturer-designated normal cycle still represents consumer preference regarding cycle selection. (GEA, No. 10 at p. 3; Whirlpool, No. 4 at p. 2).

Samsung supported DOE's initiatives to study consumer data on which cycle is most representative of consumer use. (Samsung, No. 9 at p. 2).

The CAIOUs referenced PG&E's *2016 Home Energy Use Survey* to support their claim that the tested normal cycle including any power-dry feature, in the current test procedure, is still the cycle most representative of how consumers operate dishwashers. The CAIOUs further stated that consumers would be less likely to switch from using the normal cycle if DOE were to incorporate cleaning performance in the test procedure, and recommended DOE investigate incorporating a cleaning performance test. (CAIOUs, No. 7 at pp. 1–2).

Absent data that reflects national use and frequency of use of other cycle types, DOE is not proposing changes to cycle selections for testing at this time. However, as discussed in more detail in Section III.G of this document, DOE is proposing a minimum cleaning index threshold for a test cycle to be considered valid. Under the proposal, if the normal cycle does not meet a specified threshold at any soil-load, DOE proposes that the most energy-intensive cycle be tested and used for certification purposes at that soil load. DOE believes this alternative approach would better represent an average use cycle by capturing those consumers that may select other cycles for washing dishes if the cleaning performance of the normal cycle does not meet their expectations, because higher energy use provides increased thermal and mechanical action for removing soils, thus correlating generally with improved cleaning performance.

In response to the August 2019 RFI, Samsung also commented that DOE should specify that the manufacturer-recommended cycle for normal, regular, or typical use with the lowest energy efficiency should be selected as the test cycle if multiple cycle settings meet the definition of ''normal cycle.'' (Samsung, No. 9 at p. 2).

Regarding Samsung's suggestion, DOE notes that the current test procedure at appendix C1 already defines a ''normal cycle'' in Section 1.12 as the manufacturer-recommended cycle for daily, regular, or typical use. Section 1.12 additionally specifies that if more than one cycle meets the definition of a normal cycle, the most energy-intensive cycle (*i.e.,* the cycle with the lowest energy efficiency) is considered the normal cycle. Section 1.12 of appendix C1. Therefore, the current test procedure already addresses Samsung's suggestion.

Based on the information and comments received, DOE is not proposing any changes to the dishwasher test cycle selections, except with regard to validating the test cycle pursuant to the minimum cleaning index threshold that DOE proposes to include in appendix C1 and the new appendix C2. (See Section III.G of this document.) DOE is also not proposing to add any additional cycle options to the tested normal cycle.

2. Drying Energy Measurement

Section 5.3 of appendix C1 specifies a methodology for determining the ''drying energy'' consumption of a dishwasher. Dishwashers typically incorporate technologies to assist with drying the dishes after completion of the rinse portion of the cycle. Some dishwashers use an exposed resistance heater to heat the air inside the washing chamber after the final rinse to evaporate the water from the dishware. Other dishwasher models, however, do not use a resistance heater to heat the air, but instead achieve drying by raising the temperature of the final rinse water. The heated rinse water evaporates more quickly from the dishes after completion of the rinse portion of the cycle.

Section 1.14 of appendix C1 defines ''power-dry feature'' as the introduction of electrically-generated heat into the washing chamber for the purpose of improving the drying performance of the dishwasher. Further, the definition of ''normal cycle'' in Section 1.12 of appendix C1 specifically includes the power-dry feature as part of the normal cycle. Section 5.3 of appendix C1 specifies a methodology for calculating the energy consumed by the power-dry feature *after the termination of the last rinse option* (*emphasis added*). Half of this drying energy is subtracted from the total dishwasher energy calculations of EAOC and EAEU at 10 CFR 430.23(c)(1) and (2), respectively.[14]

Because the application of Section 5.3 is limited to drying energy consumed only after the termination of the last rinse option, it would not be applicable to the drying energy use of a dishwasher

[14] This reflects consumer use of the power-dry feature for 50 percent (*i.e.,* half) of dishwasher cycles.

that employs heated rinse technology, since such energy is consumed as part of the final rinse rather than after the final rinse. Rather, the energy use associated with the heated rinse would be captured as part of the normal cycle machine energy consumption. As a result, the energy use associated with heated rinse drying technology would be factored into EAOC and EAEU in its entirety, rather than only by half, as described for units with conventional power-dry technology that occurs after the final rinse.

DOE requested information and data on the extent to which manufacturers increase the temperature of the final rinse water to improve drying performance. 84 FR 43071, 43074. DOE further requested information on the extent to which manufacturers implement such a drying strategy as part of the normal cycle, and whether and to what extent such units provide an option to eliminate this drying function. *Id.* DOE also requested data and information on the energy use associated with increasing the temperature of the final rinse water as a means to improve drying performance, including any available options. *Id.*

AHAM opposed the addition of cycle options, including a power-dry option, to appendix C1. They claimed a lack of available data to suggest that consumers were selecting a power-dry feature at a frequency that would be considered representative of ''average'' consumer use. Therefore, requiring the selection of a power-dry option while testing would add unnecessary test burden. (AHAM, No. 5 at p. 3) GEA supported AHAM's comments opposing the addition of cycle options stating that there is no justification for adding cycle options the test procedure, including the power dry feature. (GEA, No. 10 at p. 2)

In response to the comments from AHAM and GEA regarding the testing of a power-dry option, DOE notes that appendix C1 already requires testing of a power-dry cycle option, if available. Appendix C1 requires testing of dishwashers on the normal cycle, which is defined as the ''cycle type, including washing and drying temperature options, recommended in the manufacturer's instructions for daily, regular, or typical use to completely wash a full load of normally soiled dishes *including the power-dry feature*'' (*emphasis added*). Section 1.12 of appendix C1. That is, the power-dry option is already selected during testing, if available.

At this time, DOE does not propose any changes to the measurement of drying energy to accommodate units that use heated rinse to achieve drying. The current measurement of drying energy consumption is dependent upon a clearly identifiable boundary between the conclusion of the final rinse and the activation of electrically-generated heat into the washing chamber. For units that use heated rinse to achieve drying, DOE initially determines that it would be burdensome to isolate the energy specifically attributable to raising the temperature of the final rinse, since such energy use would be embedded within the total energy use measured during that portion of the cycle; *i.e.,* it would not be possible to determine the ''drying energy'' without, for example, sub-metering the electrical energy use of the internal water heater. For these reasons, DOE is not proposing any changes to the existing requirements for measuring drying energy.

3. Annual Number of Cycles

Section 5.7 of appendix C1 calculates combined low-power mode energy consumption, which factors into the EAEU calculation, using 215 annual cycles. DOE established the 215-cycle value in the August 2003 final rule, relying on data from several sources on consumer dishwasher usage behavior, including the 1997 version of RECS, several consumer dishwasher manufacturers, detergent manufacturers, energy and consumer interest groups, independent researchers, and government agencies. 68 FR 51887, 51889–51890. In the August 2019 RFI, DOE referenced an energy conservation standards NOPR published December 12, 2014 (79 FR 76142, ''December 2014 NOPR'') and chapter 7 of its accompanying technical support document (''TSD''), which provided justification for using 215 cycles as the annual cycle estimate for EAEU calculations.[15] 84 FR 43071, 43075. In the December 2014 NOPR, DOE considered survey data from the 2009 version of RECS—which suggested 171 average annual cycles—but determined that because RECS 2009 used a binning approach [16] rather than providing point estimates of usage, and because of the large data set of consumers' residential dishwasher usage habits used to develop the 215-cycle value, it would retain use of that value. 79 FR 76142, 76156. DOE also noted that 215 cycles per year is the number of cycles on which the EnergyGuide label administered by the Federal Trade Commission (''FTC'') is based. *Id.*

In the August 2019 RFI, DOE requested any additional information on annual consumer use of dishwashers, including on the appropriateness of the analysis that incorporates the 2009 RECS data and whether it results in a representative annual usage estimate. 84 FR 43071, 43075. DOE also sought feedback on the suitability of data from the 2015 RECS, the survey for which directly asked for the typical number of dishwasher cycles per week rather than providing binned response options such as those included in the 2009 RECS. *Id.*

In response, AHAM and GEA recommended that DOE consider the latest (2015) RECS data in its analysis for the annual number of cycles used in the EAEU calculations. (AHAM, No. 5 at p. 4; GEA, No. 10 at p. 3) GEA stated that, based on the consumer data it collected, 50 percent of the time consumers run fewer than 148 cycles per year, and 66 percent of the time consumers run fewer than 188 cycles per year. (GEA, No. 10 at p. 3) AHAM stated that data collected from its members show a downward trend in the number of cycles per year, with a weighted average of 174 cycles per year. (AHAM, No. 5 at p. 4) Both GEA and AHAM recommended updating the annual number of cycles of dishwasher usage to 174 cycles per year, based on the 2015 RECS data and the data they presented, which was consistent with the trends of reduced dishwasher usage found in 2015 RECS data. (AHAM, No. 5 at p. 4; GEA, No. 10 at p. 3).

In this NOPR, DOE proposes to update the current annual cycles estimate to reflect more recent trends in dishwasher usage. DOE's analysis of 2015 RECS data indicates annual use of 185 cycles.[17] While AHAM and GEA recommended 174 cycles per year, they also urged DOE to consider the 2015 RECS data in determining the number of annual cycles. Additionally, subsequent to submitting its initial comments to DOE in response to the August 2019 RFI, AHAM released AHAM DW–1–2020, which specifies a value of 184 cycles per year in AHAM DW–1–2020 based on industry consensus. DOE thus proposes to amend the current annual number of cycles estimate from 215 to

[15] December 2016 Final Determination technical support document available at *www.regulations.gov/document?D=EERE-2014-BT-STD-0021-0029.*

[16] Specifically, RECS 2009 provides data on the number of residential dishwasher cycles in the following bins: (1) Less than once per week, (2) once per week, (3) 2–3 times per week, (4) 4–6 times per week, (5) at least once per day.

[17] In the 2015 RECS, EIA collected the number of times per week that households used their dishwasher as point values rather than ranges as EIA had done in previous surveys. For households using their dishwashers, multiplying weekly usage by number of weeks in the year results in annual usage rates. A weighted average of annual usage employs the household weight and produces a nationally weighted annual usage value.

184 cycles, through reference to AHAM DW–1–2020. The proposed value closely aligns with DOE's analysis of 2015 RECS data. DOE has initially determined that the 2015 RECS is a suitable source for updating the annual number of cycles estimate because (1) it is the most recent RECS edition available, (2) RECs is nationally representative for all U.S. households, and (3) it provides direct survey data on the typical number of dishwasher cycles run by consumers each week, rather than providing binned response options. Compared to the existing estimate of 215 annual cycles, the proposed estimate of 184 annual cycles is consistent with comments from AHAM and GEA as to the downward trend in dishwasher usage.

The proposal to update the annual cycle value for calculating EAEU, if finalized, would change the certified and reported EAEU values. DOE also notes that the existing energy conservation standards are based on the EAEU as determined under the current test procedure. As such, if this proposal were adopted, use of the 184 cycles-per-year value would be in conjunction with any future amended energy conservation standards for dishwashers that accounts for the updated annual cycle value. Accordingly, DOE proposes to specify this requirement in the new appendix C2. Manufacturers would be required to use the results of testing under the new appendix C2 to determine compliance with any future amended energy conservation standards.

DOE requests input on its proposal to update the estimated number of annual cycles from 215 to 184 cycles per year for future calculations of EAEU. DOE also requests comment on its approach to propose a new appendix C2 with the updated annual number of cycles, the use of which would be required for compliance with any amended energy conservation standards.

F. Energy and Water Consumption Test Methods

1. Test Load Items

The current test load and test load items are specified in Sections 2.6 and 2.7 of appendix C1. Non-soil-sensing dishwashers are tested with six serving pieces plus eight place settings, or six serving pieces plus the number of place settings equal to the capacity of the dishwasher if the latter is less than eight place settings. Soil-sensing compact and soil-sensing standard dishwashers are tested with four place settings and eight place settings, respectively, along with six serving pieces each.

In the August 2019 RFI, DOE requested information on the following topics regarding the current test load requirements: The typical number of place settings washed by consumers in each cycle; how the typical number of place settings relate to a dishwasher's overall capacity; whether the number of place settings affects energy and water consumption; whether introducing plastic items could have an impact on energy or water use; and typical composition of place setting items, serving pieces, and flatware that are washed in consumer dishwashers, including the types of items (*e.g.,* cups, bowls, and plates) and their characteristics (*e.g.,* size and material). 84 FR 43071, 43074–43075.

AHAM recommended the continuation of using eight place settings as the test load for testing standard dishwashers, stating that the eight place settings are representative of the thermal mass consumers place in the dishwasher. AHAM further stated that if DOE were to change the number of place settings, the standard would likely need to be adjusted as well. (AHAM, No. 5 at p. 4) GEA supported AHAM's comment and stated that there had not been any nationally relevant, statistically significant data justifying a change to the test load items, and therefore, GEA opposed changing the test load items. (GEA, No. 10 at p. 2) Whirlpool commented that its confidential data supported AHAM's position that eight place settings was representative. Furthermore, Whirlpool stated that changing the test load would unnecessarily add burden and/or increase variation in test results. (Whirlpool, No. 4 at pp. 1–2).

With regard to adding plastic test load items, AHAM commented that introducing these would not change water and energy use because these items do not add to the dishwasher's thermal mass. Furthermore, AHAM asserted that adding plastic into the energy test would likely increase variation and test burden with no added benefit. (AHAM, No. 5 at p. 4).

The comments summarized above generally support the continued use of eight place settings as representative of consumer use. DOE also notes that no data has been presented that would justify changing the test load items at this time. Although no data was presented regarding the use of plastic items, DOE recognizes that the minimal thermal mass of plastic test load items would likely result in little, if any, change to the energy and water consumption.

While not discussed in the August 2019 RFI or in comments submitted by stakeholders in response to the August 2019 RFI, DOE observes that some of the test load items specified in appendix C1 differ from the items specified in Section 3.4 of AHAM DW–2–2020, which is also referenced by Section 2.7.1 of AHAM DW–1–2020. The test load items as stated in appendix C1 and AHAM DW–2–2020 are shown in Table III–1 in this document below.

TABLE III–1—TEST LOAD ITEMS IN APPENDIX C1 AND AHAM DW–2–2020

Item	Appendix C1			AHAM DW–2–2020	
	Company/ designation	Description	Alternate	Company designation	Size
Dinner Plate	Corning Comcor®/Corelle® #6003893.	10 inch Dinner Plate.		Corelle® 5256294	10 inch (25.4cm).
Bread and Butter Plate.	Corning Comcor®/Corelle® #6003887.	6.75 inch Bread & Butter.	Arzberg #8500217100 or 2000–00001–0217–1.	Corelle® 5256286	6.7 inch (17.0cm).
Fruit Bowl	Corning Comcor®/Corelle® #6003899.	10 oz. Dessert Bowl.	Arzberg #3820513100	Corelle® 5256297	10 oz. (296mL).
Cup	Corning Comcor®/Corelle® #6014162.	8 oz. Ceramic Cup.	Arzberg #1382–00001–4732	Arzberg #1382–00001–4732	7 oz. (207mL).
Saucer	Corning Comcor®/Corelle® #6010972.	6 inch Saucer	Arzberg #1382–00001–4731	Arzberg #1382–00001–4731	5.5 inch (14.0cm).
Serving Bowl	Corning Comcor®/Corelle® #6003911.	1 qt. Serving Bowl.		Corelle® #5256304	1 qt. (950mL).
Platter	Corning Comcor®/Corelle® #6011655.	9.5 inch Oval Platter.		Corelle® #6011655 OR ALTERNATE Corelle® #5256290	Oval—9.5 inch by 7.5 inch (24.1cm by 19.1cm). Round—8.5 in (21.6cm).
Glass—Iced Tea	Libbey #551HT			Libbey #551HT	12.5 oz.

TABLE III–1—TEST LOAD ITEMS IN APPENDIX C1 AND AHAM DW–2–2020—Continued

Item	Appendix C1			AHAM DW–2–2020	
	Company/ designation	Description	Alternate	Company designation	Size
Flatware—Knife	Oneida® — Accent 2619KPVF.		WMF —Gastro 0800 12.0803.6047.	WMF 12.0803.6047.	
Flatware—Dinner Fork.	Oneida® — Accent 2619FRSF.		WMF — Signum 1900 12.1905.6040.	WMF 12.1905.6040.	
Flatware—Salad Fork.	Oneida® — Accent 2619FSLF.		WMF — Signum 1900 12.1964.6040.	WMF 12.1964.6040.	
Flatware—Teaspoon.	Oneida® — Accent 2619STSF.		WMF — Signum 1900 12.1910.6040.	WMF 12.1910.6040.	
Flatware—Serving Fork.	Oneida® — Flight 2865FCM		WMF — Signum 1900 12.1902.6040.	WMF 12.1902.6040.	
Flatware—Serving Spoon.	Oneida® — Accent 2619STBF.		WMF — Signum 1900 12.1904.6040.	WMF 12.1904.6040.	

For the cup, saucer, and flatware items, the alternate options listed in appendix C1 are the primary options specified in AHAM DW–2–2020. The iced tea glass is the only item that is the same for both test procedures. The remaining items feature Corelle® as the manufacturer for both appendix C1 and AHAM DW–2–2020, but these items have new model numbers in AHAM DW–2–2020. DOE understands that the Corelle® model numbers listed in appendix C1 are no longer in production, and the model numbers listed in AHAM DW–2–2020 are the newer editions for these out of production items. Additionally, AHAM DW–2–2020 contains an alternative selection only for the serving platter. For the other test load items, AHAM DW–2–2020 provides instructions to contact AHAM for assistance to identify suitable alternatives.

As illustrated in Table III–1, AHAM DW–2–2020, which is referenced in AHAM DW–1–2020, includes newer model numbers of the test load items as compared to appendix C1. Therefore, DOE proposes to reference AHAM DW–1–2020, which specifies that the test load must be as stated in Section 3.4 of AHAM DW–2–2020 in Section 2.7.1 of the standard. Specifically, DOE would apply the provisions of Section 3.4 of AHAM DW–2–2020 to appendices C1 and C2, excluding the Note accompanying Section 3.4 regarding AHAM assistance with determining alternatives.

However, DOE is also proposing to continue including the test load items currently specified in appendix C1 as alternate options, so that test laboratories can continue using the existing test load if they already have these items. This proposal would be applicable to both appendix C1 and the new appendix C2. Pursuant to EPCA requirements, this approach would not impose an undue burden, but rather minimize test burden as it would not require manufacturers and/or test laboratories to procure new items if they already have the existing test load items.

DOE requests comment on specifying that the test load items be as specified in AHAM DW–1–2020 (which references Section 3.4 of AHAM DW–2–2020), while additionally retaining, as an alternative, the current test load specifications in appendix C1 and the new appendix C2.

2. Soils

In the August 2019 RFI, DOE requested information on whether consumer soil loads have changed since DOE established the soil loads in the August 2003 final rule. 84 FR 43071, 43075. In particular, DOE requested any data regarding soiling conditions and the frequency of pre-rinsing by consumers. *Id.* DOE also sought information on whether the types of soil required in appendix C1 resulted in a test method that measured energy and water use during a representative use cycle or period of use. *Id.* In addition to the representative quantity of soil and types of soil present for consumer use, DOE also requested information on the typical mix of soils consumers load into their dishwashers, on the appropriateness of the current composition of soil loads in appendix C1, and on whether the appendix C1 soil loads should be updated to incorporate different types of soils, including any additional fats or greases. 84 FR 43071, 43075–43076.

Samsung commented that DOE's current soiling level reflects pre-rinsing performed by the consumer. Samsung added, however, that the report on which the soil levels in the current test procedure are based is 20 years old, and there has been consumer advocacy by dishwasher manufacturers, consumer advocates, and detergent manufacturers to educate consumers against pre-rinsing. Samsung suggested that DOE revise the test procedure to incorporate a larger soil load representing the soiling condition without pre-rinsing, and that the AHAM DW–1–2009 [18] soiling levels could be consistent with such soiling levels. (Samsung, No. 9 at pp. 2–3).

AHAM stated that no data suggest that consumers no longer pre-rinse their dishes. AHAM further stated that there is no need to change the soil types because the purpose of the soil composition is to activate the turbidity sensors only (for soil-sensing dishwashers), rather than to replicate the wide array of potential soils consumers might load into their dishwashers. According to AHAM, the current soil composition already achieves that goal of activating the turbidity sensors while being representative of average consumer use both in terms of composition and quantity. AHAM opposed changing the distribution of soil loads and the soil composition for these reasons. (AHAM, No. 5 at pp. 5–6) GEA supported AHAM's comments, stating that there is no data available to justify a change to the test load soiling. (GEA, No. 10 at p. 2)

Samsung also recommended that DOE consider a field use factor for dishwashers with soil sensors. Samsung stated that dishwashers with soil sensors can adapt to a variety of soiling and loading conditions of consumer dishwasher usage, and thereby optimize energy and water use. Samsung suggested DOE consider developing a field use factor to credit soil-sensing dishwashers for such optimizations. Samsung stated that the clothes dryers test procedure at 10 CFR part 430, subpart B, appendix D1 uses a field use factor to recognize the energy benefits of dryers with automatic termination controls and requested DOE consider a

[18] The AHAM DW–1–2009 standard is the same standard as ANSI/AHAM DW–1–2010 before it received the ANSI accreditation.

similar factor for soil-sensing dishwashers. (Samsung No. 9 at p. 3)

The soil load specified in appendix C1 has been developed by DOE to produce a measure of energy and water use of soil-sensing dishwashers in a representative usage cycle. At this time, DOE does not have data on the operation of a soil-sensing function that would suggest that a field use factor to adjust testing results would be appropriate. Therefore, DOE is not proposing in this NOPR a field use factor for appendix C1 or the new appendix C2.

DOE did not receive any data regarding pre-rinsing by consumers. Although Samsung stated that there has been consumer advocacy to reduce pre-rinsing in recent years, no data have been presented to indicate whether or to what degree consumers have changed pre-rinsing habits. Absent such data, DOE is not proposing any changes to the soil loads.

DOE continues to request feedback and data regarding soiling level and whether there have been changes to consumers' pre-rinsing behavior. DOE also seeks information regarding the impact of different soil levels on energy and water use in dishwashers currently on the market.

Section 2.7.4 of appendix C1 states that the soils shall be as specified in Section 5.4 of ANSI/AHAM DW–1–2010, except for the following substitutions:

- *Margarine.* The margarine shall be Fleischmann's Original stick margarine.
- *Coffee.* The coffee shall be Folgers Classic Decaf.

Additionally, Section 2.7.5 of appendix C1 states that soils shall be prepared according to Section 5.5 of ANSI/AHAM DW–1–2010, with the following additional specifications:

- *Milk.* The nonfat dry milk shall be reconstituted before mixing with the oatmeal and potatoes. It shall be reconstituted with water by mixing 2x–3 cup of nonfat dry milk with 2 cups of water until well mixed. The reconstituted milk may be stored for use over the course of 1 day.
- *Instant mashed potatoes.* The potato mixture shall be applied within 30 minutes of preparation.
- *Ground beef.* The 1-pound packages of ground beef shall be stored frozen for no more than 6 months.

DOE notes that Table 3 in Section 5.4 of AHAM DW–2–2020 specifies Fleischmann's™ Original Stick margarine and Folgers™ Classic Decaf coffee, consistent with DOE's substitutions in Section 2.7.4 of appendix C1. These AHAM DW–2–2020 soiling specifications are also referenced in Section 2.7.4 of AHAM DW–1–2020. Therefore, DOE proposes to remove the substitution for margarine and coffee from regulatory text in appendix C1 and apply the soiling requirements in Section 2.7.4 of AHAM DW–1–2020 instead.

Additionally, Section 2.7.5 of AHAM DW–1–2020 includes the additional soil preparation requirements for milk, instant mashed potatoes, and ground beef, which are currently specified in appendix C1. Therefore, DOE proposes to remove the additional soil preparation specifications from Section 2.7.5 in appendix C1 and apply the requirements in Section 2.7.5 of AHAM DW–1–2020 instead.

DOE requests comment on its proposal to remove the soil substitution and soil preparation requirements from Sections 2.7.4 and 2.7.5 of appendix C1 and apply these same requirements from AHAM DW–1–2020 instead. DOE particularly requests data and information on how the proposed soil composition would affect energy and water use in current dishwashers.

3. Loading Pattern

Section 2.6 of appendix C1 references Section 5.8 of ANSI/AHAM DW–1–2010 for loading the dishwasher prior to running active mode tests, which requires loading in accordance with the manufacturer's recommendation. In the August 2019 RFI, DOE requested feedback on whether any additional instructions are needed beyond referencing a manufacturer's loading recommendation. 84 FR 43071, 43076. DOE also requested information on how consumers typically load dishwashers. *Id.* DOE stated that although manufacturer instructions may optimize loading patterns to maximize loading capacity and dishwasher performance, consumers may use other loading positions and alignment, leading to variability in dishwasher performance. *Id.*

AHAM stated that the lack of loading specificity in appendix C1 is a source of test procedure uncertainty. AHAM stated that the positioning of soiled items relative to unsoiled items may impact the rate at which soils are removed from the test load items, which may impact soil sensor responses. AHAM recommended that the test procedure establish the same loading instructions as Section 5.1(D) of the ENERGY STAR Cleaning Performance Test Method. AHAM added that the purpose of a specific loading pattern is to reduce variation in testing results, not necessarily to emulate consumer use. AHAM commented that consumer loading patterns are likely difficult to replicate in the test procedure. (AHAM, No. 5 at p. 6)

GEA also supported changing the loading pattern to conform with Section 5.1(D) of the ENERGY STAR Cleaning Performance Test Method. (GEA, No. 10 at p. 2) The Joint Commenters stated that they support additional specificity to the test procedure regarding the loading pattern to improve reproducibility of test results among test laboratories. (Joint Commenters, No. 8 at p. 1).

As stated in the August 2019 RFI, DOE recognizes that the positioning of soiled test load items in relation to unsoiled ones could impact the rate at which soils are removed from the test load items, and therefore also impact soil sensor responses. 84 FR 43071, 43076. This could lead to variation in energy and water consumption. Specifying a loading pattern requirement would improve the repeatability of the testing procedure and reproducibility of results across both individual tests and testing facilities. Since submitting its comments, AHAM has included the loading pattern requirements specified in the ENERGY STAR Cleaning Performance Test Method in Section 2.6.3.4 of AHAM DW–1–2020. These requirements are applicable to soil-sensing dishwashers that are tested with both, clean and soiled place settings. DOE proposes to apply these AHAM DW–1–2020 loading requirements to appendix C1 and the new appendix C2 to reduce potential variation in the test procedure. Additionally, these loading requirements would apply to both soil-sensing and non-soil-sensing dishwashers as non-soil-sensing dishwashers would be required to use soil loads for testing under DOE's cleaning index threshold proposal discussed in Section III.G of this document.

DOE requests input on its proposal to use the loading requirements specified in Section 2.6.3.4 of AHAM DW–1–2020.

4. Preconditioning Cycles

Section 2.9 of appendix C1 requires manufacturers to precondition the dishwasher by running the normal cycle twice with no load after the testing conditions are established. The prewash fill water volume, if any, and the main wash fill water volume are measured during the second preconditioning cycle to calculate the detergent amounts to be used during the energy and water consumption tests. The prescribed procedure ensures an accurate calculation of detergent dosing, priming of the water lines and sump area of the

pump, successful sensor calibration, and machine cleaning without adding significant test burdens. In the August 2019 RFI, DOE requested comment on whether two preconditioning cycles were adequate or more than is necessary to calibrate the soil sensors. DOE also requested comment on whether using the water volumes from the second preconditioning cycle continued to be appropriate for determining the detergent amounts if the sensors were still being calibrated during the second preconditioning cycle. 84 FR 43071, 43076.

AHAM commented that although sometimes unnecessary, two preconditioning cycles ensure that the dishwasher under test is properly calibrated, and manufacturers prefer to keep the existing two cycles for certainty in test results as well. (AHAM, No. 5 at p. 6) GEA supported AHAM's comment by reaffirming that two preconditioning cycles increased reliability and reproducibility in test results. (GEA, No. 10 at p. 2).

No commenter suggested the use of fewer or additional preconditioning cycles. Based on the above discussion, DOE is not proposing to modify the requirement for two preconditioning cycles currently in appendix C1, and is proposing to apply this requirement to the new appendix C2.

5. Detergent

Section 2.10 of appendix C1 specifies using Cascade with the Grease Fighting Power of Dawn powder as the detergent formulation. This section also provides the method to calculate the detergent quantities to be added to the pre-wash (if available) and main-wash compartments, which is based on the pre-wash (if available) and main wash water volumes, respectively. In the August 2019 RFI, DOE requested information on whether the current powder detergent specified in appendix C1 results in a test procedure reasonably designed to measure energy and water use during a representative use cycle or period of use and requested comment on the use of a reference detergent. 84 FR 43071, 43076. DOE also requested comment on the method for calculating detergent dosing, including: Whether to continue calculating the detergent dosing based on the measured water fill volumes in the second preconditioning cycle, or whether to specify a fixed amount of detergent; methods to differentiate between the different portions of a wash cycle and ways to appropriately calculate the corresponding detergent dosing; and reliance on manufacturer dosage recommendations. *Id.*

AHAM suggested that detergent dosing be evaluated, but advised DOE to maintain the existing powder detergent formulation, stating that this formulation was still representative of powder formulations on the market. AHAM also supported maintaining the current detergent dosage provisions. AHAM further stated that detergent impacts performance testing more than it impacts energy testing; thus, it did not need to be changed for energy testing. AHAM also commented that it would discuss updates to detergent usage as part of its AHAM DW–1 process, but that more work is needed to understand the appropriate detergent and amounts to use, and how often formulations change. (AHAM, No. 5 at p. 7) GEA supported AHAM's comment and stated that there is insufficient data on the impact of detergents to the current test procedure or to other test procedures that may be run at the same time [19] to make any change to detergents at this time. (GEA, No. 10 at pp. 1, 2) Whirlpool also agreed with AHAM and commented that the current powder detergent referenced in appendix C1 is representative of powder detergents on the market. Whirlpool further commented that, although single dose detergents are the most commonly used detergent type, given the recent rising popularity of single dose detergents, their formulations are not stable because detergent manufacturers make frequent changes and improvements. Whirlpool also suggested that further evaluation was needed to assess the impact of single dose detergents on energy use. (Whirlpool, No. 4 at p. 3) Since publication of the August 2019 RFI and the subsequent end of the comment period, AHAM informed DOE, during the task group's meetings to establish AHAM DW–1–2020, that the powder detergent currently specified in appendix C1—Cascade with the Grease Fighting Power of Dawn—is no longer commercially available. Instead, a new powder detergent, Cascade Complete Powder, which has a slightly different formulation [20] from Cascade with the Grease Fighting Power of Dawn, is now available on the market. AHAM has updated AHAM DW–2–2020 to reference this new detergent for testing purposes. AHAM DW–1–2020 references AHAM DW–2–2020, both for detergent formulation as well as dosage.

In addition to a change in the detergent to be used for testing, both AHAM DW–1–2020 and AHAM DW–2–2020 also specify new dosage requirements in comparison to the current requirements of appendix C1.[21] Section 4.1 of AHAM DW–2–2020 specifies the detergent dosage as 1.8 grams per place setting in the main compartment of the detergent dispenser and 1.8 grams per place setting in the prewash compartment of the detergent dispenser or other location. Section 2.10.1 of AHAM DW–1–2020 further specifies to use half the quantity of detergent that is specified in Section 4.1 of AHAM DW–2–2020 for both prewash and main-wash detergent for the energy and water consumption tests. Prewash detergent is specified only for those units if it is recommended by the manufacturer's instructions for conditions that are consistent with the test procedure. This includes, but is not limited to, manufacturer instructions that recommend the use of prewash detergent for the normal cycle, normally soiled loads, or for water hardness between 0 and 85 ppm. Additionally, if manufacturer instructions lead to the use of the prewash detergent requirements, the prewash detergent is placed as instructed by the manufacturer or, if no instructions are provided, the prewash detergent is placed on the inner door near the detergent cup.

DOE performed preliminary investigative testing on four standard dishwashers to compare the energy and water consumption results when using (1) the current detergent (Cascade with the Grease Fighting Power of Dawn) with the current dosage method; (2) the new detergent (Cascade Complete Powder) with the current dosage method; and (3) the new detergent with the new dosage method. Table III–2 presents the detergent quantities for each of the three investigative tests for the four units. Table III–3 presents the measured water consumption and estimated annual energy use for these four units when tested according to the three scenarios.

[19] GEA did not specify which other test procedures it was referring to that may be run at the same time as the DOE test procedure.

[20] Stakeholders mentioned during the AHAM task group calls that they were informed by the detergent manufacturer that the only difference between Cascade with the Grease Fighting Power of Dawn and Cascade Complete Powder is related to the enzymes used in the detergent. DOE was not able to verify this information independently because the ingredient list for Cascade with the Grease Fighting Power of Dawn is not available on product packaging (or online).

[21] As discussed, the detergent dosage for appendix C1 is based on measurements of the prewash fill water volume, if any, and the main wash fill water volume measured during the second preconditioning cycle.

TABLE III–2—DETERGENT DOSAGE (IN GRAMS) FOR EACH INVESTIGATIVE TEST

Test unit	Appendix C1		New detergent with current dosage		New detergent with new dosage	
	Prewash detergent (g)	Main wash detergent (g)	Prewash detergent (g)	Main wash detergent (g)	Prewash detergent (g)	Main wash detergent (g)
1	0	10.5	0	10.5	7.2	7.2
2	0	12.5	0	13	0	7.2
3	0	105	0	11	0	7.2
4	11	11	11	11	7.2	7.2

TABLE III–3—MEASURED WATER CONSUMPTION AND ESTIMATED ANNUAL ENERGY USE FOR EACH INVESTIGATIVE TEST

Test unit	Appendix C1		New detergent with current dosage		New detergent with new dosage	
	Water (gal/cycle)	EAEU (kWh/year)	Water (gal/cycle)	EAEU (kWh/year)	Water (gal/cycle)	EAEU (kWh/year)
1	2.3	211	2.4	204	2.5	204
2	3.1	257	3.3	256	3.3	261
3	3.2	269	3.2	265	3.1	274
4	3.4	273	5.9	357	3.9	301

Table III–3 indicates that for test units 1, 2, and 3, the water consumption among the three tests varied within a range of 0.1–0.2 gal/cycle. For unit 4, the ''Appendix C1'' test and the ''New Detergent with New Dosage'' test yielded equivalent water consumption values; however, the water consumption of the ''New Detergent with Current Dosage'' test was 2.5 gal/cycle higher, an increase of 73 percent over the other two tests. Similar percentage differences were observed for EAEU among the three tests. Given the small sample size of only 4 test units, DOE believes that additional testing would be required to determine whether the observed variation in results is due to the change in detergent and dosage, or whether it could be attributed to unrelated differences in the sensor response of these soil-sensing dishwashers, or other factors.

Given the uncertainty about whether the new detergent and dosing requirements would impact the energy and water consumption of dishwashers, DOE proposes that both the current detergent and dosage requirement as well as the new detergent and new dosage requirement would be allowable to use for testing according to appendix C1. By maintaining the use of the current detergent and dosing requirements, manufacturers would not be required to re-test currently certified dishwashers. Because DOE is proposing the detergent type and dosage specifications in AHAM DW–1–2020 in addition to the current requirements, this proposal would not require the re-rating or re-certification of dishwashers currently on the market. Additionally, permitting the optional use of the detergent and dosing specifications in AHAM DW–1–2020 would avoid the need for manufacturers to request test procedure waivers should the currently required detergent become unavailable and would harmonize with current industry practice.

For the new appendix C2, which would be required at the time compliance is required with updated energy and water conservation standards, DOE proposes to specify only the new detergent and dosage requirements from AHAM DW–1–2020.

The current dosage requirements specify detergent dosage based on water volume, which requires distinguishing the water used in the pre-wash from the water used in the main wash. DOE has observed, and stakeholders have also expressed, that uncertainty in differentiating the pre-wash and main wash cycles to estimate detergent dosage could be a potential source of test variation. As stated, the new detergent dosage is based on the number of place settings rather than measurement of pre-wash and main wash water volumes, potentially providing more consistent dosing. More consistent dosing would improve the repeatability and reproducibility of the results. Additionally, the new dosage would reduce test burden since it would eliminate the need to identify, isolate, and calculate the pre-wash and main wash water volumes.

DOE requests comment on its proposal to adopt in appendix C1 the new detergent and new dosage requirements as specified in AHAM DW–1–2020, while also retaining the current detergent and dosage requirements in appendix C1. The use of either set of detergent requirements would be allowable for testing under appendix C1. DOE also requests comment on the detergent currently being used by manufacturers and test laboratories for testing and certification of dishwashers.

If stakeholder comments indicate that the currently specified detergent, Cascade with the Grease Fighting Power of Dawn, is no longer being used by manufacturers, DOE may instead consider including only the new detergent, Cascade Complete Powder, and dosage requirements from AHAM DW–1–2020 in appendix C1, rather than allowing both the current and new detergent and dosage requirements.

DOE also welcomes comments and data on the impact of the new detergent and dosage on energy and water use.

6. Rinse Aid

Section 2.1 of appendix C1 currently requires that testing be conducted without the use of rinse aid, and that any rinse aid reservoirs remain empty for testing.

In the August 2019 RFI, DOE noted that a standard from IEC, IEC 60436: ''Electric Dishwashers for Household Use—Methods for Measuring the Performance'' (''IEC 60436'') specifies the use of rinse aid during testing. 84 FR 43071, 43077. IEC 60436 requires the use of a standard rinse aid formulation rather than a commercially marketed brand. DOE sought information from stakeholders on consumer use of rinse

aid, and on whether the use of rinse aid had any effect on measured energy and water consumption. *Id.*

AHAM commented that rinse aid does not impact energy and water use. AHAM further commented that IEC 60436 specifies use of rinse aid because there is a performance element to that test. As such, AHAM did not support a proposal to add a rinse aid requirement or a need to collect consumer data on rinse aid usage. (AHAM, No. 5 at p. 7)

Based on these comments, and the lack of data regarding the effect of rinse aid on measured energy and water usage and consumer usage of it, DOE maintains its conclusions from past rulemakings that the test procedure should preclude the use of rinse aid, and that the rinse aid container should remain empty during testing. 68 FR 51887, 51891. Adding a rinse aid requirement would increase test burden without information indicating that it would improve the representativeness of the test results, and it could potentially cause variation in test results. For these reasons, DOE is not proposing a rinse aid requirement in appendix C1 or the new appendix C2, which is consistent with the specifications in AHAM DW–1–2020 that DOE proposes to reference in this NOPR.

7. Water Softener Regeneration Cycles

In the October 2012 final rule, DOE adopted a method for measuring the energy consumed during regeneration cycles for water softeners built into certain residential dishwashers. 77 FR 65942, 65960. The adopted approach relies on manufacturer-reported values for the energy and water use for each regeneration cycle and the number of annual regeneration cycles. *Id.* The current calculations for water softener regeneration cycles are provided in Sections 5.1.3, 5.4.3, 5.5.1.2, 5.5.2.2, 5.6.1.2, and 5.6.2.2 of appendix C1. In the August 2019 RFI, DOE requested comment on whether any dishwasher had a water softener regeneration cycle at every or nearly every cycle, and if any additional instructions should be specified in appendix C1 to avoid repeatedly accounting for the water and energy use during water softener regeneration. 84 FR 43071, 43077.

DOE did not receive any comment regarding the energy and water use during water softener regeneration cycles, and thus does not propose any changes in this NOPR with regards to water softener regeneration cycles, aside from maintaining the associated definitions and calculations specified in AHAM DW–1–2020.

8. Water Re-Use System

On November 1, 2013, DOE published a Decision and Order (''November 2013 Decision and Order'') granting Whirlpool a test procedure waiver (''Whirlpool waiver'') for testing specified basic models equipped with a ''water use system,'' in which water from the final rinse cycle is stored for use in the subsequent cycle, with periodic draining (''drain out'') and cleaning (''clean out'') events. 78 FR 65629 (Case No. DW–11).[22] Whirlpool is required to test the basic model specified in the November 2013 Decision and Order using appendix C1, with the following modifications:

(1) ''Water use system'' water and energy consumption shall be accounted for during dishwasher water and energy measurement and reporting, subject to the following:

(2) For ''drain out'' events, constant values of 0.072 gallons per cycle and 2.6 kWh/year shall be added to values measured by appendix C1.

(3) For ''clean out'' events, constant values of 0.071 gallons per cycle and 10.3 kWh/year shall also be added to values measured by appendix C1.

(4) To calculate the detergent quantity for testing, a constant value of 0.91 gallons for the water fill amount shall be used, representing both saved water fill and house supply water fill.

(5) If a ''drain out'' or ''clean out'' event occurs during testing, any results from that use of the test procedure shall be disregarded. Disconnect and reconnect power to the dishwasher, then restart the test procedure.

(6) To detect a ''drain out'' event, measure the water volume supplied during the first fill. A cycle shall be considered to have a ''drain out'' event if the first fill uses approximately 1 gallon from the water supply. Without a ''drain out'' event, the first fill would use approximately 0.11 gallons from the water supply.

(7) To detect a ''clean out'' event, monitor the temperature of the sump water using an additional temperature measuring device. The device shall be placed inside the sump in an area such that the device will always be submerged in water and will not interfere with the operation of the dishwasher. A cycle shall be considered to have a ''clean out'' event if the temperature of the sump water during wash and rinse portions of the cycle reaches 150 °F. Without a ''clean out'' event, the highest sump water temperatures would reach approximately 140 °F.

78 FR 65629, 65631.

In the August 2019 RFI, DOE requested feedback on whether the test procedure waiver provisions were generally appropriate for testing basic models with the same attributes as those subject to the November 2013 Decision and Order. 84 FR 43071, 43078.

In response, both GEA and AHAM supported incorporating the provisions of the Whirlpool waiver into appendix C1. (AHAM, No. 5 at p. 9; GE, No. 10 at p. 2) Subsequently, AHAM published the AHAM DW–1–2020 standard, which includes provisions for testing water re-use system dishwashers. Specifically, Sections 1.3, 1.9, and 1.29 of AHAM DW–1–2020 include definitions for a clean out event, drain out event, and water re-use system dishwasher, respectively. These definitions are consistent with those specified in the November 2013 Decision and Order granted in November 2013. AHAM DW–1–2020 also specifies the detergent dosing requirements, methods to measure the energy and water consumption of water re-use system dishwashers, including detection of drain out and clean out events, and calculations for energy and water consumption. Sections 2.10.2, 4.1.3, 5.1.4, 5.15, 5.4.4, 5.4.5, 5.5.1.3, 5.5.1.4, 5.5.2.3, 5.5.2.4, 5.6.1.3, 5.6.1.4, 5.6.2.3, and 5.6.2.4 of AHAM DW–1–2020. All of these requirements are consistent with the alternate test procedure specified in the November 2013 Decision and Order granting the waiver to Whirlpool for water re-use systems, except for the specified water energy consumption equations in Sections 5.6.1.3, 5.6.1.4, 5.6.2.3, and 5.6.2.4, which use an incorrect constant.[23]

As soon as practicable after the granting of any waiver, DOE is required to publish in the **Federal Register** a notice of proposed rulemaking to amend its regulations so as to eliminate any need for the continuation of such waiver. 10 CFR 430.27(l). As soon thereafter as practicable, DOE will publish in the **Federal Register** a final rule. *Id.* Since AHAM DW–1–2020 includes the language from the Whirlpool waiver, DOE proposes to reference these requirements in appendix C1 and the new appendix C2, with added modifications to the equations in Sections 5.6.1.3, 5.6.1.4, 5.6.2.3, and 5.6.2.4 of AHAM DW–1–2020.

DOE requests comment on its proposal to reference in appendix C1 and the new appendix C2 the testing provisions from AHAM DW–1–2020 to address the Whirlpool waiver for water re-use system dishwashers.

G. Cleaning Performance

EPCA requires DOE to establish test procedures that are reasonably designed

[22] All materials regarding the Whirlpool waiver are available in docket EERE–2013–BT–WAV–0042 at *www.regulations.gov.*

[23] The equations in the noted sections improperly use the constant K = specified heat of water in kWh per gal per °F, instead of C/e, where C = specific heat of water in Btu's per gal per °F, and e = nominal gas or oil water heater recovery efficiency.

to produce test results that measure energy efficiency, energy use, water use (for certain products), or estimated annual operating cost of a covered product during a representative average use cycle or period of use, as determined by the Secretary, and shall not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3)) DOE's test procedure for dishwashers identifies the ''normal cycle'' as the cycle representative of consumer use, defines the term ''normal cycle,'' requires testing using the ''normal cycle,'' and compliance with the applicable standards is determined based on the measured energy and water use of the ''normal cycle.'' 10 CFR 430.23(c) and 10 CFR 430 subpart B appendix C1. The ''normal cycle'' is defined as the cycle type, including washing and drying temperature options, recommended in the manufacturer's instructions for daily, regular, or typical use to completely wash a full load of normally soiled dishes including the power-dry feature. If no cycle or more than one cycle is recommended in the manufacturer's instructions for daily, regular, or typical use to completely wash a full load of normally soiled dishes, the most energy-intensive of these cycles shall be considered the normal cycle. In the absence of a manufacturer recommendation on washing and drying temperature options, the highest energy consumption options must be selected. Section 1.12 of appendix C1. As such, the existing test procedure does not define what constitutes ''completely wash[ing]'' a full load of normally soiled dishes (*i.e.,* the cleaning performance).

For dishwashers, the cleaning performance at the completion of a cycle influences how a consumer uses the product. If the cleanliness of the dishware after completion of a cleaning cycle does not meet consumer expectations, consumers may alter their use of the dishwasher. For example, consumers may alter the use of the product by selecting a cycle that consumes more energy and water to provide a higher level of cleaning, operating the selected cycle multiple times, or pre-washing the dishware before loading into the dishwasher to achieve an acceptable level of cleaning. DOE received comment from Samsung expressing concern in response to the August 2019 RFI, in which Samsung stated that consumers unsatisfied with the cleaning performance of the normal cycle may opt to select a different mode that could result in increased energy consumption. (Samsung, No. 9 at p. 3) Thus, it is possible that dishwashers exist on the market that are currently tested by manufacturers using a ''normal cycle'' that does not ''completely wash'' dishes.

In general, a consumer-acceptable level of cleaning performance (*i.e.,* a representative average use cycle) can be easier to achieve through the use of higher amounts of energy and water use during the dishwasher cycle.[24] Conversely, maintaining acceptable cleaning performance can be more difficult as energy and water levels are reduced.[25] Improving one aspect of dishwasher performance, such as reducing energy and/or water use as a result of energy conservation standards, may require a trade-off with one or more other aspects of performance, such as cleaning performance. DOE expects, however, that consumers maintain the same expectations of cleaning performance regardless of the efficiency of the dishwasher. As the dishwasher market continuously evolves to higher levels of efficiency—either as a result of mandatory minimum standards or in response to voluntary programs such as ENERGY STAR—it becomes increasingly more important that DOE ensures that its test procedure continues to reflect representative use. As such, the normal cycle that is used to test the dishwasher for energy and water performance must be one that provides a consumer-acceptable level of cleaning performance, even as efficiency increases.

In order for DOE's test procedure to more accurately and fully test dishwashers during a representative average use cycle, DOE believes that amending the test procedure to define what constitutes completely washing a full load of normally soiled dishes (*i.e.,* the cleaning performance) will better represent consumer use of the product. As such, DOE proposes additional direction for selecting the appropriate test cycle, *i.e.,* for determining whether the cycle ''can completely wash a full load of normally soiled dishes.'' DOE is proposing to include a cleaning index methodology and minimum threshold to validate the selection of the test cycle in appendix C1 and the newly proposed appendix C2.[26] This proposal is discussed in detail in the following sections.

This proposal is in line with comments DOE received in response to the August 2019 RFI regarding the adoption of cleaning performance into the test procedure. Samsung commented that the tested cycle (*i.e.,* the normal cycle) should perform at or above a minimum level of acceptable functionality because some consumers may select test cycles other than the default mode that perform better without recognizing the resulting increase in the energy consumption of the dishwasher. (Samsung, No. 9 at p. 3) The CAIOUs commented that, while the test procedure is representative of current energy and water consumption, they believe there is merit in investigating a dishwasher cleaning performance test method to ensure future consumer benefit. (CAIOUs, No. 7 at p. 2)

1. Cleaning Performance Test Method

DOE is proposing to adopt a cleaning performance test method that will help determine if a dishwasher when tested according to the DOE test procedure ''completely washes a normally soiled load of dishes,'' according to the representative consumer use. Specifically, DOE proposes to include the cleaning performance evaluation setup, procedures, and calculations that are specified in the ENERGY STAR Cleaning Performance Test Method, which references ANSI/AHAM DW–1–2010, in appendix C1 and newly proposed appendix C2.

In response to the August 2019 RFI, Samsung recommended that DOE incorporate by reference the ENERGY STAR Cleaning Performance Test Method in the dishwasher test procedure and adopt the minimum cleaning index, as established for the ENERGY STAR Most-Efficient Program. (Samsung, No. 9 at p. 3)

The ENERGY STAR Cleaning Performance Test Method specifies a procedure to determine cleaning performance at the same test loads described in the DOE test method. For soil-sensing dishwashers, cleaning

[24] Higher energy use may provide increased thermal and mechanical action for removing soils. Similarly, higher water use may provide better rinsing performance by reducing the amount of soil re-deposition on the dishware.

[25] In the December 2014 NOPR that proposed amended energy and water use standards for dishwashers, DOE noted that cleaning performance could be maintained up to Efficiency Level 3, which was defined as 234 kWh/yr and 3.1 gal/cycle. 79 FR 76141, 76165. In the December 2016 Final Determination, DOE additionally noted that manufacturers generally indicated that by using all available design options to improve efficiency, they would likely be able to maintain performance with a maximum energy consumption between 250 and 260 kWh/year and water consumption at 3.1 gal/cycle. 81 FR 90072, 90082.

[26] This approach is analogous to the one used for clothes dryers, in which the DOE test procedure at appendix D2 defines a threshold dryness level for automatic cycle termination clothes dryers as a condition for the test cycle to be valid. Specifically, Section 3.3.2 of appendix D2 specifies that if the final moisture content after completion of the drying cycle is greater than 2 percent, the test shall be invalid and a new run shall be conducted using the highest dryness level setting.

performance is evaluated on the same cycles that are used to determine energy and water consumption (*i.e.,* the heavy, medium, and light soil loads). (ENERGY STAR Cleaning Performance Test Method Section 5.1.B) For non-soil-sensing dishwashers, cleaning performance is evaluated on three additional cycles at the heavy, medium, and light soil loads that are run immediately after the clean-load cycle that is used to determine energy and water consumption. (ENERGY STAR Cleaning Performance Test Method Section 5.1.C) Each test load item is quantitatively evaluated for cleanliness under prescribed lighting conditions referenced from ANSI/AHAM DW–1–2010. (ENERGY STAR Cleaning Performance Test Method Section 4.B) Additionally, Section 5.2 of the ENERGY STAR Test Method specifies the criteria to grade the load; it references Section 5.10 of ANSI/AHAM DW–1–2010, which specifies the following requirements: Each test load item receives a score based on the number and size of soil particles that remain on the item following the termination of a test cycle. Glassware items are additionally evaluated for the number and size of remaining spots, streaks, and rack contact marks. A score of 0 indicates a completely clean test load item, and a single test load item cannot exceed a cumulative score of 9. The number of test items that receive each score is counted (*i.e.,* number of items in the test load that receive a score of 0, 1, 2, . . ., 9) and the weighted average of these counts is subtracted from 100 to produce a final cleaning index for the test cycle. A score of 100 indicates perfect cleaning performance.

Accordingly, DOE proposes to include the requirements specified in Sections 4(B), 5.2, and 5.3, of the ENERGY STAR Cleaning Performance Test Method, as follows:

Section 4(B) of the ENERGY STAR Cleaning Performance Test Method establishes the lighting requirements for the evaluation room for scoring the test load, as specified in ANSI/AHAM DW–1–2010. These same lighting requirements are also specified in Section 5.10 of AHAM DW–2–2020; therefore, DOE proposes to reference Section 5.10 of AHAM DW–2–2020 to specify the lighting requirements for the evaluation room.

Section 5.2 of the ENERGY STAR Cleaning Performance Test Method establishes the scoring procedure to evaluate each dishware item in the test load after completion of the test cycle, as specified in ANSI/AHAM DW–1–2010. The scoring method is also specified in Section 5.10.1 of AHAM DW–2–2020; therefore, DOE proposes to reference the scoring requirements specified in AHAM DW–2–2020.

Section 5.3 of the ENERGY STAR Cleaning Performance Test Method specifies the equation for calculating a cleaning index for each test cycle, which is also specified in Section 5.12.3.2 of AHAM DW–2–2020; therefore, DOE proposes to reference the calculation of cleaning index for each test cycle from AHAM DW–2–2020.

DOE notes that the calculation to determine per-cycle cleaning index is based on the individual score of each item such that dishware and flatware are scored based on soil particles, while glassware are scored based on soil particles as well as spots, streaks, and rack contact marks. DOE further notes that AHAM DW–2–2020 provides two separate equations for calculating the total cleaning index for one test run. The equation in Section 5.12.3.1 of AHAM DW–2–2020 specifies a soil-only cleaning index, which is calculated using the scores of each test load item (including glassware) based only on soil particles. Section 5.12.3.2 of AHAM DW–2–2020 uses the same equation as that in the ENERGY STAR Cleaning Performance Test Method (and ANSI/AHAM DW–1–2010), and defines the total cleaning index calculation using the scores of dishware and flatware cleaning performance based on soil particles and glassware based on soil particles as well as spots, streaks, and rack contact marks. DOE is proposing to reference Section 5.12.3.2 of AHAM DW–2–2020 to calculate the total cleaning index of a cycle because DOE expects that consumers would evaluate the cleanliness of their load items at the completion of a cycle . DOE requests feedback on whether it should consider referencing Section 5.12.3.1 of AHAM DW–2–2020 instead, which would calculate the cleaning index based on soil particles only. If DOE were to calculate the cleaning index using soil particles only, it would reevaluate the per-cycle cleaning index threshold value (discussed further in Section III.G.2 of this document) to reflect this change. DOE requests stakeholder feedback on an appropriate threshold to consider.

DOE requests feedback on the proposed methodology to test, score, and calculate a cleaning index to validate the tested cycle and seeks comment if other methodologies should be considered for validating the cleaning performance of the tested cycle.

DOE requests feedback on whether it should consider referencing Section 5.12.3.1 of AHAM DW–2–2020 to measure cleaning performance, which would calculate the cleaning index based on soil particles only. DOE notes that if it were to calculate cleaning index using soil particles only, it would reevaluate the per-cycle cleaning index threshold value to reflect this change.

2. Cleaning Index Threshold

In response to the August 2019 RFI, Samsung commented that DOE should use the ENERGY STAR Most-Efficient cleaning index threshold when establishing the standard for dishwashers in the future standards rulemaking. (Samsung, No. 9 at p. 3)

In this NOPR, DOE proposes to provide direction in the test procedure as to what constitutes whether a cycle under test can completely wash a full load of normally soiled dishes, by establishing a minimum cleaning index threshold as a condition for each individual test cycle to be valid. The threshold is intended to represent a level of cleaning such that if the dishwasher did not meet this threshold after operating in the ''normal cycle,'' the consumer would be expected to operate the dishwasher using a more energy-intensive cycle than the ''normal cycle.'' Specifically, DOE proposes that if the normal cycle at a particular soil level (*i.e.,* heavy, medium, or light) does not achieve the defined cleaning index threshold, that soil level (*i.e.,* heavy, medium, or light) would need to be re-tested using the most energy-intensive cycle (to be determined using the proposed methodology discussed in Section III.G.4 of this document) that achieves the defined cleaning index threshold. The data from the most energy-intensive cycle would be used to represent that soil level in the downstream calculations.

To determine an appropriate threshold value, DOE aggregated confidential consumer cycle selection data provided by industry for this NOPR, and considered past consumer comments and test data collected in support of the October 2020 Final Rule.[27]

DOE understands general consumer satisfaction as a fundamental characteristic of a functioning market, and that consumers are largely satisfied with the performance of dishwashers currently on the market. However, based on Samsung's comments discussed in Section III.G of this document as well as qualitative comments that DOE received during the rulemaking that culminated in the October 2020 Final Rule, DOE

[27] See Dishwasher NODA Test Data (5–21–20), available at: *www.regulations.gov/document/EERE-2018-BT-STD-0005-3213.*

recognizes that the cleaning performance of the normal cycle may not always meet consumer expectations of cleaning performance. (See for example: Toronto, EERE–2018–BT–STD–0005, No. 2304 at p. 1; Carley, EERE–2018–BT–STD–0005, No. 2950 at p. 1; Bruggeman, EERE–2018–BT–STD–0005, No. 3038 at p. 1; *etc.*) Further, confidential data submitted by manufacturers indicate, in the aggregate, that roughly 25–45 percent of all dishwasher cycles are conducted on a cycle other than the normal cycle. DOE recognizes that among these other selected cycles, some would be expected to be less energy intensive than the normal cycle (*e.g.,* a glassware cycle), while others would be expected to be more energy intensive than the normal cycle (*e.g.,* a pots and pans cycle). The data provided by manufacturers do not indicate which types of cycles comprise the percentage of cycles not conducted on the normal cycle. In lieu of additional details regarding the dataset, DOE has proceeded under the assumption that either option (selecting a more energy-intensive or less energy-intensive alternate cycle) is equally as likely. Accordingly, DOE estimates that one-half (*i.e.,* 12 to 23 percent) of cycles not conducted on the normal cycle are instead conducted on a cycle that is more energy intensive than the normal cycle.

Since DOE expects that consumers unsatisfied with the cleaning performance of the normal cycle would select alternate cycles that are more energy-intensive to achieve better cleaning results, the cycle selection data serves as a reasonable proxy for consumer acceptance of the cleaning performance of the normal cycle. To identify an appropriate cleaning index threshold, DOE sought to select a cleaning index value that aligned with the cycle selection data. That is, DOE sought to identify the cleaning index value that was achieved between 77 to 88 percent of the time when a dishwasher was operated on the normal cycle, indicating that the remaining 12 to 23 percent of the time the cleaning performance on the normal cycle would be worse and thus would result in consumers selecting more energy-intensive cycles. DOE evaluated the cleaning indices measured for the heavy, medium, and light soil load cycles as defined in the DOE dishwasher test procedure, using the market-representative dishwasher test sample from the October 2020 Final Rule.[28] Using these data, DOE plotted the rate at which test cycles would achieve each potential cleaning index threshold level (in increments of 5 on the Cleaning Index scale). Figure III.1 shows the percentage of each of the soil test cycles that meet the threshold at each potential threshold level among all the units in the test sample. The proposed threshold level of 65 is indicated by the dashed line and is described further as follows.

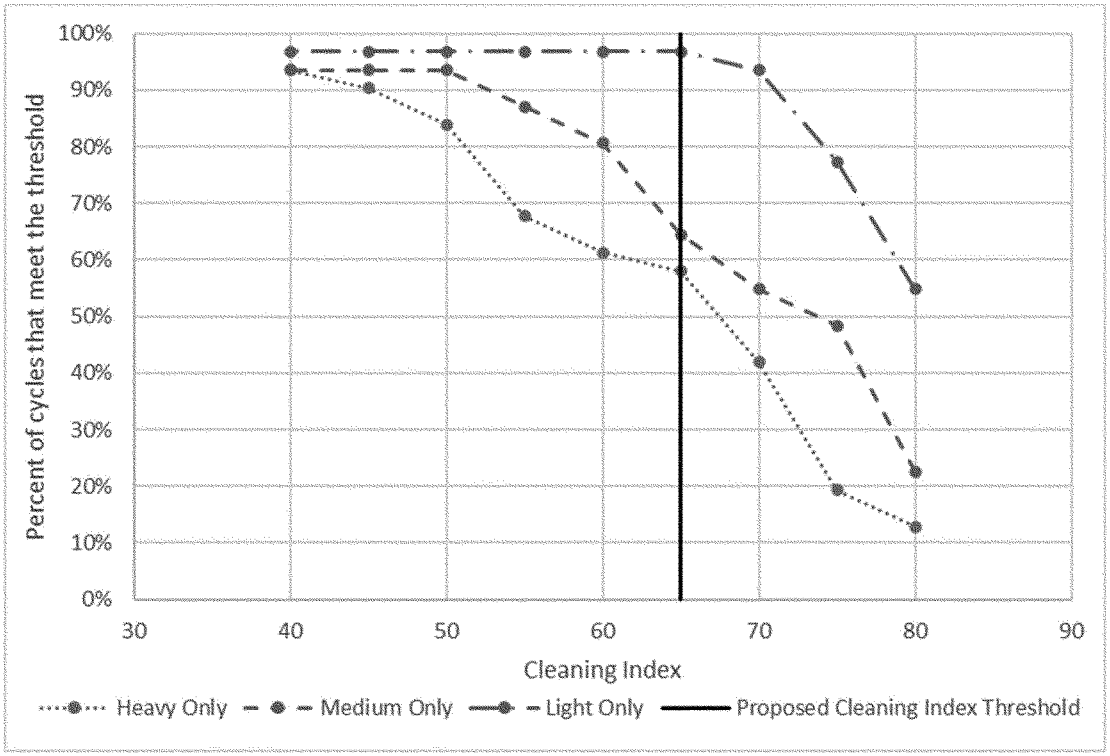

Figure III.1 Percent of Heavy, Medium, and Light Soil Test Cycles that Meet Potential Cleaning Index Thresholds

In determining a threshold, DOE seeks to establish a level that ensures the tested cycle produces test results, which measure energy use and water use of the dishwasher during a representative average use cycle. Establishing a threshold level that is ''too high'' would indicate that a substantial number of dishwasher cycles performed by consumers do not meet consumer expectations for cleaning performance on the normal cycle, which would not

[28] The test sample consisted of 31 units spanning 13 brands. The units selected for testing represented over 95 percent of dishwasher manufacturers and were broadly representative of the current dishwasher market. 85 FR 68723, 68724.

appropriately reflect general consumer usage of the normal cycle. Whereas, establishing a threshold that is ''too low'' would not appropriately reflect the percentage of cycles for which consumers are likely to select a more energy-intensive cycle to achieve better cleaning performance than can be achieved on the normal cycle.

DOE used the data presented in Figure III.1 and the consumer usage weighting factors specified in appendix C1 (and proposed to be retained in appendix C1 and the newly proposed appendix C2) for the heavy (0.05), medium (0.33), and light (0.62) soil loads to calculate the percentage of cycles that would need to be tested at a more energy-intensive cycle than the normal cycle (*i.e.,* the percentage of cycles that would not meet the threshold at each point).[29] The percentage of cycles that would need to be tested at a more energy-intensive cycle than the normal cycle is shown in Figure III.2, along with the range for the percentage of cycles that would operate on a more energy-intensive cycle than the normal cycle as estimated from industry data.

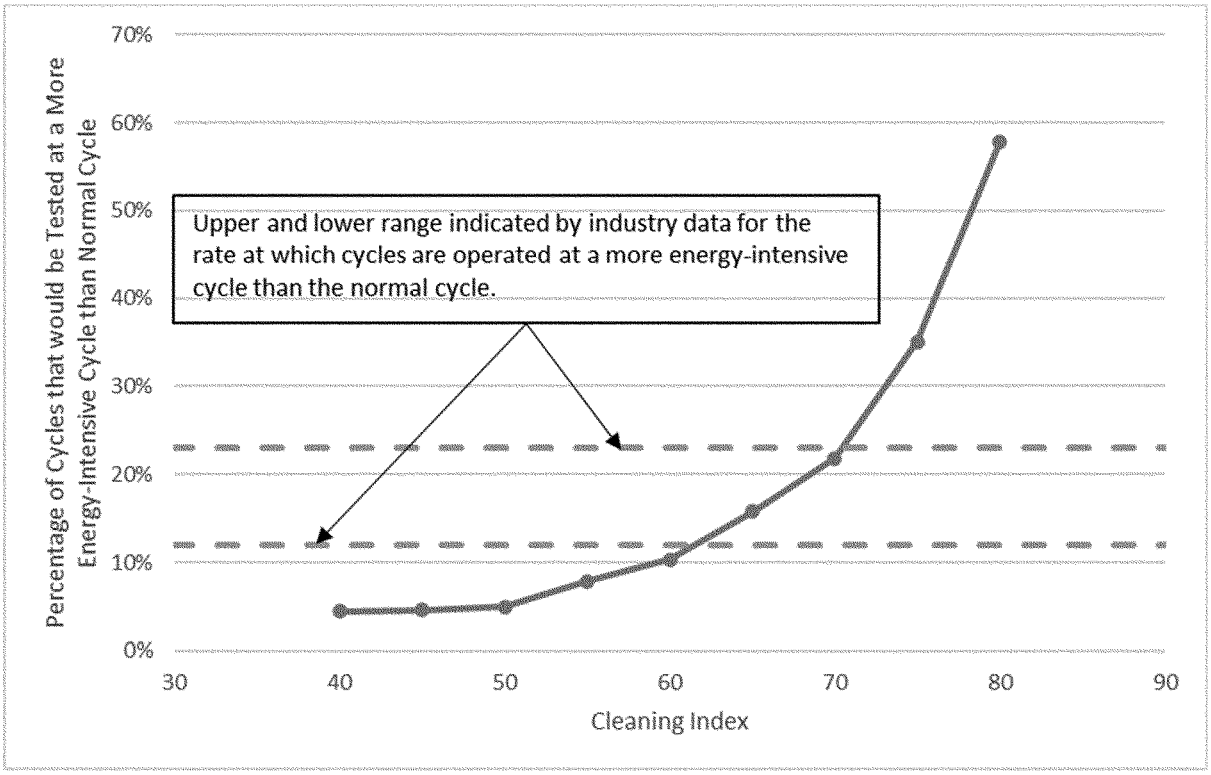

Figure III.2 Percentage of Cycles that Would Be Tested at a More Energy-Intensive Cycle than the Normal Cycle at each Cleaning Index Threshold

Based on the results in Figure III.1 and Figure III.2, DOE proposes establishing a minimum cleaning index of 65 as the threshold level for a test cycle to be valid. At a cleaning index of 65, the percentage of test cycles at each soil level that would achieve the minimum cleaning index threshold is 97 percent for lightly soiled loads, 65 percent for medium soiled loads, and 58 percent for heavily soiled loads. On a weighted-average basis, the measured normal test cycles would reach the threshold cleaning index of 65 approximately 84 percent of the time (*i.e.,* 16 percent of cycles would not meet the threshold, as shown in Figure III.2).[30] The 16-percent rate—representing the overall percentage of cycles that would need to be tested using the most energy-intensive cycle—would align with DOE's estimate of roughly 12 to 23 percent of cycles being operated using a more energy-intensive cycle than the normal cycle.

DOE also considered other cleaning index threshold values, such as 70, which would align with the ENERGY STAR Most-Efficient criteria, and values below 65. However, for a cleaning index threshold of 70, 22 percent of the cycles would need to be tested at the most energy-intensive cycle, which is close to the upper bound of DOE's estimated threshold (*i.e.,* 23 percent) for the percentage of cycles that would likely be tested at a more energy-intensive cycle compared to the normal cycle. At a cleaning index threshold of 60, only 10 percent of cycles would need to be tested at the most energy-intensive cycle, which is outside the representative range estimated by DOE from industry-supplied data. While the percentage of cycles estimated to operate at the most energy-intensive cycle to meet a cleaning index threshold of 70 is within the range of cycles that DOE estimates are conducted on a more energy-intensive cycle than the normal cycle, DOE is proposing a cleaning index threshold of 65 because it is closer to the mid-point of the range of 12 to 23 percent of cycles that are likely

[29] Percent of cycles likely to be operated on a more energy-intensive cycle than the normal cycle calculated as (100 percent − percentage of cycles meeting the threshold level at each point).

[30] DOE estimates the overall rate as a weighted average of the rate at each soil load times the frequency of consumer usage of each soil load; *i.e.,* (97 percent lightly soiled × 0.62) + (65 percent × 0.33) + (58 percent × 0.05) = 84 percent overall rate that meets a threshold of 65. Therefore, 16 percent of cycles would not meet the threshold of 65.

to be tested on a more energy-intensive cycle compared to the normal cycle. However, if stakeholder feedback indicates that a cleaning index threshold of 70 is appropriate, DOE will consider establishing 70 as the cleaning index threshold value for a test cycle to be considered valid.

DOE proposes to specify the same cleaning index threshold value for all tested soil loads because it does not have information to suggest that consumer expectations for the cleaning performance of the load at the end of the cycle differ based on the initial soil load of the dishware.

DOE requests feedback on the proposed cleaning index threshold value of 65 for each test cycle or whether it should consider a threshold value of 70 instead.

DOE requests additional data on consumer dishwasher cycle selections. In particular, DOE requests data indicating the frequency with which consumers select the normal cycle; and, for cycles not conducted on the normal cycle, the frequency with which a more energy-intensive cycle is selected.

DOE also requests additional data on how frequently consumers are dissatisfied with the cleaning performance of the normal cycle as well as the actions, and the frequency of each action, that consumers would take if the load is not satisfactorily clean.

3. Validation of the Test Cycle

Similar to the ENERGY STAR Cleaning Performance Test Method, DOE proposes that the cleaning index of the test cycles be determined for the same test cycles required for the energy and water tests for both soil-sensing and non-soil-sensing dishwashers. The following paragraphs discuss specific details regarding implementation of this proposal for soil-sensing and non-soil-sensing dishwashers, respectively.

For soil-sensing dishwashers, Section 2.6.3 of appendix C1 specifies that the normal cycle shall be tested first for the sensor heavy response, then for the sensor medium response, and finally for the sensor light response, using a defined combination of soiled and clean test load items for each test cycle. DOE proposes maintaining this test sequence, which is also specified in Section 2.6.3 of AHAM DW–1–2020. As discussed, DOE proposes that each of the sensor heavy, medium, and light response test cycles would be required to achieve a cleaning index of 65 or greater to constitute a valid cycle. If a test cycle at a particular soil level does not achieve the defined cleaning index threshold, that soil level would need to be re-tested using the most energy-intensive cycle (to be determined using the proposed methodology discussed in Section III.G.4 of this document) that achieves a cleaning index threshold of 65 or greater. For the soil level under consideration, the test results from the most energy-intensive valid cycle that achieves a cleaning index threshold of 65 or greater would be used in the calculation of EAOC, EAEU, and per-cycle water consumption.

In the event that a test cycle at a particular soil level does not achieve the defined cleaning index threshold, DOE proposes that the filter should be cleaned prior to testing the soil level at the most energy-intensive cycle that achieves a cleaning index of 65 or greater. Cleaning the filter before transitioning from the normal cycle to the specified most energy-intensive cycle at a given soil load would ensure that residual particles from the normal cycle test run do not impact the cleaning performance evaluation for that most energy-intensive cycle. It would also promote repeatability and reproducibility of the test results when testing according to the proposed amendments (in which the sequence of test cycles may requiring switching from the normal cycle to a different program cycle).

Non-soil-sensing dishwashers are currently tested with a clean (*i.e.,* unsoiled) test load. Under the proposal that a test cycle would be considered valid if its cleaning index threshold is 65 or greater, DOE proposes that non-soil-sensing dishwashers must be tested instead with a soiled load. Specifically, for non-soil-sensing dishwashers, DOE proposes incorporating the same procedure for evaluating the validity of the normal cycle and, if necessary, testing the most energy-intensive cycle that achieves a cleaning index threshold of 65 or greater, as proposed for soil-sensing dishwashers. The same equations specified for soil-sensing dishwashers in Section 5 of appendix C1 and newly proposed appendix C2, Calculations of Derived Results from Test Measurements, would apply to non-soil-sensing dishwashers. The proposed test procedure would specify testing the heavy, medium, and light soil levels, in that sequence.

Since non-soil-sensing dishwashers consume a fixed amount of water and energy independent of the amount of soil present in the test load, it is assumed that if the normal cycle obtains a cleaning index of 65 or greater at a given soil load (*e.g.,* for the sensor heavy response test), that the normal cycle would also achieve the cleaning index threshold for any lesser soil loads (*e.g.,* the sensor medium and sensor light response tests). Therefore, if a tested soil load for a non-soil-sensing dishwasher meets the defined threshold criteria when tested on the normal cycle, no additional testing would be required of cycles with lesser soil loads. If a non-soil-sensing dishwasher is not tested at a certain soil load because the preceding heavier soil load(s) meets the cleaning index threshold on the normal cycle, the energy and water consumption values of the preceding soil load would be used to calculate the weighted-average energy and water consumption values. For example, if the sensor medium response and sensor light response tests on the normal cycle are not conducted, the values of the sensor heavy response test on the normal cycle would be used for all three soil loads; whereas, if only the sensor light response test is not conducted, the values of the sensor medium response test on the normal cycle would be used for the sensor medium and the sensor light response tests.

DOE could also consider other potential methods to validate that the measured energy and water consumption of dishwashers is representative of consumer use. For example, the test procedure could define an energy ''adder'' or multiplicative factor that would be applied to the energy and water consumption values for any test cycle that does not meet the defined cleaning index threshold (*e.g.,* DOE could specify a constant adder that could be included to the measured energy consumption of a cycle that does not meet the cleaning index threshold). Such adder or multiplicative factor would compensate for the additional energy and water needed to achieve a consumer-accepted level of cleaning. This example approach would eliminate the need to run additional test cycles, thereby mitigating test burden.

As discussed at the beginning of Section III.G of this document, the representative average use of a dishwasher is represented in DOE's test procedure by the normal cycle. The normal cycle definition includes the phrase ''completely wash a full load of normally soiled dishes.'' See 10 CFR part 430 subpart B appendix C1. The discussion in Sections III.G.1–3 of this document illustrates that it is likely that dishwashers exist that are testing using the ''normal cycle,'' but are not ''completely washing'' dishes, leading consumers to pre-rinse and use additional cycles, *etc.* Thus, the testing of those dishwashers is not representative of energy use, energy efficiency, and water use during a representative average use cycle. In

order to ensure that the testing of all dishwashers more accurately measures energy and water use during representative consumer use (*i.e.,* completely washing a normally soiled load of dishes), DOE is proposing to adopt a cleaning performance threshold.

Further, under 42 U.S.C. 6293(e)(1), DOE is required to determine whether an amended test procedure will alter the measured energy use of any covered product. If an amended test procedure does alter measured energy use, DOE is required to make a corresponding adjustment to the applicable energy conservation standard to ensure that minimally-compliant covered products remain compliant. (42 U.S.C. 6293(e)(2)) The measured energy use of certain dishwashers could change if a more-energy intensive cycle is required to verify that a dishwasher model completely washes a normally soiled load of dishes (*i.e.,* dishwashers for which the cycle recommended in the manufacturer's instructions for daily, regular, or typical use to completely wash a full load of normally soiled dishes does not completely wash a full load of normally soiled dishes). However, DOE does not expect that this proposal would impact the measured energy of dishwasher models for which the normal cycle completely washes a full load of normally soiled dishes as required by the current DOE test procedure. Further, DOE does not expect that this proposal would impact minimally compliant models. As discussed in the December 2016 Final Determination, DOE relied on cleaning performance data from the ENERGY STAR Cleaning Performance Test Method, which showed that cleaning performance began to drop off at energy and water consumptions below Efficiency Level 3 (255kWh/year and 3.1 gal/cycle). 81 FR 90072, 90082. Additionally, testing conducted in support of the October 2020 Final Rule included two minimally-compliant units, both of which exceeded the proposed cleaning index threshold of 65 at each of the three soil loads on the normal cycle. As such, DOE expects that manufacturers would likely be able to maintain cleaning performance, up to a score of 70, with a maximum energy consumption between 250 and 260 kWh/year and water consumption at 3.1 gal/cycle. DOE has tentatively determined that this proposal would not require an adjustment to the energy conservation standard for dishwashers to ensure that minimally-compliant dishwashers remain compliant.

DOE requests feedback on its proposed approach to ensure that the test procedure produces test results which measure energy use and water use during a representative average use cycle.

DOE requests comment on its proposal that, if a test cycle at a particular soil level is re-tested using the most energy-intensive cycle, the filter should be cleaned prior to testing the soil level at the most energy-intensive cycle.

DOE requests feedback on its proposal to require testing non-soil-sensing dishwashers using a soiled load for the purpose of being able to evaluate the cleaning index of each tested cycle.

DOE requests comment on its proposed approach for non-soil-sensing dishwashers; particularly that if a tested soil load meets the defined threshold criteria when tested on the normal cycle, no additional testing is required of cycles with lesser soil loads.

DOE requests comment and data on the test cycles currently selected by manufacturers for rating the energy and water use of dishwashers compared to the test cycles that would be selected under the proposed cleaning index threshold of 65 as a condition for a valid test cycle. In particular, DOE requests data on the extent to which manufacturers would need to test a more-energy intensive cycle, or redefine the normal cycle, to meet the proposed cleaning index threshold of 65.

DOE requests information on other potential methods to validate that the measured energy and water consumption of dishwashers is representative of consumer use, such as the example approaches of applying an ''adder'' or multiplicative factor to the energy and water consumption values for any test cycles that do not achieve the defined cleaning index threshold. If stakeholders recommend such an approach, DOE requests data and information that could be used to determine this factor.

DOE requests comment and related supporting data on whether this proposal would result in an altered measured energy use for dishwashers that are currently minimally-compliant with the existing energy conservation standards for dishwashers.

DOE notes that compact dishwashers that are non-soil-sensing are currently tested at the manufacturer-stated capacity, if the capacity of the dishwasher is less than eight place settings. Section 2.6.2 of appendix C1. Under the proposal to test non-soil-sensing dishwashers with a soiled load, the instructions specify that compact dishwashers must be tested using four place settings plus six serving pieces, and that some of the place settings are soiled for the different soiled loads. However, DOE is aware that the rated capacity of some compact, non-soil-sensing dishwashers is less than four place settings (*e.g.,* the basic models for which CNA and FOTILE submitted waiver petitions and discussed in Sections III.D.5 and III.D.6, respectively, of this document). For such dishwashers, as well as any soil-sensing compact dishwashers that have a rated capacity of less than four place settings, DOE proposes the following requirements for soiling the test load:

- *Heavy soil load:* Soil two-thirds of the place settings, excluding flatware and serving pieces (rounded up to the nearest integer) or one place setting, whichever is greater;
- *Medium soil load:* Soil one-quarter of the place settings, excluding flatware and serving pieces (rounded up to the nearest integer) or one place setting, whichever is smaller;
- *Light soil load:* Soil one-quarter of the place settings, excluding flatware and serving pieces (rounded up to the nearest integer) or one place setting, whichever is smaller, using half the quantity of soils specified for one place setting.

DOE requests comment on whether the soil loads proposed for compact dishwashers that have a capacity of less than four place settings is appropriate. If stakeholders recommend different quantity of soils for such dishwashers, DOE requests feedback on the soil level that should be used for such small capacity dishwashers.

4. Determining the Most Energy-Intensive Cycle

To determine the most energy-intensive cycle that achieves a cleaning index of 65 or greater for a given soil load, if the normal cycle does not achieve this threshold level, DOE proposes a new Section 4.1.1 in appendix C1 and newly proposed appendix C2 to provide instructions for determining the most energy-intensive cycle type, to be conducted only if required for this purpose. DOE proposes that the most energy-intensive cycle would be determined by conducting a single test cycle with a clean test load for each available cycle (*e.g.,* Normal, Heavy Duty, Pots and Pans, *etc.*).

DOE also considered that the most energy-intensive cycle be determined for each sensor response test cycle using the respective soil load (*i.e.,* the most energy-intensive sensor heavy response test cycle would require testing each available cycle type with the heavy soil load; the most energy-intensive sensor medium response and sensor light response test cycles would be determined similarly). However, DOE is

not proposing this approach due to the significant burden associated with soiling the load and running the cycle for each available cycle type at each potential soil level. If stakeholder comments indicate that such an approach would be more representative to determine the most energy-intensive cycle, DOE would consider it.

DOE also proposes that prior to running the clean load test to determine the most energy-intensive cycle, the dishwasher filter should be cleaned so that soil particles from any previous tests does not affect the determination of the most energy-intensive cycle.

DOE requests feedback on its proposed methodology for determining the most energy-intensive cycle. DOE also requests feedback on whether it should consider determination of the most energy-intensive cycle for sensor response test cycle using the respective soil load.

DOE requests feedback on its proposal to require cleaning of the dishwasher filter prior to running the clean load test to determine the most energy-intensive test cycle.

H. Standby Mode Test Method

1. Standby Power Measurement

Section 4.2 of appendix C1 provides instructions for measuring standby mode and off mode power. These instructions do not currently specify if the dishwasher door is to be open or closed when testing in standby mode and off mode. In the August 2019 RFI, DOE requested comment on whether testing with the door closed is representative of energy use in standby mode or off mode during a representative average use cycle or period of use (*i.e.,* the door is closed when the dishwasher is not in active mode). 84 FR 43071, 43077. Additionally, DOE requested feedback on whether energy is consumed when the door is open, and if so, whether the energy consumption with the door open is significantly different from the energy consumed with the door closed. *Id.*

AHAM commented that it was further investigating the inquiry about whether standby testing with the door closed is representative of energy use in standby mode and whether energy consumed with the door open is significantly different than when the door is closed. (AHAM, No. 5 at p. 7) The Joint Commenters recommended that the test procedure specify that the door remain closed during standby and off mode power testing. (Joint Commenters, No. 8 at p. 2) Both CEC and the CAIOUs stated that DOE should specify that standby testing be conducted with the door closed. (CEC, No. 6 at p. 2; CAIOUs, No. 7 at p. 3) CEC further stated that, ''intuitively, most consumers will keep the dishwasher door closed to prevent disruption of foot traffic patterns in their kitchen.'' (CEC, No. 6 at p. 2) CEC reiterated that DOE should fully specify the conditions under which measurements are to be made to improve repeatability. (CEC, No. 6 at p. 2)

DOE reviewed recent models from different manufacturers and observed that some newer models have LED lights inside the dishwasher tub as well as other indicators either on the door or on the electronic control panel that illuminate when the dishwasher door is open. Additional energy use by any such lights and/or indicators could affect the standby power consumption and the resulting EAEU measurement; for example, a 1-watt increase in the standby power consumption could impact the EAEU by up to 5 percent, *i.e.,* conducting standby mode testing with the dishwasher door open as compared to testing with the door closed could result impact test results for EAEU by up to 5 percent if the lights consumed an additional 1 watt of power.

Section 4.2 of the new AHAM DW–1–2020 standard also includes specific instructions for the door orientation during standby mode testing. It specifies that the standby mode test must be conducted after completing the last active mode test as part of the energy test sequence. Thereafter, the dishwasher door must be opened and immediately closed without changing the control panel settings used for the active mode wash cycle and without disconnecting the electrical supply to the dishwasher. Once the door is closed, the standby mode and off mode measurements should begin.

DOE proposes to reference this requirement from AHAM DW–1–2020 regarding opening and closing the door prior to starting the standby mode and off mode tests. DOE has initially concluded that performing standby mode and off mode testing with the door closed is likely to be most representative of average consumer use while also providing a representative measurement, in particular noting CEC's comment that most consumers will keep the dishwasher door closed to prevent disruption of foot traffic patterns in their kitchen.

Based on DOE's interactions with test laboratories, dishwashers are already tested with the door closed in standby mode. Therefore, DOE does not expect any increase in costs to manufacturers from this proposed update were it made final.

DOE requests input on its proposal to apply the standby mode and off mode test requirements from Section 4.2 of AHAM DW–1–2020 to appendix C1 and proposed new appendix C2.

2. Annual Combined Low-Power Mode Energy Consumption Calculation

Section 5.7 of appendix C1 specifies the method to calculate the annual combined low-power mode energy consumption. The combined low-power mode energy consumption includes the power consumption in inactive mode [31] and off mode,[32] depending on whether a unit can enter both of these modes or only one of these modes. To calculate the annual low-power mode energy consumption, Section 5.7 of appendix C1 currently assigns 8,465 hours annually to low-power modes for units that do not have a fan-only mode. For units that have a fan-only mode, the annual hours assigned to low-power modes are calculated for each individual unit based on the tested duration in active mode and fan-only mode. Section 5.7 of appendix C1. That is, the combined low-power annual hours for all available modes other than active mode, S_{LP}, is calculated as:

$S_{LP} = [H - \{N \times (L + L_F)\}]$ for dishwashers capable of operating in fan-only mode; otherwise, S_{LP} = 8,465

Where,

H = the total number of hours per year = 8,766 hours per year,

N = the representative average dishwasher use of 215 cycles per year,

L = the average of the duration of the normal cycle and truncated normal cycle, for non-soil-sensing dishwashers with a truncated normal cycle; the duration of the normal cycle, for non-soil-sensing dishwashers without a truncated normal cycle; the average duration of the sensor light response, truncated sensor light response, sensor medium response, truncated sensor medium response, sensor heavy response, and truncated sensor heavy response, for soil-sensing dishwashers with a truncated cycle option; the average duration of the sensor light response, sensor medium response, and sensor heavy response, for

[31] *Inactive mode* means a standby mode that facilitates the activation of active mode by remote switch (including remote control), internal sensor, or timer, or that provides continuous status display. Section 1.10 of appendix C1.

[32] *Off mode* means a mode in which the dishwasher is connected to a mains power source and is not providing any active mode or standby mode function, and where the mode may persist for an indefinite time. An indicator that only shows the user that the product is in the off position is included within the classification of an off mode. Section 1.15 of appendix C1.

soil-sensing dishwashers without a truncated cycle option, and

L_F = the duration of the fan-only mode for the normal cycle for non-soil-sensing dishwashers; the average duration of the fan-only mode for sensor light response, sensor medium response, and sensor heavy response for soil-sensing dishwashers. Section 5.7, appendix C1.

Section 5.7 of AHAM DW–1–2020 updated this calculation such that the combined low-power annual hours, S_{LP}, is a calculated value for all units. That is, dishwashers that do not have a fan-only mode would use the same equation to calculate S_{LP} as dishwashers that do have a fan-only mode. The only difference in calculation of S_{LP} for units without a fan-only mode is that L_F would be equal to 0 for such units.

DOE proposes to reference the annual low-power mode energy consumption calculation specified in Section 5.7 of AHAM DW–1–2020, which would also include the updated calculation method for combined low-power annual hours, S_{LP}. This approach would change the hours assigned to low-power mode from 8,465 hours for dishwashers that do not have a fan-only mode to a value that is dependent on the duration of the normal cycle. Calculating the annual low-power mode energy consumption utilizing the measured active mode duration for each individual unit rather than assigning a constant value across all units would provide a more representative result.

The proposed change to the combined low-power annual hours would potentially impact the measured EAEU. DOE also notes that the current energy conservation standard was developed using the method for determining the combined low-power annual hours specified in appendix C1. As such, DOE proposes that, if this proposal were adopted, this change would go into effect in conjunction with any amended energy conservation standards for dishwashers. Accordingly, DOE is proposing that the updated calculation of annual low-power mode energy consumption be included only in the new appendix C2. Appendix C1 would continue using the current method for calculating the annual low-power mode energy consumption.

DOE requests comment on its proposal to use the updated combined low-power annual hours, specified in Section 5.7 of AHAM DW–1–2020, for the calculation of annual combined low-power mode energy consumption in the proposed new appendix C2.

I. Network Mode

Appendix C1 currently does not address ''network mode'' power consumption. DOE received two comments that recommended incorporating a network mode power consumption test method into appendix C1. Specifically, the Joint Commenters stated that DOE should consider incorporating a network mode power consumption measurement in the test procedure for ''connected'' dishwashers so consumers can have a better understanding of the energy associated with connected functionality, adding that as of September 2019, there were 11 ENERGY STAR-qualified connected models on the market. (Joint Commenters, No. 8 at p. 2) Additionally, the CAIOUs recommended that DOE define a ''network mode'' for smart dishwashers and implement a method to measure power consumption in network mode so that consumers have a better understanding of the power usage for connected units. (CAIOUs, No. 7 at p. 3)

DOE is aware of dishwashers with network capabilities that are currently on the market. However, DOE does not have sufficient data at this time regarding the energy use and consumer use patterns associated with such capabilities to evaluate potential test procedure provisions related to network capabilities. Therefore, DOE is proposing that all network functions must be disabled during testing. Specifically, DOE proposes to include a requirement in appendix C1 and the proposed new appendix C2 that for dishwashers which can communicate through a network (*e.g.,* Bluetooth® or internet connection), all network functions must be disabled, if it is possible to disable it by means provided in the manufacturer's user manual, for the duration of testing. If the manufacturer instructions provided in the user manual do not provide for disabling a connected function, the standby power test procedure is conducted with the connected function in the ''as-shipped'' condition. DOE seeks comment on its proposal to require the disablement of all network functions throughout the duration of testing.

DOE seeks the following information regarding connected dishwashers that could inform future test procedure considerations:

DOE requests feedback on connected dishwashers currently on the market. Specifically, DOE requests input on the types of features or functionality enabled by connected dishwashers that exist on the market or that are under development.

DOE requests data on the percentage of users purchasing connected dishwashers, and, for those users, the percentage of the time when the connected functionality of the dishwashers is used.

DOE requests data on the amount of additional or reduced energy use of connected dishwashers.

DOE requests data on the pattern of additional or reduced energy use of connected dishwashers; for example, whether it is constant, periodic, or triggered by the user.

DOE requests information on any existing testing protocols that account for connected features of dishwashers, as well as any testing protocols that may be under development within the industry.

J. Test Cycle Duration

As stated, DOE established a separate product class for standard size dishwashers with a cycle time for the normal cycle of less than one hour from washing through drying. 10 CFR 430.32(f)(1)(iii). *See also* 85 FR 68723. The definition for the new product class of standard size dishwashers with a ''normal'' cycle time of 60 minutes or less defines ''normal'' cycle time by reference to Section 1.12 of appendix C1. 10 CFR 430.32(f)(1)(iii). The new product class definition, as well as the previously established definitions for standard size dishwasher and compact size dishwasher, reference ANSI/AHAM DW–1–2010 for specifying the place settings used to distinguish between ''standard'' and ''compact.'' 10 CFR 430.32(f)(1)(i)–(iii).

On December 29, 2020, the National Resources Defense Council (''NRDC''), Sierra Club, Consumer Federation of America, and Massachusetts Union of Public Housing Tenants petitioned the U.S. Court of Appeals for the Second Circuit to review and set aside the October 2020 Final Rule. *Natural Resources Defense Council* v. *U.S. Dep't of Energy,* No. 20–4256 (2d Cir.). On the same day, the States of California, Connecticut, Illinois, Maine, Michigan, Minnesota, New Jersey, New Mexico, New York, Nevada, Oregon, Vermont, and Washington, the Commonwealth of Massachusetts, the District of Columbia, and the City of New York filed a separate petition for review of the October 2020 Final Rule in the U.S. Court of Appeals for the Second Circuit. *California* v. *U.S. Dep't of Energy,* No. 20–4285 (2d Cir.). These two cases have been consolidated in the Second Circuit and have been placed in abeyance pending DOE's review of the October 2020 Final Rule in compliance with Executive Order 13990.

Further, on March 1, 2021, AHAM petitioned DOE to reconsider the October 2020 Final Rule that established

and amended standards for short-cycle residential dishwashers (Docket EERE–2021–BT–STD–0002, No. 001 at p. 2).[33] On April 28, 2021, the NRDC, Sierra Club, the Consumer Federation of America, and the Massachusetts Union of Public Housing Tenants (''NRDC, et al.'') also submitted a petition for DOE to repeal the same October 2020 Final Rule (''NRDC petition for reconsideration'').[34]

On August 11, 2021, DOE published a NOPR (''August 2021 NOPR'') stating that the October 2020 Final Rule resulted in amended energy conservation standards for the new product class without properly determining whether the relevant statutory criteria for amending standards were met. 86 FR 43970. As a result, DOE proposed to revoke the October 2020 Final Rule establishing the new short cycle product class. *Id.*

As stated, DOE is proposing to incorporate by reference AHAM DW–1–2020 in its entirety into 10 CFR part 430, and amend the dishwasher test procedure to reference specified provisions of the standard. Specifically, DOE is proposing to amend 10 CFR 430.32(f)(1)(iii) to remove the existing reference to appendix C1, and instead reference AHAM DW–1–2020 for the definition of ''normal cycle.'' DOE is also proposing to specify the method for determining cycle duration in Section 5.3 of appendix C1 and the proposed new appendix C2. DOE proposes the test duration is the weighted average of the sensor heavy response, sensor medium response, and sensor light response tests for all dishwashers (*i.e.,* both soil-sensing and non-soil-sensing dishwashers). Additionally, DOE is proposing to update the references to AHAM DW–1 in the standard size dishwasher and compact size dishwasher descriptions in 10 CFR 430.32. In light of the August 2021 NOPR, DOE is not proposing at this time to require reporting of the test duration.

DOE requests comment on the proposal to update the standard size dishwasher, compact size dishwasher, and standard size dishwasher with a ''normal'' cycle time of 60 minutes or less descriptions at 10 CFR 430.32(f)(1)(i)–(iii). DOE also requests comment on the proposal to explicitly provide the method for determining cycle duration in appendices C1 and C2.

K. Test Procedure Costs and Harmonization

1. Test Procedure Costs and Impact

In this NOPR, DOE proposes to amend the existing test procedure for dishwashers at appendix C1 and adopt a new test procedure at appendix C2. The proposed amendments to appendix C1 would establish requirements for water hardness, relative humidity, and loading pattern; update requirements for ambient temperature, detergent dosage, and standby power measurement; include testing approaches from published waivers for dishwashers; and include provisions for evaluating cleaning performance and establishing a minimum per-cycle cleaning index threshold as a condition for a valid test. The newly proposed appendix C2 would additionally include an updated annual number of cycles and low-power mode hours for the calculation of energy consumption.

The proposed amendments to appendix C1 would establish new requirements for water hardness and relative humidity and would update the requirements for ambient temperature. DOE does not expect these proposals to increase test burden as compared to current industry practice because it expects that laboratories already control water hardness, relative humidity, and ambient temperature to within the proposed specifications, as indicated by manufacturer comments supporting these proposals, as well as general industry acceptance for these requirements as they pertain to dishwashers and other appliances.

DOE also proposes to establish in appendix C1 a new requirement for loading soiled dishes. DOE does not expect this proposal to change the rated energy and water use because the thermal mass inside the dishwasher chamber would be the same, regardless of how the dishes are loaded in the unit. DOE also does not expect this proposal to increase the cost of conducting the test procedure as compared to the current test procedure based on the large number of brands currently participating in the ENERGY STAR qualification and Most Efficient programs (which requires the loading pattern proposed in this NOPR) and based on AHAM's statements expressing support on behalf of the industry.

Further, DOE is also proposing a new detergent type and approach for calculating the detergent dosage in appendix C1. However, DOE is also proposing to retain the current detergent type and dosing requirement. As such, DOE does not expect this proposal to increase test burden as compared to current industry practice.

DOE is further proposing in appendix C1 that standby mode power consumption be measured with the door closed. Based on DOE's interactions with test laboratories, dishwashers are already tested with the door closed in standby mode. Therefore, DOE does not expect any increase in costs to manufacturers from this proposed update if it were made final.

Finally, DOE is proposing the evaluation of cleaning performance in appendix C1. Specifically, DOE is proposing that each tested soil load must meet a minimum per-cycle cleaning index threshold of 65 for a test cycle to be considered valid. As discussed, DOE understands the market to reflect general consumer satisfaction with the cleaning performance of currently available dishwashers, and the proposed test cycle validation index would reflect that consumer acceptance.

Were a currently certified dishwasher model to require retesting, or new models be tested for certification under the proposed amendments to appendix C1, if made final, DOE estimated the cost to test a dishwasher basic model according to the proposed appendix C1. DOE estimates the costs to test a soil-sensing dishwasher to be approximately $2,330 per basic model and that for a non-soil-sensing dishwasher to be approximately $790 per basic model. These costs were estimated as follows.

Based on its experience conducting dishwasher testing, DOE estimates the total duration to test dishwashers currently, according to appendix C1, to be 25 hours for a soil-sensing dishwasher and 6 hours for a non-soil-sensing dishwasher. The additional time required to score a load at the end of cycle and calculate the cleaning index is estimated to be 1 hour per soil load. Therefore, DOE estimates the test duration under the proposed updates to appendix C1 to be 28 hours for soil-sensing dishwashers (25 hours currently + 1 hour per soil load to score the load and calculate cleaning index).

For non-soil-sensing dishwashers, DOE's proposal requires testing on the heavy soil load. This would increase testing time by approximately 2.5 hours (in addition to the 1 hour associated with scoring and calculating cleaning index) due to the additional time associated with preparing the soils, soiling the load, allowing the soils to dry, and loading the soiled dishes. To

[33] AHAM submitted its petition pursuant to the Administrative Procedure Act (''APA''), 5 U.S.C. 551 *et seq.,* which provides among other things, that ''[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.'' (5 U.S.C. 553(e)) The AHAM petition is available in the docket to this rulemaking, EERE–2021–BT–STD–0002, at *www.regulations.gov.*

[34] NRDC also submitted its petition pursuant to the APA, 5 U.S.C. 553(e), to repeal the final rule. The NRDC petition is available in the docket to this rulemaking, EERE–2021–BT–STD–0002, at *www.regulations.gov.*

mitigate burden, DOE's proposal additionally specifies that non-soil-sensing dishwashers are required to test the medium and light soil loads only if the next-greater soil load requires the use of the most energy-intensive cycle. To estimate the testing burden associated with this proposal, DOE estimates that most non-soil-sensing dishwashers would only be tested at the heavy soil load. Therefore, DOE estimates the total testing duration for non-soil sensing dishwashers under the proposed appendix C1 to be 9.5 hours (2.5 hours to soil the load + 1 hour to score the load and calculate cleaning index).

Based on data from the Bureau of Labor Statistics' (''BLS's'') Occupational Employment and Wage Statistics, the mean hourly wage for electrical and electronic engineering technologist and technician is $29.27.[35] Additionally, DOE used data from BLS's Employer Costs for Employee Compensation to estimate the percent that wages comprise the total compensation for an employee. DOE estimates that wages make up 70.4 percent of the total compensation for private industry employees.[36] Therefore, DOE estimated that the total hourly compensation (including all fringe benefits) of a technician performing these tests is approximately $41.58.[37] Using these labor rates and time estimates, DOE estimated that it would cost dishwasher manufacturers approximately $1,165 to conduct a single test on a soil-sensing dishwasher unit and approximately $395 to conduct a single test on a non-soil-sensing dishwasher unit.[38]

DOE requires at least two units to be tested for each basic model prior to certifying a rating with DOE. Therefore, DOE estimates that manufacturers would incur testing costs of approximately $2,330 per soil-sensing dishwasher basic model and approximately $790 per non-soil-sensing dishwasher basic model. The incremental increase in testing costs under the proposed updates to appendix C1 compared to the current appendix C1 would be approximately $250 per soil-sensing dishwasher basic model and approximately $290 per non-soil-sensing dishwasher basic model.

DOE requests comment on its initial determination as to the impacts from the proposed amendments to appendix C1 related to the rated energy and water use of currently certified dishwashers. DOE also requests comment on the potential impact to manufacturers from the updates proposed to appendix C1. Finally, DOE requests comment on its estimated costs for testing soil-sensing and non-soil-sensing dishwashers according to the proposed appendix C1.

In addition to the proposed amendments to appendix C1, DOE is also proposing a new appendix C2. As proposed, use of appendix C2 would be required in conjunction with the compliance date of future amendments to the energy conservation standards for dishwashers, should such amendments be adopted. The proposed change to the annual number of cycles and low-power mode hours, both of which are used for the calculation of energy consumption, would change certain inputs to the calculation, but would not impact the burden as compared to conducting the calculation under the current test procedure.

Another proposed update in the proposed appendix C2 would require the use of a new detergent type and method to calculate the detergent dosage. Based on testing that DOE conducted in support of the October 2020 Final Rule, DOE estimates that the updated detergent dosage methodology would reduce testing time by about 1 hour because the new methodology estimates detergent dosage based on the number of place settings as opposed to the prewash and main wash fill water volumes as required under the current (and proposed) appendix C1 test procedure. Determination of the prewash and main wash fill water volumes requires about 1 hour to identify the prewash and main wash phases of a test cycle, isolating the water consumed during these specific portions of the cycle, and then calculating the quantity of detergent required.

Based on these estimates DOE anticipates the total duration to test soil-sensing dishwashers according to the newly proposed appendix C2 would be 27 hours. Similarly, DOE's estimate of the total duration to test non-soil-sensing dishwashers according to proposed appendix C1 would be 9.5 hours. Therefore, the total duration to test non-soil-sensing dishwashers according to the newly proposed appendix C2 would be 8.5 hours. Using the same labor rates as those used to estimate the testing costs for the updates proposed to appendix C1, DOE estimated that it would cost dishwasher manufacturers approximately $2,246 per soil-sensing dishwasher basic model and approximately $705 per non-soil-sensing dishwasher basic model.[39]

These costs would be for testing pursuant to newly proposed appendix C2, and as proposed, testing pursuant to new appendix C2 would only be required at such time as compliance is required with amended energy conservation standards for dishwashers, should such amendments be adopted. DOE will address the expected costs to industry if and when DOE establishes energy conservation standards for dishwashers.

DOE requests comment on the potential impact to manufacturers from the updates proposed to the newly proposed appendix C2. Specifically, DOE requests comment on the per basic model test costs associated with testing soil-sensing and non-soil-sensing dishwashers.

2. Harmonization With Industry Standards

DOE's established practice is to adopt industry test standards as DOE test procedures for covered products and equipment, unless such methodology would be unduly burdensome to conduct or would not produce test results that reflect the energy efficiency, energy use, water use (as specified in EPCA) or estimated operating costs of that equipment during a representative average use cycle. Section 8(c) of 10 CFR part 430 subpart C appendix A. In cases where the industry standard does not meet EPCA statutory criteria for test procedures, DOE will make modifications through the rulemaking process to these standards as the DOE test procedure.

The current test procedure for dishwashers at appendix C1 references ANSI/AHAM DW–1–2010 in definitions and for testing conditions, and IEC 62301 Ed. 2.0 for test conditions, equipment, and standby mode power consumption measurement. The industry standards DOE proposes to reference via amendments described in this notice are discussed in further detail in Section III.B and Section IV.M of this document. DOE requests comments on the benefits and burdens

[35] DOE used the mean hourly wage of the ''17–3027 Mechanical Engineering Technologists and Technicians'' from the most recent BLS Occupational Employment and Wage Statistics (May 2020) to estimate the hourly wage rate of a technician assumed to perform this testing. See *www.bls.gov/oes/current/oes173027.htm.* Last accessed on July 26, 2021.

[36] DOE used the March 2021 ''Employer Costs for Employee Compensation'' to estimate that for ''Private Industry Workers,'' ''Wages and Salaries'' are 70.4 percent of the total employee compensation. See *www.bls.gov/news.release/archives/ecec_06172021.pdf.* Last accessed on July 26, 2021.

[37] $29.27 ÷ 0.704 = $41.58.

[38] Soil-sensing dishwasher: $41.58 × 28 hours = $1,164.24 (rounded to $1,165) Non-soil-sensing dishwasher: $41.58 × 9.5 hours = $395.01 (rounded to $395).

[39] 27 hours testing time per soil-sensing unit × $41.58 per hour × 2 units per basic model = $2,245.32 (rounded to $2,245) and 8.5 hours test time per non-soil-sensing unit × $41.58 per hour × 2 units per basic model = $706.86 (rounded to $705)

of the proposed updates and additions to industry standards referenced in the test procedure for dishwashers.

DOE notes that certain of its proposed modifications would not require retesting and recertification of dishwasher basic models as compared to adopting AHAM DW–1–2020 and AHAM DW–2–2020 without modification, while maintaining the representativeness of the DOE test procedure. DOE is proposing to maintain the list of test load items currently in appendix C1 as an alternative to the test load items specified in AHAM DW–1–2020, so test laboratories that currently have the test load items are not required to purchase new items. The proposal to maintain the current detergent and dosage requirements as alternatives to the detergent and dosage requirements specified in AHAM DW–1–2020 would allow manufacturers to continue to rely on existing test data and would not require re-testing or re-certification of dishwashers on the market. Additionally, DOE is proposing to maintain the annual number of cycles and low-power mode hours currently specified in appendix C1 because these values can impact the EAEU, which provides the basis for the existing energy conservation standards. DOE proposes to adopt the annual number of cycles and low-power mode hours from AHAM DW–1–2020 for the newly proposed appendix C2, which would be applicable upon the compliance date of any future amended energy conservation standards for dishwashers. DOE is also proposing to adopt the test procedure waiver provisions applicable to dishwashers for which water is supplied through a manually filled attached tank and for in-sink dishwashers without a main detergent compartment. AHAM DW–1–2020 does not have comparable provisions. The DOE proposal would eliminate the need of manufacturers of such products from having to seek waivers and thereby reduce compliance burden. These modifications would ensure, as required by EPCA, that the DOE test procedure is not unduly burdensome to conduct.

Additionally, AHAM DW–1–2020 references the relevant sections of AHAM DW–2–2020 and IEC 62301 Ed. 2.0 for the requirements where appendix C1 currently references ANSI/AHAM DW–1–2010 and IEC 62301 Ed. 2.0, respectively. Further, DOE's proposal to incorporate a methodology for measuring cleaning performance and including a consumer-representative minimum cleaning performance threshold as a condition for a cycle to be valid is to be referenced from the relevant sections of AHAM DW–2–2020.

L. Compliance Date and Waivers

EPCA prescribes that, if DOE amends a test procedure, all representations of energy efficiency and energy use, including those made on marketing materials and product labels, must be made in accordance with that amended test procedure, beginning 180 days after publication of such a test procedure final rule in the **Federal Register**. (42 U.S.C. 6293(c)(2))

If DOE were to publish an amended test procedure, EPCA provides an allowance for individual manufacturers to petition DOE for an extension of the 180-day period if the manufacturer may experience undue hardship in meeting the deadline. (42 U.S.C. 6293(c)(3)) To receive such an extension, petitions must be filed with DOE no later than 60 days before the end of the 180-day period and must detail how the manufacturer will experience undue hardship. (*Id.*)

Upon the compliance date of an amended test procedure, should DOE issue such an amendment, any waivers that had been previously issued and are in effect that pertain to issues addressed by the amended test procedure are terminated. 10 CFR 430.27(h)(3). Recipients of any such waivers would be required to test the products subject to the waiver according to the amended test procedure as of the compliance date of the amended test procedure. The amendments proposed in this NOPR pertain to issues addressed by waivers granted to Whirlpool, Case No. DW–011, Miele, Case No. DW–012, CNA, Case No. 2020–008, and FOTILE, Case No. 2020–020. 78 FR 65629, 82 FR 17227, 85 FR 79171, and 86 FR 26712, respectively.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Order 12866

The Office of Management and Budget (''OMB'') has determined that this test procedure does not constitute a ''significant regulatory action'' under Section 3(f) of Executive Order (''E.O.'') 12866, Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993). Accordingly, this action was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs (''OIRA'') in OMB.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (''IRFA'') for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website: *www.energy.gov/gc/office-general-counsel.*

DOE reviewed this proposed rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. DOE certifies that the proposed rule, if adopted, would not have significant economic impact on a substantial number of small entities. The factual basis of this certification is set forth in the following paragraphs.

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section be reasonably designed to produce test results which measure energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use and not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

EPCA also requires that, at least once every 7 years, DOE evaluate test procedures for each type of covered product, including dishwashers, to determine whether amended test procedures would more accurately or fully comply with the requirements for the test procedures to not be unduly burdensome to conduct and be reasonably designed to produce test results that reflect energy efficiency, energy use, and estimated operating costs during a representative average use cycle or period of use. (42 U.S.C. 6293(b)(1)(A))

In addition, EPCA requires that DOE amend its test procedures for all covered products to integrate measures of standby mode and off mode energy consumption. (42 U.S.C. 6295(gg)(2)(A)) Standby mode and off mode energy consumption must be incorporated into the overall energy efficiency, energy consumption, or other energy descriptor for each covered product unless the current test procedures already account

for and incorporate standby and off mode energy consumption or such integration is technically infeasible. If an integrated test procedure is technically infeasible, DOE must prescribe a separate standby mode and off mode energy use test procedure for the covered product, if technically feasible. (42 U.S.C. 6295(gg)(2)(A)(ii)) Any such amendment must consider the most current versions of the IEC Standard 62301 and IEC Standard 62087 as applicable. (42 U.S.C. 6295(gg)(2)(A))

DOE is proposing amendments to the test procedure for dishwashers in satisfaction of its statutory obligations under EPCA.

In this NOPR, DOE proposes to incorporate by reference into 10 CFR part 430 the new industry standard, AHAM DW–1–2020, and update the industry standard incorporated by reference in 10 CFR part 430 from ANSI/AHAM DW–1–2010 to AHAM DW–2–2020. Specifically, DOE proposes to:

(1) Incorporate by reference AHAM DW–1–2020 into 10 CFR part 430 and apply certain provisions of the industry standards to appendix C1, including the following:

a. Add the water hardness specification in Section 2.11 of AHAM DW–1–2020;

b. Add the relative humidity specification in Section 2.5.1 of AHAM DW–1–2020 and the associated tolerance for the measurement instrument in Section 3.7 of AHAM DW–1–2020;

c. Update the active mode ambient temperature as specified in Section 2.5.1 of AHAM DW–1–2020;

d. Update the loading pattern requirement by applying the direction specified in Section 2.6 of AHAM DW–1–2020;

e. Update the specifications for detergent usage consistent with Section 2.10 of AHAM DW–1–2020. This includes changing the type of detergent used, and the calculation of detergent dosage to be used for the pre-wash and main-wash cycles of dishwashers other than water re-use system dishwashers;

f. Add specific dishwasher door configuration requirements during standby mode testing, by incorporating the specifications in Section 4.2 of AHAM DW–1–2020 and update the annual combined low-power mode hours based on cycle duration; and,

g. Incorporate the requirements from AHAM DW–1–2020 for the test methods pertaining to two granted waivers for dishwashers with specific design features.

(2) Establish new appendix C2, which would generally require testing as in appendix C1, with the following additional update:

a. Updated number of annual cycles and low-power mode hours used for calculating the estimated annual energy use as specified in Section 5 of AHAM DW–1–2020.

For both, appendices C1 and C2, DOE additionally proposes to:

(1) Specify provisions for scoring the test load and calculating a per-cycle cleaning index metric as specified in AHAM DW–2–2020 and establish a minimum cleaning index threshold of 65 as a condition for a test cycle to be valid.

(2) Incorporate the test methods specified in a waiver for testing a basic model of dishwashers that does not hook up to a water supply line but has a manually filled, built-in water tank. Additionally, incorporate the test methods specified in a waiver for basic models of dishwashers that are installed in-sink (as opposed to built-in to the cabinetry or placed on countertops).

The Small Business Administration (''SBA'') considers a business entity to be small business, if, together with its affiliates, it employs less than a threshold number of workers specified in 13 CFR part 121. DOE used SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. These size standards and codes are established by the North American Industry Classification System (''NAICS'') and are available at *www.sba.gov/document/support--table-size-standards.* Dishwashers are classified under NAICS 335220, ''Major Household Appliance Manufacturing.'' The SBA sets a threshold of 1,500 employees or fewer for an entity to be considered as a small business for this category.

DOE used DOE's Compliance Certification Database [40] and California Energy Commission's Modernized Appliance Efficiency Database System (''MAEDbS'') [41] to create a list of companies that sell dishwashers covered by this rulemaking in the United States. DOE consulted publicly available data to identify original equipment manufacturers (''OEMs''). DOE relied on public data and subscription-based business information tools to determine company location, headcount, and annual revenue.

DOE identified 14 companies that are OEMs of dishwashers. In reviewing the 14 OEMs, DOE did not identify any domestic companies that met the SBA criteria for a small entity. Given the lack of small entities with a direct compliance burden, DOE concludes that the impacts of the proposed test procedure amendments outlined in this NOPR would not have a ''significant economic impact on a substantial number of small entities.'' DOE will transmit the certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

DOE seeks comment on its findings that there are no small businesses that are OEMs of dishwashers in the United States. DOE also seeks comment on its conclusion that the proposed test procedure amendments would not have significant impacts on a substantial number of small manufacturers.

C. Review Under the Paperwork Reduction Act of 1995

Manufacturers of dishwashers must certify to DOE that their products comply with any applicable energy conservation standards. To certify compliance, manufacturers must first obtain test data for their products according to the DOE test procedures, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including dishwashers. (*See generally* 10 CFR part 429.) The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (''PRA''). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act

In this proposed rule, DOE proposes test procedure amendments that it expects will be used to develop and

[40] *www.regulations.doe.gov/certification-data.* Last accessed April 22, 2021.

[41] *cacertappliances.energy.ca.gov/Pages/Search/AdvancedSearch.aspx.* Last accessed April 22, 2021.

implement future energy conservation standards for dishwashers. DOE has determined that this proposed rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, DOE has determined that adopting test procedures for measuring energy efficiency of consumer products and industrial equipment is consistent with activities identified in 10 CFR part 1021, appendix A to subpart D, A5 and A6. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

E.O. 13132, ''Federalism,'' 64 FR 43255 (Aug. 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The E.O. requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The E.O. also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed rule and has determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by E.O. 13132.

F. Review Under Executive Order 12988

Regarding the review of existing regulations and the promulgation of new regulations, Section 3(a) of E.O. 12988, ''Civil Justice Reform,'' 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. Section 3(b) of E.O. 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation (1) clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of E.O. 12988 requires executive agencies to review regulations in light of applicable standards in Sections 3(a) and 3(b) to determine whether they are met, or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, the proposed rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), Section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at *energy.gov/gc/office-general-counsel.* DOE examined this proposed rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This proposed rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

DOE has determined, under E.O. 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights'' 53 FR 8859 (March 18, 1988), that this proposed regulation would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). Pursuant to OMB Memorandum M–19–15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at *www.energy.gov/sites/prod/files/2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf.* DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to

prepare and submit to OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under E.O. 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

The proposed regulatory action to amend the test procedure for measuring the energy efficiency of dishwashers is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under Section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with Section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; ''FEAA'') Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, Section 32(c) requires DOE to consult with the Attorney General and the Chairman of the FTC concerning the impact of the commercial or industry standards on competition.

The proposed modifications to the test procedure for dishwashers would incorporate testing methods contained in certain sections of the following commercial standards: AHAM DW–1–2020, AHAM DW–2–2020, and IEC 62301 Ed. 2.0. DOE has evaluated these standards and is unable to conclude whether they fully comply with the requirements of Section 32(b) of the FEAA (*i.e.,* whether it was developed in a manner that fully provides for public participation, comment, and review.) DOE will consult with both the Attorney General and the Chairman of the FTC concerning the impact of these test procedures on competition, prior to prescribing a final rule.

M. Description of Materials Incorporated by Reference

In this NOPR, DOE proposes to incorporate by reference into 10 CFR part 430 the test standard published by AHAM, titled ''Uniform Test Method for Measuring the Energy Consumption of Dishwashers,'' AHAM DW–1–2020, and the test standard published by IEC, titled ''Household electrical appliances—Measurement of standby power,'' IEC 62301 Ed. 2.0 for both, appendix C1 and the new appendix C2. Additionally, DOE proposes to update the industry standard incorporated by reference in 10 CFR part 430 from ANSI/AHAM DW–1–2010 to AHAM DW–2–2020.

AHAM DW–1–2020 is a voluntary industry-accepted test procedure that measures the energy and water consumption of household electric dishwashers. The test procedure amendments proposed in this NOPR generally reference AHAM DW–1–2020 including provisions to address: Water hardness, relative humidity, ambient temperature, test load items, loading pattern, detergent, standby power measurement, dishwashers with 208 V power source, and water re-use system dishwashers. Additionally, this NOPR proposes to incorporate by reference AHAM DW–1–2020 in its entirety in the new appendix C2. In addition to the updates proposed to appendix C1, the new appendix C2 would include updated requirements for the annual number of cycles and calculation of low-power mode energy consumption.

DOE also proposes to incorporate by reference into 10 CFR part 430 AHAM DW–2–2020, ''Household Electric Dishwashers,'' which is a standard to determine the cleaning performance of dishwashers. For some of the provisions that DOE is proposing to reference from AHAM DW–1–2020, the standard references AHAM DW–2–2020; these include certain definitions and requirements for test cycle and load, soils, and detergent. Additionally, DOE's proposed requirements for evaluating cleaning performance in appendix C1 and the new appendix C2 would also be referenced from the relevant sections of AHAM DW–2–2020.

DOE also proposes to apply specified provisions of the IEC Standard, IEC 62301 Ed. 2.0, to the new appendix C2. IEC 62301 Ed. 2.0, already incorporated by reference into 10 CFR part 430 for application to appendix C1, is an international standard that specifies methods of measurement of electrical power consumption of household appliances in standby mode(s) and other low power modes, as applicable. The proposed new appendix C2 would include references to IEC 62301 Ed. 2.0 for the measurement of dishwasher standby power consumption.

Copies of AHAM DW–1–2020 and AHAM DW–2–2020 may be purchased from AHAM at 1111 19th Street NW, Suite 402, Washington, DC 20036; or by going to AHAM's online store at *www.aham.org/AHAM/AuxStore.*

Copies of IEC 62301 Ed. 2.0 can be obtained from—3, rue de Varembé, P.O. Box 131, CH—1211 Geneva 20—Switzerland, or by visiting *www.iec.ch.* Copies of the IEC standards are also available at American National Standards Institute, 25 W 43rd Street, 4th Floor, New York, NY 10036, (212) 642–4936, or by visiting *webstore.ansi.org.*

V. Public Participation

A. Participation in the Webinar

The time and date of the webinar are listed in the **DATES** section at the beginning of this document. If no participants register for the webinar, it will be cancelled. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website: *www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=38&action=viewlive.* Participants are responsible for ensuring their systems are compatible with the webinar software.

B. Procedure for Submitting Prepared General Statements for Distribution

Any person who has an interest in the topics addressed in this proposed rulemaking, or who is representative of a group or class of persons that has an interest in these issues, may request an opportunity to make an oral presentation at the webinar. Such persons may submit requests to speak by email to: *ApplianceStandardsQuestions@ee.doe.gov.* Persons who wish to speak should include with their request a computer file in WordPerfect, Microsoft Word, PDF, or text (ASCII) file format the briefly describes the nature of their interest in this rulemaking and the topics they wish to discuss. Such persons should also provide a daytime telephone number where they can be reached.

Persons requesting to speak should briefly describe the nature of their interest in this rulemaking and provide a telephone number for contact. DOE requests persons selected to make an oral presentation to submit an advance copy of their statements at least two weeks before the webinar. At its discretion, DOE may permit persons who cannot supply an advance copy of their statement to participate, if those persons have made advance alternative arrangements with the Building Technologies Office. As necessary, requests to give an oral presentation should ask for such alternative arrangements.

C. Conduct of the Webinar

DOE will designate a DOE official to preside at the webinar and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with Section 336 of EPCA (42 U.S.C. 6306). A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the webinar. There shall not be discussion of proprietary information, costs or prices, market share, or other commercial matters regulated by U.S. anti-trust laws. After the webinar and until the end of the comment period, interested parties may submit further comments on the proceedings and any aspect of the rulemaking.

The webinar will be conducted in an informal, conference style. DOE will present summaries of comments received before the webinar, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this rulemaking. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will allow, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly and comment on statements made by others. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this rulemaking. The official conducting the webinar will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the above procedures that may be needed for the proper conduct of the webinar.

A transcript of the webinar will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of this document and will be accessible on the DOE website. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule no later than the date provided in the **DATES** section at the beginning of this proposed rule.[42] Interested parties may submit comments using any of the methods described in the **ADDRESSES** section at the beginning of this NOPR.

Submitting comments via www.regulations.gov. The *www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (''CBI'')). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email. Comments and documents submitted via email will be posted to *www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. Following these instructions, the cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. No telefacsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to

[42] DOE has historically provided a 75-day comment period for test procedure NOPRs pursuant to the North American Free Trade Agreement, U.S.-Canada-Mexico (''NAFTA''), Dec. 17, 1992, 32 I.L.M. 289 (1993); the North American Free Trade Agreement Implementation Act, Public Law 103–182, 107 Stat. 2057 (1993) (codified as amended at 10 U.S.C.A. 2576) (1993) (''NAFTA Implementation Act''); and Executive Order 12889, ''Implementation of the North American Free Trade Agreement,'' 58 FR 69681 (Dec. 30, 1993). However, on July 1, 2020, the Agreement between the United States of America, the United Mexican States, and the United Canadian States (''USMCA''), Nov. 30, 2018, 134 Stat. 11 (*i.e.,* the successor to NAFTA), went into effect, and Congress's action in replacing NAFTA through the USMCA Implementation Act, 19 U.S.C. 4501 *et seq.* (2020), implies the repeal of E.O. 12889 and its 75-day comment period requirement for technical regulations. Thus, the controlling laws are EPCA and the USMCA Implementation Act. Consistent with EPCA's public comment period requirements for consumer products, the USMCA only requires a minimum comment period of 60 days. Consequently, DOE now provides a 60-day public comment period for test procedure NOPRs.

500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that they believe to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery/courier two well-marked copies: One copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked non-confidential with the information believed to be confidential deleted. Submit these documents via email to *ResDishwasher2016TP0012@ee.doe.gov* or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

E. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

(1) DOE requests comment on its proposal to incorporate by reference into 10 CFR part 430 the most recent version of the industry standard for dishwasher energy and water use measurement, AHAM DW–1–2020, as well as the industry performance standard, AHAM DW–2–2020, both with modifications. DOE seeks comment on its preliminary conclusion that the proposed modifications to the industry standards are necessary so that the DOE test method satisfies the requirements of EPCA.

(2) DOE requests comment on its proposal to require use of the water hardness requirements from Section 2.11 of AHAM DW–1–2020.

(3) DOE requests comment on its proposal to reference AHAM DW–1–2020 for the relative humidity and associated instrumentation requirements, which specifies a relative humidity test condition of 35 percent ±15 percent, and a resolution of at least 1 percent relative humidity and an accuracy of at least ±6 percent relative humidity over the temperature range of 75 °F ±5 °F for the relative humidity measuring device. To the extent that stakeholder have additional information, DOE requests data regarding the impact of relative humidity on dishwasher energy and water usage.

(4) DOE requests input on its proposal to specify a target nominal ambient temperature of 75 °F for active mode testing, as referenced from AHAM DW–1–2020.

(5) DOE requests comment on its proposal to reference in appendix C1 and the new appendix C2 the testing provisions from AHAM DW–1–2020 to address the Miele waiver for dishwashers that operate at 208-volts.

(6) DOE requests comment on its proposal to incorporate the requirements of the CNA waiver for any dishwasher with a built-in reservoir. In particular, DOE requests stakeholder feedback on using the detergent dosage requirement based on number of place settings rather than main wash water volume in the new appendix C2, for dishwashers with built-in reservoirs.

(7) DOE requests comment on its proposal to incorporate into appendix C1 and the new appendix C2 the installation requirements for in-sink dishwashers from the FOTILE waiver.

(8) DOE requests comment on its proposal that the detergent must be placed directly into the dishwasher chamber for any dishwasher that does not have a prewash or main wash detergent compartment.

(9) DOE requests input on its proposal to update the estimated number of annual cycles from 215 to 184 cycles per year for future calculations of EAEU. DOE also requests comment on its approach to propose a new appendix C2 with the updated annual number of cycles, the use of which would be required for compliance with any amended energy conservation standards.

(10) DOE requests comment on specifying that the test load items be as specified in AHAM DW–1–2020 (which references Section 3.4 of AHAM DW–2–2020), while additionally retaining, as an alternative, the current test load specifications in appendix C1 and the new appendix C2.

(11) DOE continues to request feedback and data regarding soiling level and whether there have been changes to consumers' pre-rinsing behavior. DOE also seeks information regarding the impact of different soil levels on energy and water use in dishwashers currently on the market.

(12) DOE requests comment on its proposal to remove the soil substitution and soil preparation requirements from Sections 2.7.4 and 2.7.5 of appendix C1 and apply these same requirements from AHAM DW–1–2020 instead. DOE particularly requests data and information on how the proposed soil composition would affect energy and water use in current dishwashers.

(13) DOE requests input on its proposal to use the loading requirements specified in Section 2.6.3.4 of AHAM DW–1–2020.

(14) DOE requests comment on its proposal to adopt in appendix C1 the new detergent and new dosage requirements as specified in AHAM DW–1–2020, while also retaining the current detergent and dosage requirements in appendix C1. The use of either set of detergent requirements would be allowable for testing under appendix C1. DOE also requests comment on the detergent currently being used by manufacturers and test laboratories for testing and certification of dishwashers.

(15) DOE also welcomes comments and data on the impact of the new detergent and dosage on energy and water use.

(16) DOE requests comment on its proposal to reference in appendix C1 and the new appendix C2 the testing provisions from AHAM DW–1–2020 to address the Whirlpool waiver for water re-use system dishwashers.

(17) DOE requests feedback on the proposed methodology to test, score, and calculate a cleaning index to validate the tested cycle and seeks comment if other methodologies should be considered for validating the cleaning performance of the tested cycle.

(18) DOE requests feedback on whether it should consider referencing Section 5.12.3.1 of AHAM DW–2–2020 to measure cleaning performance, which would calculate the cleaning index based on soil particles only. DOE notes that if it were to calculate cleaning index using soil particles only, it would reevaluate the per-cycle cleaning index threshold value to reflect this change.

(19) DOE requests feedback on the proposed cleaning index threshold value of 65 for each test cycle or whether it should consider a threshold value of 70 instead.

(20) DOE requests additional data on consumer dishwasher cycle selections. In particular, DOE requests data indicating the frequency with which consumers select the normal cycle; and, for cycles not conducted on the normal cycle, the frequency with which a more energy-intensive cycle is selected.

(21) DOE also requests additional data on how frequently consumers are dissatisfied with the cleaning performance of the normal cycle as well as the actions, and the frequency of each action, that consumers would take if the load is not satisfactorily clean.

(22) DOE requests feedback on its proposed approach to ensure that the test procedure produces test results which measure energy use and water use during a representative average use cycle.

(23) DOE requests comment on its proposal that, if a test cycle at a particular soil level is re-tested using the most energy-intensive cycle, the filter should be cleaned prior to testing the soil level at the most energy-intensive cycle.

(24) DOE requests feedback on its proposal to require testing non-soil-sensing dishwashers using a soiled load for the purpose of being able to evaluate the cleaning index of each tested cycle.

(25) DOE requests comment on its proposed approach for non-soil-sensing dishwashers; particularly that if a tested soil load meets the defined threshold criteria when tested on the normal cycle, no additional testing is required of cycles with lesser soil loads.

(26) DOE requests comment and data on the test cycles currently selected by manufacturers for rating the energy and water use of dishwashers compared to the test cycles that would be selected under the proposed cleaning index threshold of 65 as a condition for a valid test cycle. In particular, DOE requests data on the extent to which manufacturers would need to test a more-energy intensive cycle, or redefine the normal cycle, to meet the proposed cleaning index threshold of 65.

(27) DOE requests information on other potential methods to validate that the

measured energy and water consumption of dishwashers is representative of consumer use, such as the example approaches of applying an ''adder'' or multiplicative factor to the energy and water consumption values for any test cycles that do not achieve the defined cleaning index threshold. If stakeholders recommend such an approach, DOE requests data and information that could be used to determine this factor.

(28) DOE requests comment and related supporting data on whether this proposal would result in an altered measured energy use for dishwashers that are currently minimally-compliant with the existing energy conservation standards for dishwashers.

(29) DOE requests comment on whether the soil loads proposed for compact dishwashers that have a capacity of less than four place settings is appropriate. If stakeholders recommend different quantity of soils for such dishwashers, DOE requests feedback on the soil level that should be used for such small capacity dishwashers.

(30) DOE requests feedback on its proposed methodology for determining the most energy-intensive cycle. DOE also requests feedback on whether it should consider determination of the most energy-intensive cycle for sensor response test cycle using the respective soil load.

(31) DOE requests feedback on its proposal to require cleaning of the dishwasher filter prior to running the clean load test to determine the most energy-intensive test cycle.

(32) DOE requests input on its proposal to apply the standby mode and off mode test requirements from Section 4.2 of AHAM DW–1–2020 to appendix C1 and proposed new appendix C2.

(33) DOE requests comment on its proposal to use the updated combined low-power annual hours, specified in Section 5.7 of AHAM DW–1–2020, for the calculation of annual combined low-power mode energy consumption in the proposed new appendix C2.

(34) DOE requests feedback on connected dishwashers currently on the market. Specifically, DOE requests input on the types of features or functionality enabled by connected dishwashers that exist on the market or that are under development.

(35) DOE requests data on the percentage of users purchasing connected dishwashers, and, for those users, the percentage of the time when the connected functionality of the dishwashers is used.

(36) DOE requests data on the amount of additional or reduced energy use of connected dishwashers.

(37) DOE requests data on the pattern of additional or reduced energy use of connected dishwashers; for example, whether it is constant, periodic, or triggered by the user.

(38) DOE requests information on any existing testing protocols that account for connected features of dishwashers, as well as any testing protocols that may be under development within the industry.

(39) DOE requests comment on the proposal to update the standard size dishwasher, compact size dishwasher, and standard size dishwasher with a ''normal'' cycle time of 60 minutes or less descriptions at 10 CFR 430.32(f)(1)(i)–(iii). DOE also requests comment on the proposal to explicitly provide the method for determining cycle duration in appendices C1 and C2.

(40) DOE requests comment on its initial determination as to the impacts from the proposed amendments to appendix C1 related to the rated energy and water use of currently certified dishwashers. DOE also requests comment on the potential impact to manufacturers from the updates proposed to appendix C1. Finally, DOE requests comment on its estimated costs for testing soil-sensing and non-soil-sensing dishwashers according to the proposed appendix C1.

(41) DOE requests comment on the potential impact to manufacturers from the updates proposed to the newly proposed appendix C2. Specifically, DOE requests comment on the per basic model test costs associated with testing soil-sensing and non-soil-sensing dishwashers.

(42) DOE seeks comment on its findings that there are no small businesses that are OEMs of dishwashers in the United States. DOE also seeks comment on its conclusion that the proposed test procedure amendments would not have significant impacts on a substantial number of small manufacturers.

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of proposed rulemaking and request for comment.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Signing Authority

This document of the Department of Energy was signed on December 3, 2021, by Kelly J. Speakes-Backman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on December 8, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

For the reasons stated in the preamble, DOE is proposing to amend part 430 of Chapter II of Title 10, Code of Federal Regulations as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Amend § 430.3 by:

■ a. Redesignating paragraphs (i)(2) through (6) as (i)(3) through (7);

■ b. Adding a new paragraph (i)(2); and

■ c. Revising newly redesignated paragraphs (i)(3); and

■ d. Revising paragraph (o)(6).

The addition and revisions read as follows:

§ 430.3 Materials incorporated by reference.

* * * * *

(i) * * *

(2) ANSI/AHAM DW–1–2020 (''AHAM DW–1–2020''), Uniform Test Method for Measuring the Energy Consumption of Dishwashers, (approved October 2020), IBR approved for § 430.32 and appendices C1 and C2 to subpart B.

(3) AHAM DW–2–2020, Household Electric Dishwashers, (approved 2020), IBR approved for appendices C1 and C2 to subpart B.

* * * * *

(o) * * *

(6) IEC 62301 (''IEC 62301''), Household electrical appliances—Measurement of standby power, (Edition 2.0, 2011–01), IBR approved for appendices C1, C2, D1, D2, F, G, H, I, J2, N, O, P, Q, X, X1, Y, Z, BB, and CC to subpart B.

* * * * *

■ 3. Section 430.23 is amended by revising paragraph (c) to read as follows:

§ 430.23 Test procedures for the measurement of energy and water consumption.

* * * * *

(c) *Dishwashers.* (1) The Estimated Annual Operating Cost (EAOC) for dishwashers must be rounded to the nearest dollar per year and is defined as follows:

(i) When cold water (50 °F) is used,

$EAOC = (De \times ETLP) + (De \times N \times (M + MWS + MDO + MCO + EF - (ED/2)))$.

Where,

D_e = the representative average unit cost of electrical energy, in dollars per kilowatt-hour, as provided by the Secretary,

E_{TLP} = the annual combined low-power mode energy consumption in kilowatt-hours per year and determined according to section 5 of appendix C1 or appendix C2 to this subpart, as applicable,

N = the representative average dishwasher use of 215 cycles per year when EAOC is determined pursuant to appendix C1 to this subpart, and 184 cycles per year when EAOC is determined pursuant to appendix C2 to this subpart,

M = the machine energy consumption per cycle, in kilowatt-hours and determined according to section 5 of appendix C1 or appendix C2 to this subpart, as applicable,

M_{WS} = the machine energy consumption per cycle for water softener regeneration, in kilowatt-hours and determined pursuant to section 5 of appendix C1 or appendix C2 to this subpart, as applicable,

M_{DO} = for water re-use system dishwashers, the machine energy consumption per cycle during a drain out event in kilowatt-hours and determined according to section 5 of appendix C1 or appendix C2 to this subpart, as applicable,

M_{CO} = for water re-use system dishwashers, the machine energy consumption per cycle during a clean out event, in kilowatt-hours and determined according to section 5 of appendix C1 or appendix C2 to this subpart, as applicable,

E_F = the fan-only mode energy consumption per cycle, in kilowatt-hours and determined according to section 5 of appendix C1 or appendix C2 to this subpart, as applicable, and

E_D = the drying energy consumption, in kilowatt-hours and determined according to section 5 of appendix C1 or appendix C2 to this subpart, as applicable.

(ii) When electrically-heated water (120 °F or 140 °F) is used,

$EAOC = (D_e \times E_{TLP}) + (D_e \times N \times (M + M_{WS} + M_{DO} + M_{CO} + E_F - (E_D/2))) + (D_e \times N \times (W + W_{WS} + W_{DO} + W_{CO}))$.

Where,

D_e, E_{TLP}, N, M, M_{WS}, M_{DO}, M_{CO}, E_F, and E_D, are defined in paragraph (c)(1)(i) of this section,

W = the water energy consumption per cycle, in kilowatt-hours and determined according to section 5 of appendix C1 or appendix C2 to this subpart, as applicable,

W_{ws} = the water softener regeneration water energy consumption per cycle in kilowatt-hours and determined according to section 5 of appendix C1 or appendix C2 to this subpart, as applicable,

W_{DO} = The drain out event water energy consumption per cycle in kilowatt-hours and determined according to section 5 of appendix C1 or appendix C2 to this subpart, as applicable, and

W_{CO} = The clean out event water energy consumption per cycle in kilowatt-hours and determined according to section 5 of appendix C1 or appendix C2 to this subpart, as applicable.

(iii) When gas-heated or oil-heated water is used,

$EAOC_g = (D_e \times E_{TLP}) + (D_e \times N \times (M + M_{WS} + M_{DO} + M_{CO} + E_F - (E_D/2))) + (D_g \times N \times (W_g + W_{WSg} + W_{DOg} + W_{COg}))$.

Where,

D_e, E_{TLP}, N, M, M_{WS}, M_{DO}, M_{CO}, E_F, and E_D, are defined in paragraph (c)(1)(i) of this section,

D_g = the representative average unit cost of gas or oil, as appropriate, in dollars per BTU, as provided by the Secretary,

W_g = the water energy consumption per cycle, in Btus and determined according to section 5 of appendix C1 or appendix C2 to this subpart, as applicable.

W_{WSg} = the water softener regeneration energy consumption per cycle in Btu per cycle and determined according to section 5 of appendix C1 or appendix C2 to this subpart, as applicable,

W_{DOg} = the drain out water energy consumption per cycle in kilowatt-hours and determined according to section 5 of appendix C1 or appendix C2 to this subpart, as applicable, and

W_{COg} = the clean out water energy consumption per cycle in kilowatt-hours and determined according to section 5 of appendix C1 or appendix C2 to this subpart, as applicable.

(2) The estimated annual energy use, EAEU, expressed in kilowatt-hours per year must be rounded to the nearest kilowatt-hour per year and is defined as follows:

$EAEU = (M + M_{WS} + M_{DO} + M_{CO} + E_F - (E_D/2) + W + W_{WS} + W_{DO} + W_{CO}) \times N + E_{TLP}$

Where,

M, M_{WS}, M_{DO}, M_{CO}, E_F, E_D, E_{TLP} are all defined in paragraph (c)(1)(i) and W, W_{WS}, W_{DO}, W_{CO} are defined in paragraph (c)(1)(ii) of this section.

(3) The sum of the water consumption, V, the water consumption during water softener regeneration, V_{WS}, the water consumption during drain out events for dishwashers equipped with a water re-use system, V_{DO}, and the water consumption during clean out events for dishwashers equipped with a water re-use system, V_{CO}, expressed in gallons per cycle and defined pursuant to section 5 of appendix C1 or appendix C2 to this subpart, as applicable, must be rounded to one decimal place.

(4) Other useful measures of energy consumption for dishwashers are those which the Secretary determines are likely to assist consumers in making purchasing decisions and which are derived from the application of appendix C1 to this subpart or appendix C2 to this subpart, as applicable.

* * * * *

■ 4. Appendix C1 to subpart B of part 430 is revised to read as follows:

Appendix C1 to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Dishwashers

Note: Manufacturers must use the results of testing under this appendix (published on [*Date of Publication of the final rule*]) to determine compliance with the relevant standard from § 430.32(f)(1) as it appeared in the January 1, 2021 edition of 10 CFR parts 200–499. For any amended standards for dishwashers published after January 1, 2021, manufacturers must use the results of testing under appendix C2 to determine compliance. Representations related to energy or water consumption must be made in accordance with the appropriate appendix that applies (*i.e.,* appendix C1 or appendix C2) when determining compliance with the relevant standard. Manufacturers may also use appendix C2 to certify compliance with any amended standards prior to the applicable compliance date for those standards.

0. Incorporation by Reference

DOE incorporated by reference in § 430.3, AHAM DW–1–2020, AHAM DW–2–2020, and IEC 62301 in their entirety. The following enumerated provisions of AHAM DW–1–2020, AHAM DW–2–2020, and IEC 62301 are applicable to this appendix, as follows:

(1) AHAM DW–1–2020: Uniform Test Method for Measuring the Energy Consumption of Dishwashers

(i) Sections 1.1 through 1.30 as referenced in section 1 of this appendix;

(ii) Section 2.1 as referenced in sections 2 and 2.1 of this appendix;

(iii) Sections 2.2 through 2.3.3, sections 2.5 and 2.7, sections 2.7.2 through 2.8, and section 2.11, as referenced in section 2 of this appendix;

(iv) Section 2.4 as referenced in sections 2 and 2.2 of this appendix;

(v) Section 2.6.3 as referenced in sections 2 and 2.3 of this appendix;

(vi) Section 2.7.1 as referenced in sections 2 and 2.4 of this appendix;

(vii) Section 2.9 as referenced in sections 2 and 2.5 of this appendix;

(viii) Section 2.10 as referenced in sections 2 and 2.6 of this appendix;

(ix) Sections 3.1 through 3.2 and sections 3.5 through 3.7 as referenced in section 3 of this appendix;

(x) Section 3.3 as referenced in sections 3 and 3.1 of this appendix;

(xi) Section 3.4 as referenced in sections 3 and 3.2 of this appendix;

(xii) Sections 4.1 as referenced in sections 4 and 4.1 of this appendix;

(xiii) Section 4.1.4 as referenced in sections 4 and 4.1.2 of this appendix; and

(xiv) Section 5 as referenced in section 5 of this appendix.

(2) AHAM DW–2–2020: Household Electric Dishwashers

(i) Section 5.10 as referenced in sections 2 and 2.8 of this appendix;

(ii) Sections 5.10.1 as referenced in sections 4 and 4.2 of this appendix; and

(iii) Section 5.12.3.2 as referenced in sections 5 and 5.1 of this appendix.

(3) IEC 62301: Household Electrical Appliances—Measurement of Standby Power

(i) Sections 4.2, 4.3.2, and 5.2 as referenced in section 2 of this appendix; and

(ii) Sections 5.1, note 1, and 5.3.2 as referenced in section 4 of this appendix.

1. Definitions

The definitions in Section 1.1 through 1.30 of AHAM DW–1–2020 apply to this test procedure, including the applicable provisions of AHAM DW–2–2020 as referenced in Sections 1.5, 1.18, 1.19. 1.20, and 1.22 of AHAM DW–1–2020.

2. Testing Conditions

The testing conditions in Sections 2.1 through 2.11 of AHAM DW–1–2020, except Sections 2.6.1 and 2.6.2, and the testing conditions in Section 5.10 of AHAM DW–2–2020 apply to this test procedure, including the following provisions of:

(1) Sections 4.2, 4.3.2, and 5.2 of IEC 62301 as referenced in Sections 2.1, 2.2.4, and 2.5.2 of AHAM DW–1–2020, respectively, and

(2) Sections 5.3 through 5.8 of AHAM DW–2–2020 as referenced in Sections 2.6.3.1, 2.6.3.2, and 2.6.3.3; section 3.4 of AHAM DW–2–2020, excluding the accompanying Note, as referenced in Section 2.7.1 of AHAM DW–1–2020; Section 5.4 of AHAM DW–2–2020 as referenced in Section 2.7.4 of AHAM DW–1–2020; Section 5.5 of AHAM DW–2–2020 as referenced in Section 2.7.5 of AHAM DW–1–2020, and Section 4.1 of AHAM DW–2–2020 as referenced in Section 2.10.1 of AHAM DW–1–2020. Additionally, the following requirements are also applicable.

2.1 *Installation Requirements.*

The installation requirements described in Section 2.1 of AHAM DW–1–2020 are applicable to all dishwashers, with the following additions:

2.1.1 *In-Sink Dishwashers.*

For in-sink dishwashers, the requirements pertaining to the rectangular enclosure for under-counter or under-sink dishwashers are not applicable. For such dishwashers, the rectangular enclosure must consist of a front, a back, two sides, and a bottom. The front, back, and sides of the enclosure must be brought into the closest contact with the appliance that the configuration of the dishwasher will allow. The height of the enclosure shall be as specified in the manufacturer's instructions for installation height. If no instructions are provided, the enclosure height shall be 36 inches. The dishwasher must be installed from the top and mounted to the edges of the enclosure.

2.1.2 *Dishwashers without a Direct Water Line.*

Manually fill the built-in water reservoir to the full capacity reported by the manufacturer, using water at a temperature in accordance with Section 2.3 of AHAM DW–1–2020.

2.2 *Water pressure.*

The water pressure requirements described in Section 2.4 of AHAM DW–1–2020 are applicable to all dishwashers except dishwashers that do not have a direct water line.

2.3 *Non-soil-sensing and soil-sensing dishwashers to be tested at a nominal inlet temperature of 50 °F, 120 °F, or 140 °F.*

The test load and soiling requirements for all non-soil-sensing and soil-sensing dishwashers shall be the same as those requirements specified in Section 2.6.3 of AHAM DW–1–2020 for soil-sensing dishwashers. Additionally, both non-soil-sensing and soil-sensing compact dishwashers that have a capacity of less than four place settings shall be tested at the rated capacity of the dishwasher and the test load shall be soiled as follows at each soil load:

a. *Heavy soil load:* Soil two-thirds of the place settings, excluding flatware and serving pieces (rounded up to the nearest integer) or one place setting, whichever is greater;

b. *Medium soil load:* Soil one-quarter of the place settings, excluding flatware and serving pieces (rounded up to the nearest integer) or one place setting, whichever is smaller;

c. *Light soil load:* Soil one-quarter of the place settings, excluding flatware and serving pieces (rounded up to the nearest integer) or one place setting, whichever is smaller, using half the quantity of soils specified for one place setting.

2.4 *Test load items.*

The test load items described in Section 2.7.1 of AHAM DW–1–2020 apply to this test procedure, including the applicable provisions of AHAM DW–2–2020, as referenced in Section 2.7.1 of AHAM DW–1–2020. The following test load items may be used in the alternative.

Dishware/glassware/ flatware item	Primary source	Description	Primary No.	Alternate source	Alternate source No.
Dinner Plate	Corning Comcor®/Corelle®	10 inch Dinner Plate	6003893		
Bread and Butter Plate	Corning Comcor®/Corelle®	6.75 inch Bread & Butter.	6003887	Arzberg	8500217100 or 2000–00001–0217–1.
Fruit Bowl	Corning Comcor®/Corelle®	10 oz. Dessert Bowl	6003899	Arzberg	3820513100.
Cup	Corning Comcor®/Corelle®	8 oz. Ceramic Cup	6014162	Arzberg	1382–00001–4732.
Saucer	Corning Comcor®/Corelle®	6 inch Saucer	6010972	Arzberg	1382–00001–4731.
Serving Bowl	Corning Comcor®/Corelle®	1 qt. Serving Bowl	6003911		
Platter	Corning Comcor®/Corelle®	9.5 inch Oval Platter	6011655		
Glass—Iced Tea	Libbey		551 HT		
Flatware—Knife	Oneida®—Accent		2619KPVF	WMF—Gastro 0800	12.0803.6047.
Flatware—Dinner Fork	Oneida®—Accent		2619FRSF	WMF—Signum 1900	12.1905.6040.
Flatware—Salad Fork	Oneida®—Accent		2619FSLF	WMF—Signum 1900	12.1964.6040.
Flatware—Teaspoon	Oneida®—Accent		2619STSF	WMF—Signum 1900	12.1910.6040.
Flatware—Serving Fork	Oneida®—Flight		2865FCM	WMF—Signum 1900	12.1902.6040.
Flatware—Serving Spoon	Oneida®—Accent		2619STBF	WMF—Signum 1900	12.1904.6040.

2.5 *Preconditioning requirements.*

The preconditioning requirements described in Section 2.9 of AHAM DW–1–2020 are applicable to all dishwashers. For dishwashers that do not have a direct water line, measurement of the prewash fill water volume, V_{pw}, if any, and measurement of the main wash fill water volume, V_{mw}, are not taken.

2.6 *Detergent.*

The detergent requirements described in Section 2.10 of AHAM DW–1–2020 are applicable to all dishwashers. For any dishwasher that does not have a detergent compartment, determine the amount of main wash detergent (in grams) according to Section 2.10 of AHAM DW–1–2020, or as specified below, and place the detergent directly into the dishwasher chamber.

Additionally, the following detergent and dosage may also be used for all dishwashers. Note that if the detergent specified in Section 2.10 of AHAM DW–1–2020 is used, then the dosage requirements specified in Section 2.10 of AHAM DW–1–2020 must be used. Alternately, if the detergent specified below is used, the dosage requirements specified below must be used.

Use Cascade with the Grease Fighting Power of Dawn powder as the detergent formulation. For all dishwashers other than water re-use system dishwashers determine the amount of detergent (in grams) to be added to the prewash compartment (if provided) or elsewhere in the dishwasher (if recommended by the manufacturer) and the main wash compartment according to Sections 2.6.1 and 2.6.2 of this appendix.

2.6.1 *Detergent Dosing for Dishwashers other than Water Re-use System Dishwashers.*

2.6.1.1 *Prewash Detergent Dosing.* If the cycle setting for the test cycle includes prewash, determine the quantity of dry prewash detergent, $D_{pw,}$ in grams (g) that results in 0.25 percent concentration by mass in the prewash fill water as:

$$D_{pw} = V_{pw} \times \rho \times k \times 0.25/100$$

where,

V_{pw} = the prewash fill volume of water in gallons,

ρ = water density = 8.343 pounds (lb)/gallon for dishwashers to be tested at a nominal inlet water temperature of 50 °F (10 °C), 8.250 lb/gallon for dishwashers to be tested at a nominal inlet water temperature of 120 °F (49 °C), and 8.205 lb/gallon for dishwashers to be tested at a nominal inlet water temperature of 140 °F (60 °C), and

k = conversion factor from lb to g = 453.6 g/lb.

2.6.1.2 *Main Wash Detergent Dosing.* Determine the quantity of dry main wash detergent, $D_{mw,}$ in grams (g) that results in 0.25 percent concentration by mass in the main wash fill water as:

$$D_{mw} = V_{mw} \times \rho \times k \times 0.25/100$$

where,

V_{mw} = the main wash fill volume of water in gallons, and ρ and k are defined in Section 2.5.1.1 of this appendix.

For dishwashers that do not have a direct water line, the V_{mw} is equal to the manufacturer reported water capacity used in the main wash stage of the test cycle.

2.6.2 *Detergent Dosing for Water Re-use System Dishwashers.* Use the same detergent dosing requirement as specified in Section 2.10.2 of AHAM DW–1–2020.

2.7 *Connected functionality.*

For dishwashers that can communicate through a network (*e.g.,* Bluetooth® or internet connection), disable all network functions that can be disabled by means provided in the manufacturer's user manual, for the duration of testing. If network functions cannot be disabled by means provided in the manufacturer's user manual, conduct the standby power test with network function in the ''as-shipped'' condition.

2.8 *Evaluation Room Lighting Conditions.*

The lighting setup in the evaluation room where the test load is scored shall be according to the requirements specified in Section 5.10 of AHAM DW–2–2020.

3. Instrumentation

For this test procedure, the test instruments are to be calibrated annually according to the specifications in Sections 3.1 through 3.7 of AHAM DW–1–2020, including the applicable provisions of IEC 62301 as referenced in Section 3.6 of AHAM DW–1–2020. Additionally, the following requirements are also applicable.

3.1 *Water meter.*

The water meter requirements described in Section 3.3 of AHAM DW–1–2020 are applicable to all dishwashers except dishwashers that do not have a direct water line. For such dishwashers these water meter conditions do not apply and water is added manually pursuant to Section 2.1.1 of this appendix.

3.2 *Water pressure gauge.*

The water pressure gauge requirements described in Section 3.4 of AHAM DW–1–2020 are applicable to all dishwashers except dishwashers that do not have a direct water line. For such dishwashers these water pressure gauge conditions do not apply and water is added manually pursuant to Section 2.1.1 of this appendix.

4. Test Cycle and Measurements

The test cycle and measurement specifications in Sections 4.1 through 4.2 of AHAM DW–1–2020 and the scoring specifications in Section 5.10.1 of AHAM DW–2–2020 apply to this test procedure, including Section 5.1, note 1, and Section 5.3.2 of IEC 62301 as referenced in Section 4.2 of AHAM DW–1–2020. Additionally, the following requirements are also applicable.

4.1 *Active mode cycle.*

The active mode energy consumption measurement requirements described in Section 4.1 of AHAM DW–1–2020 are applicable to all dishwashers. Additionally, the following requirements are also applicable:

a. After the completion of each test cycle (sensor heavy response, sensor medium response, and sensor light response), the test load shall be scored according to Section 4.2 of this appendix and its cleaning index calculated according to Section 5.1 of this appendix.

b. A test cycle is considered valid if its cleaning index is 65 or higher; otherwise, the test cycle is invalid and the data from that test run is discarded.

c. For soil-sensing dishwashers, if the test cycle at any soil load is invalid, clean the dishwasher filter according to manufacturer's instructions and repeat the test at that soil load on the most energy-intensive cycle (determined as provided in Section 4.1.1 of this appendix) that achieves a cleaning index of 65 or higher.

d. For non-soil-sensing dishwashers, perform testing as described in Sections 4.1.a through 4.1.c of this appendix, except that, if a test cycle at a given soil load meets the cleaning index threshold criteria of 65 when tested on the normal cycle, no further testing is required for test cycles at lesser soil loads.

4.1.1 *Determination of most energy-intensive cycle.*

To determine the most energy-intensive cycle, ensure the filter is cleaned as specified in the manufacturer's instructions and test each available cycle type, selecting the default cycle options for that cycle type. In the absence of manufacturer recommendations on washing and drying temperature options, the highest energy consumption options must be selected. Following the completion of each test cycle, the machine electrical energy consumption and water consumption shall be measured according to Section 4.1.1 and 4.1.4 of AHAM DW–1–2020, respectively. The total cycle energy consumption, E_{MEI}, of each tested cycle type shall be calculated according to Section 5.2 of this appendix. The most energy-intensive cycle is the cycle type with the highest value of E_{MEI}.

For standard dishwashers, test each cycle with a clean load of eight place settings plus six serving pieces, as specified in Section 2.7 of AHAM DW–1–2020. For compact dishwashers, test each cycle with a clean load of four place settings plus six serving pieces, as specified in Section 2.7 of AHAM DW–1–2020. If the capacity of the dishwasher, as stated by the manufacturer, is less than four place settings, then the test load must be the stated capacity.

4.1.2 *Water consumption.*

The water consumption requirements described in Section 4.1.4 of AHAM DW–1–2020 are applicable to all dishwashers except dishwashers that do not have a direct water line. For such dishwashers these water consumption measurement requirements do not apply and water consumption, V, is the value reported by the manufacturer.

4.2 *Scoring*

Following the termination of an active mode test, each item in the test load shall be scored on a scale from 0 to 9 according to the instructions in Section 5.10.1 of AHAM DW–2–2020.

5. Calculation of Derived Results From Test Measurements

The calculations in Section 5.1 through 5.7 of AHAM DW–1–2020 and Section 5.12.3.2 of AHAM DW–2–2020 apply to this test procedure. The following additional requirements are also applicable:

a. In Sections 5.1.3, 5.1.4, 5.1.5, 5.4.3, 5.4.4, 5.4.5, and 5.7 of AHAM DW–1–2020, use N = 215 cycles/year in place of N = 184 cycles/year.

b. In Section 5.7 of AHAM DW–1–2020, use SLP = 8,465 for dishwashers that are not capable of operating in fan-only mode.

c. For both soil-sensing and non-soil-sensing dishwashers, use the equations specified for soil-sensing dishwashers.

d. If a non-soil-sensing dishwasher is not tested at a certain soil load as specified in Section 4.1.d of this appendix, use the energy and water consumption values of the preceding soil load when calculating the weighted average energy and water consumption values (*i.e.,* if the sensor medium response and sensor light response tests on the normal cycle are not conducted, use the values of the sensor heavy response test for all three soil loads; if only the sensor light response test is not conducted, use the values of the sensor medium response test for the sensor light response test).

e. For dishwashers that do not have a direct water line, water consumption is equal to the volume of water use in the test cycle, as specified by the manufacturer.

f. In Sections 5.6.1.3, 5.6.1.4, 5.6.2.3, and 5.6.2.4 of AHAM DW–1–2020, use (C/e) in place of K.

5.1 *Cleaning Index.*

Determine the per-cycle cleaning index for each test cycle using the equation in Section 5.12.3.2 of AHAM DW–2–2020.

5.2 *Calculation for determination of the most energy-intensive cycle type.*

The total cycle energy consumption for the determination of the most energy-intensive cycle specified in Section 4.1.1 of this appendix is calculated for each tested cycle type as:

$$E_{MEI} = M + E_F - (E_D/2) + W$$

where,

M = per-cycle machine electrical energy consumption, expressed in kilowatt hours per cycle,

E_F = fan-only mode electrical energy consumption, if available on the tested cycle type, expressed in kilowatt hours per cycle,

E_D = drying energy consumed using the power-dry feature after the termination of the last rinse option of the tested cycle

type, if available on the tested cycle type, expressed in kilowatt hours per cycle, and

W = water energy consumption and is defined as:

$V \times T \times K$, for dishwashers using electrically heated water, and

$V \times T \times C/e$, for dishwashers using gas-heated or oil-heated water.

Additionally,

V = water consumption in gallons per cycle,

T = nominal water heater temperature rise and is equal to 90 °F for dishwashers that operate with a nominal 140 °F inlet water temperature, and 70 °F for dishwashers that operate with a nominal 120 °F inlet water temperature,

K = specific heat of water in kilowatt-hours per gallon per degree Fahrenheit = 0.0024,

C = specific heat of water in Btu's per gallon per degree Fahrenheit = 8.2, and

e = nominal gas or oil water heater recovery efficiency = 0.75.

5.3 *Calculation of cycle duration.*

The cycle duration, t, expressed in hours, is calculated as:

$t = (t_{hr} \times F_{hr}) + (t_{mr} \times F_{mr}) + (t_{lr} \times F_{lr})$

where,

t_{hr} = the duration of the sensor heavy response cycle including the power-dry feature,

t_{mr} = the duration of the sensor medium response cycle including the power-dry feature,

t_{lr} = the duration of the sensor light response cycle including the power-dry feature,

F_{hr} = the weighting factor based on consumer use of heavy response = 0.05,

F_{mr} = the weighting factor based on consumer use of medium response = 0.33, and

F_{lr} = the weighting factor based on consumer use of light response = 0.62.

■ 5. Appendix C2 to subpart B of part 430 is added to read as follows:

Appendix C2 to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Dishwashers

Note: Manufacturers must use the results of testing under this appendix C2 to determine compliance with any standards for dishwashers provided in § 430.32(f)(1) that are published after January 1, 2021. Representations related to energy or water consumption must be made in accordance with the appropriate appendix that applies (*i.e.,* appendix C1 or appendix C2) when determining compliance with the relevant standard. Manufacturers may also use appendix C2 to certify compliance with any amended standards prior to the applicable compliance date for those standards.

0. Incorporation by Reference

DOE incorporated by reference in § 430.3, AHAM DW–1–2020, AHAM DW–2–2020, and IEC 62301 in their entirety. The following enumerated provisions of AHAM DW–1–2020, AHAM DW–2–2020, and IEC 62301 are applicable to this appendix, as follows:

(1) AHAM DW–1–2020: Uniform Test Method for Measuring the Energy Consumption of Dishwashers

(i) Sections 1.1 through 1.30 as referenced in section 1 of this appendix;

(ii) Section 2.1 as referenced in sections 2 and 2.1 of this appendix;

(iii) Sections 2.2 through 2.3.3, sections 2.5 and 2.7, sections 2.7.2 through 2.8, and section 2.11, as referenced in section 2 of this appendix;

(iv) Section 2.4 as referenced in sections 2 and 2.2 of this appendix;

(v) Section 2.6.3 as referenced in sections 2 and 2.3 of this appendix;

(vi) Section 2.7.1 as referenced in sections 2 and 2.4 of this appendix;

(vii) Section 2.9 as referenced in sections 2 and 2.5 of this appendix;

(viii) Section 2.10 as referenced in sections 2 and 2.6 of this appendix;

(ix) Sections 3.1 through 3.2 and sections 3.5 through 3.7 as referenced in section 3 of this appendix;

(x) Section 3.3 as referenced in sections 3 and 3.1 of this appendix;

(xi) Section 3.4 as referenced in sections 3 and 3.2 of this appendix;

(xii) Section 4.1 as referenced in sections 4 and 4.1 of this appendix;

(xiii) Section 4.1.4 as referenced in sections 4 and 4.1.2 of this appendix; and

(xiv) Section 5 as referenced in section 5 of this appendix.

(2) AHAM DW–2–2020: Household Electric Dishwashers

(i) Section 5.10 as referenced in sections 2 and 2.8 of this appendix;

(ii) Sections 5.10.1 as referenced in sections 4 and 4.2 of this appendix; and

(iii) Section 5.12.3.2 as referenced in sections 5 and 5.1 of this appendix.

(3) IEC 62301: Household Electrical Appliances—Measurement of Standby Power

(i) Sections 4.2, 4.3.2, and 5.2 as referenced in section 2 of this appendix; and

(ii) Sections 5.1, note 1, and 5.3.2 as referenced in section 4 of this appendix.

1. Definitions

The definitions in Sections 1.1 through 1.30 of AHAM DW–1–2020 apply to this test procedure, including the applicable provisions of AHAM DW–2–2020 as referenced in Sections 1.5, 1.18, 1.19, 1.20, and 1.22 of AHAM DW–1–2020.

2. Testing Conditions

The testing conditions in Section 2.1 through 2.11 of AHAM DW–1–2020, except Sections 2.6.1 and 2.6.2, and the testing conditions in Section 5.10 of AHAM DW–2–2020 apply to this test procedure, including the following provisions of:

(1) Sections 4.2, 4.3.2, and 5.2 of IEC 62301 as referenced in Sections 2.1, 2.2.4, and 2.5.2 of AHAM DW–1–2020, respectively, and

(2) Sections 5.3 through 5.8 of AHAM DW–2–2020 as referenced in Sections 2.6.3.1, 2.6.3.2, and 2.6.3.3; Section 3.4 of AHAM DW–2–2020, excluding the accompanying Note, as referenced in Section 2.7.1 of AHAM DW–1–2020; Section 5.4 of AHAM DW–2–2020 as referenced in Section 2.7.4 of AHAM DW–1–2020; Section 5.5 of AHAM DW–2–2020 as referenced in Section 2.7.5 of AHAM DW–1–2020, and Section 4.1 of AHAM DW–2–2020 as referenced in Section 2.10.1 of AHAM DW–1–2020. Additionally, the following requirements are also applicable.

2.1 *Installation Requirements.*

The installation requirements described in Section 2.1 of AHAM DW–1–2020 are applicable to all dishwashers, with the following additions:

2.1.1 *In-Sink Dishwashers.*

For in-sink dishwashers, the requirements pertaining to the rectangular enclosure for under-counter or under-sink dishwashers are not applicable. For such dishwashers, the rectangular enclosure must consist of a front, a back, two sides, and a bottom. The front, back, and sides of the enclosure must be brought into the closest contact with the appliance that the configuration of the dishwasher will allow. The height of the enclosure shall be as specified in the manufacturer's instructions for installation height. If no instructions are provided, the enclosure height shall be 36 inches. The dishwasher must be installed from the top and mounted to the edges of the enclosure.

2.1.2 *Dishwashers without a Direct Water Line.*

Manually fill the built-in water reservoir to the full capacity reported by the manufacturer, using water at a temperature in accordance with Section 2.3 of AHAM DW–1–2020.

2.2 *Water pressure.*

The water pressure requirements described in Section 2.4 of AHAM DW–1–2020 are applicable to all dishwashers except dishwashers that do not have a direct water line.

2.3 *Non-soil-sensing and soil-sensing dishwashers to be tested at a nominal inlet temperature of 50 °F, 120 °F, or 140 °F.*

The test load and soiling requirements for all non-soil-sensing and soil-sensing dishwashers shall be the same as those requirements specified in Section 2.6.3 of AHAM DW–1–2020 for soil-sensing dishwashers. Additionally, both non-soil-sensing and soil-sensing compact dishwashers that have a capacity of less than four place settings shall be tested at the rated capacity of the dishwasher and the test load shall be soiled as follows at each soil load:

a. *Heavy soil load:* Soil two-thirds of the place settings, excluding flatware and serving pieces (rounded up to the nearest integer) or one place setting, whichever is greater;

b. *Medium soil load:* Soil one-quarter of the place settings, excluding flatware and serving pieces (rounded up to the nearest integer) or one place setting, whichever is smaller;

c. *Light soil load:* Soil one-quarter of the place settings, excluding flatware and serving pieces (rounded up to the nearest integer) or one place setting, whichever is smaller, using half the quantity of soils specified for one place setting.

2.4 *Test load items.*

The test load items described in Section 2.7.1 of AHAM DW–1–2020 apply to this test procedure, including the applicable provisions of AHAM DW–2–2020, as referenced in Section 2.7.1 of AHAM DW–1–2020. The following test load items may be used in the alternative.

Dishware/glassware/ flatware item	Primary source	Description	Primary No.	Alternate source	Alternate source No.
Dinner Plate	Corning Comcor®/Corelle®	10 inch Dinner Plate	6003893		
Bread and Butter Plate	Corning Comcor®/Corelle®	6.75 inch Bread & Butter.	6003887	Arzberg	8500217100 or 2000–00001–0217–1
Fruit Bowl	Corning Comcor®/Corelle®	10 oz. Dessert Bowl	6003899	Arzberg	3820513100
Cup	Corning Comcor®/Corelle®	8 oz. Ceramic Cup	6014162	Arzberg	1382–00001–4732
Saucer	Corning Comcor®/Corelle®	6 inch Saucer	6010972	Arzberg	1382–00001–4731
Serving Bowl	Corning Comcor®/Corelle®	1 qt. Serving Bowl	6003911		
Platter	Corning Comcor®/Corelle®	9.5 inch Oval Platter	6011655		
Glass—Iced Tea	Libbey		551 HT		
Flatware—Knife	Oneida®—Accent		2619KPVF	WMF—Gastro 0800	12.0803.6047
Flatware—Dinner Fork	Oneida®—Accent		2619FRSF	WMF—Signum 1900.	12.1905.6040
Flatware—Salad Fork	Oneida®—Accent		2619FSLF	WMF—Signum 1900.	12.1964.6040
Flatware—Teaspoon	Oneida®—Accent		2619STSF	WMF—Signum 1900.	12.1910.6040
Flatware—Serving Fork	Oneida®—Flight		2865FCM	WMF—Signum 1900.	12.1902.6040
Flatware—Serving Spoon	Oneida®—Accent		2619STBF	WMF—Signum 1900.	12.1904.6040

2.5 *Preconditioning requirements*

The preconditioning requirements described in Section 2.9 of AHAM DW–1–2020 are applicable to all dishwashers except the measurement of the prewash fill water volume, V_{pw}, if any, and measurement of the main wash fill water volume, V_{mw}, are not required.

2.6 *Detergent.*

The detergent requirements described in Section 2.10 of AHAM DW–1–2020 are applicable to all dishwashers. For any dishwasher that does not have a detergent compartment, place the detergent directly into the dishwasher chamber.

2.7 *Connected functionality.*

For dishwashers that can communicate through a network (*e.g.,* Bluetooth® or internet connection), disable all network functions that can be disabled by means provided in the manufacturer's user manual, for the duration of testing. If network functions cannot be disabled by means provided in the manufacturer's user manual, conduct the standby power test with network function in the ''as-shipped'' condition.

2.8 *Evaluation Room Lighting Conditions.*

The lighting setup in the evaluation room where the test load is scored shall be according to the requirements specified in Section 5.10 of AHAM DW–2–2020.

3. Instrumentation

For this test procedure, the test instruments are to be calibrated annually according to the specifications in Section 3.1 through 3.7 of AHAM DW–1–2020, including the applicable provisions of IEC as referenced in Section 3.6 of AHAM DW–1–2020. Additionally, the following requirements are also applicable.

3.1 *Water meter.*

The water meter requirements described in Section 3.3 of AHAM DW–1–2020 are applicable to all dishwashers except dishwashers that do not have a direct water line. For such dishwashers these water meter conditions do not apply and water is added manually pursuant to Section 2.1.1 of this appendix.

3.2 *Water pressure gauge.*

The water pressure gauge requirements described in Section 3.4 of AHAM DW–1–2020 are applicable to all dishwashers except dishwashers that do not have a direct water line. For such dishwashers these water pressure gauge conditions do not apply and water is added manually pursuant to Section 2.1.1 of this appendix.

4. Test Cycle and Measurements

The test cycle and measurement specifications in Sections 4.1 through 4.2 of AHAM DW–1–2020 and the scoring specifications in Section 5.10.1 of AHAM DW–2–2020 apply to this test procedure, including Section 5.1, note 1, and Section 5.3.2 of IEC 62301 as referenced in Section 4.2 of AHAM DW–1–2020. Additionally, the following requirements are also applicable.

4.2 *Active mode cycle.*

The active mode energy consumption measurement requirements described in Section 4.1 of AHAM DW–1–2020 are applicable to all dishwashers. Additionally, the following requirements are also applicable:

a. After the completion of each test cycle (sensor heavy response, sensor medium response, and sensor light response), the test load shall be scored according to Section 4.2 of this appendix and its cleaning index calculated according to Section 5.1 of this appendix.

b. A test cycle is considered valid if its cleaning index is 65 or higher; otherwise, the test cycle is invalid and the data from that test run is discarded.

c. For soil-sensing dishwashers, if the test cycle at any soil load is invalid, clean the dishwasher filter according to manufacturer's instructions and repeat the test at that soil load on the most energy-intensive cycle (determined as provided in Section 4.1.1 of this appendix) that achieves a cleaning index of 65 or higher.

d. For non-soil-sensing dishwashers, perform testing as described in Section 4.1.a through 4.1.c of this appendix, except that, if a test cycle at a given soil load meets the cleaning index threshold criteria of 65 when tested on the normal cycle, no further testing is required for test cycles at lesser soil loads.

4.1.1 *Determination of most energy-intensive cycle.*

To determine the most energy-intensive cycle, ensure the filter is cleaned as specified in the manufacturer's instructions and test each available cycle type, selecting the default cycle options for that cycle type. In the absence of manufacturer recommendations on washing and drying temperature options, the highest energy consumption options must be selected. Following the completion of each test cycle, the machine electrical energy consumption and water consumption shall be measured according to Sections 4.1.1 and 4.1.4 of AHAM DW–1–2020, respectively. The total cycle energy consumption, E_{MEI}, of each tested cycle type shall be calculated according to Section 5.2 of this appendix. The most energy-intensive cycle is the cycle type with the highest value of E_{MEI}.

For standard dishwashers, test each cycle with a clean load of eight place settings plus six serving pieces, as specified in Section 2.7 of AHAM DW–1–2020. For compact dishwashers, test each cycle with a clean load of four place settings plus six serving pieces, as specified in Section 2.7 of AHAM DW–1–2020. If the capacity of the dishwasher, as stated by the manufacturer, is less than four place settings, then the test load must be the stated capacity.

4.1.2 *Water consumption.*

The water consumption requirements described in Section 4.1.4 of AHAM DW–1–2020 are applicable to all dishwashers except dishwashers that do not have a direct water line. For such dishwashers these water consumption measurement requirements do not apply and water consumption, V, is the value reported by the manufacturer.

4.2 *Scoring.*

Following the termination of an active mode test, each item in the test load shall be scored on a scale from 0 to 9 according to the instructions in Section 5.10.1 of AHAM DW–2–2020.

5. Calculation of Derived Results From Test Measurements

The calculations in Sections 5.1 through 5.7 of AHAM DW–1–2020 and Section 5.12.3.2 of AHAM DW–2–2020 apply to this test procedure. The following additional requirements are also applicable:

a. For both soil-sensing and non-soil-sensing dishwashers, use the equations specified for soil-sensing dishwashers.

b. If a non-soil-sensing dishwasher is not tested at a certain soil load as specified in Section 4.1.d of this appendix, use the energy and water consumption values of the preceding soil load when calculating the weighted average energy and water consumption values (*i.e.,* if the sensor medium response and sensor light response tests on the normal cycle are not conducted, use the values of the sensor heavy response test for all three soil loads; if only the sensor light response test is not conducted, use the values of the sensor medium response test for the sensor light response test).

c. For dishwashers that do not have a direct water line, water consumption is equal to the volume of water use in the test cycle, as specified by the manufacturer.

d. In Sections 5.6.1.3, 5.6.1.4, 5.6.2.3, and 5.6.2.4 of AHAM DW–1–2020, use (C/e) in place of K.

5.1 *Cleaning Index.*

Determine the per-cycle cleaning index for each test cycle using the equation in Section 5.12.3.2 of AHAM DW–2–2020.

5.2 *Calculation for determination of the most energy-intensive cycle type.*

The total cycle energy consumption for the determination of the most energy-intensive cycle specified in Section 4.1.1 of this appendix is calculated for each tested cycle type as:

$E_{MEI} = M + E_F - (E_D/2) + W$

where,

M = per-cycle machine electrical energy consumption, expressed in kilowatt hours per cycle,

E_F = fan-only mode electrical energy consumption, if available on the tested cycle type, expressed in kilowatt hours per cycle,

E_D = drying energy consumed using the power-dry feature after the termination of the last rinse option of the tested cycle type, if available on the tested cycle type, expressed in kilowatt hours per cycle, and

W = water energy consumption and is defined as:

$V \times T \times K$, for dishwashers using electrically heated water, and

$V \times T \times C/e$, for dishwashers using gas-heated or oil-heated water.

Additionally,

V = water consumption in gallons per cycle,

T = nominal water heater temperature rise and is equal to 90 °F for dishwashers that operate with a nominal 140 °F inlet water temperature, and 70 °F for dishwashers that operate with a nominal 120 °F inlet water temperature,

K = specific heat of water in kilowatt-hours per gallon per degree Fahrenheit = 0.0024,

C = specific heat of water in Btu's per gallon per degree Fahrenheit = 8.2, and

e = nominal gas or oil water heater recovery efficiency = 0.75.

5.3 *Calculation of cycle duration.*

The cycle duration, t, expressed in hours, is calculated as:

$t = (t_{hr} \times F_{hr}) + (t_{mr} \times F_{mr}) + (t_{lr} \times F_{lr})$

where,

t_{hr} = the duration of the sensor heavy response cycle including the power-dry feature,

t_{mr} = the duration of the sensor medium response cycle including the power-dry feature,

t_{lr} = the duration of the sensor light response cycle including the power-dry feature,

F_{hr} = the weighting factor based on consumer use of heavy response = 0.05,

F_{mr} = the weighting factor based on consumer use of medium response = 0.33, and

F_{lr} = the weighting factor based on consumer use of light response = 0.62.

■ 6. Section 430.32 is amended by revising paragraph (f)(1) to read as follows:

§ 430.32 Energy and water conservation standards and their compliance dates.

* * * * *

(f) *Dishwashers.* (1) All dishwashers manufactured on or after May 30, 2013, shall meet the following standard—

(i) Standard size dishwashers shall not exceed 307 kwh/year and 5.0 gallons per cycle. Standard size dishwashers have a capacity equal to or greater than eight place settings plus six serving pieces as specified in AHAM DW–1–2020 (incorporated by reference, see § 430.3) using the test load specified in section 2.4 of appendix C1 or appendix C2 in subpart B of this part, as applicable.

(ii) Compact size dishwashers shall not exceed 222 kwh/year and 3.5 gallons per cycle. Compact size dishwashers have a capacity less than eight place settings plus six serving pieces as specified in AHAM DW–1–2020 using the test load specified in section 2.4 of appendix C1 or appendix C2 in subpart B of this part, as applicable.

(iii) Standard size dishwashers with a ''normal cycle'', as defined in AHAM DW–1–2020, of 60 minutes or less are not currently subject to energy or water conservation standards. Standard size dishwashers have a capacity equal to or greater than eight place settings plus six serving pieces as specified in AHAM DW–1–2020 using the test load specified in section 2.4 of appendix C1 or appendix C2 in subpart B of this part, as applicable. ''Normal cycle'' duration is determined according to section 5.3 of appendix C1 or appendix C2 in subpart B of this part, as applicable.

* * * * *

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The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available at *https://www.govinfo.gov*. Some laws may not yet be available.

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To redesignate the Federal building located at 167 North Main Street in Memphis, Tennessee as the ''Odell Horton Federal Building''. (Dec. 21, 2021; 135 Stat. 1515)

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