

# Proposed Rules

Federal Register

Vol. 84, No. 84

Wednesday, May 1, 2019

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 ENERGY

### 10 CFR Parts 430 and 431

[EERE-2019-BT-NOA-0011]

RIN 1904-AE24

#### Test Procedure Interim Waiver Process

**AGENCY:** Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy.

**ACTION:** Notice of proposed rulemaking; request for comment.

**SUMMARY:** The U.S. Department of Energy (DOE) proposes to streamline its test procedure waiver decision-making process to require the Department to notify, in writing, an applicant for an interim waiver of the disposition of the request within 30 business days of receipt of the application. Should DOE fail to satisfy this requirement, the request for interim waiver would be deemed granted based on the criteria in DOE regulations. Specifically, DOE regulations require that DOE grant an interim waiver if it determines that it is desirable for public policy reasons to grant immediate relief pending a determination of the petition for waiver. An interim waiver would remain in effect until a waiver decision is published or until DOE publishes a new or amended test procedure that addresses the issues presented in the application, whichever is earlier. This proposal is intended to address delays in DOE's current process for considering requests for interim waivers and waivers from the DOE test method, which in turn can result in significant delays for manufacturers in bringing new and innovative products to market.

**DATES:** The comment period for this proposed rule will end on July 1, 2019.

**ADDRESSES:** You may submit comments, identified by docket number [EERE-2019-BT-NOA-0011], and/or Regulation Identification Number (RIN) 1904-AE24 in one of four ways (please select only one of the ways listed):

1. *Federal e-Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

2. *Email:* [TPWaiverProcess2019NOA0011@ee.doe.gov](mailto:TPWaiverProcess2019NOA0011@ee.doe.gov). Include docket number [EERE-2019-BT-NOA-0011] and/or RIN 1904-AE24 in the subject line of the email. Please include the full body of your comments in the text of the message or as an attachment. If you have additional information such as studies or journal articles and cannot attach them to your electronic submission, please send them on a CD or USB flash drive to the address listed in paragraph 4. The additional material must clearly identify your electronic comments by name, date, subject, and docket number [EERE-2019-BT-NOA-0011].

3. *Mail:* Address written comments to Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE-5B, 1000 Independence Avenue SW, Washington, DC 20585-0121 (due to potential delays in DOE's receipt and processing of mail sent through the U.S. Postal Service, we encourage respondents to submit comments electronically to ensure timely receipt). If possible, please submit all items on a CD or USB flash drive, in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, Suite 600, Washington, DC 20024. Telephone (202) 287-1445. If possible, please submit all items on a CD or USB flash drive, in which case it is not necessary to include printed copies.

For detailed instructions on submitting comments and additional information on the rulemaking process, see Section IV of this document (Public Participation).

*Docket:* The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at <http://www.regulations.gov>. All documents in the docket are listed in the <http://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. A link to the docket web page

can be found at: <http://www.regulations.gov/docket?D=EERE-2019-BT-NOA-0011>. The <http://www.regulations.gov> web page contains instructions on how to access all documents, including public comments, in the docket. See Section IV of this document (Public Participation) for further information on how to submit comments through <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Ms. Jennifer Tiedeman, U.S. Department of Energy, Office of the General Counsel, GC-33, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (202) 287-6111. Email: [Jennifer.Tiedeman@hq.doe.gov](mailto:Jennifer.Tiedeman@hq.doe.gov).

#### SUPPLEMENTARY INFORMATION:

- I. Legal Background
- II. Discussion of Proposed Amendments
- III. Discussion of Data
- IV. Procedural Requirements
  - A. Review Under Executive Orders 12866 and 13563
  - B. Review Under Executive Orders 13771 and 13777
  - C. Review Under the Regulatory Flexibility Act
  - D. Review Under the Paperwork Reduction Act
  - E. Review Under the National Environmental Policy Act
  - F. Review Under Executive Order 12988
  - G. Review Under Executive Order 13132
  - H. Review Under Executive Order 13175
  - I. Review Under the Unfunded Mandates Reform Act of 1995
  - J. Review Under Executive Order 13211
  - K. Review Under the Treasury and General Government Appropriations Act, 1999
  - L. Review Under the Treasury and General Government Appropriations Act, 2001
- V. Public Participation
  - A. Submission of Information
  - B. Issues on Which DOE Seeks Information
- VI. Approval of the Office of the Secretary

#### I. Legal Background

The Energy Policy and Conservation Act of 1975 ("EPCA" or "the Act"),<sup>1</sup> Public Law 94-163 (42 U.S.C. 6291-6317) authorizes DOE to regulate the energy efficiency of a number of consumer products and industrial equipment types. Title III, Part B<sup>2</sup> of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles. Title

<sup>1</sup> All references to EPCA in this document refer to the statute as amended through the Energy Efficiency Improvement Act of 2015, Public Law 114-11 (April 30, 2015).

<sup>2</sup> For editorial reasons, Part B was redesignated as Part A upon codification in the U.S. Code.

III, Part C<sup>3</sup> of EPCA established the Energy Conservation Program for Certain Industrial Equipment. Under EPCA, DOE's energy conservation program consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures.

The Federal testing requirements consist of test procedures that manufacturers of covered products and equipment must use as the basis for: (1) Certifying to DOE that their products or equipment complies with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6295(s); 42 U.S.C. 6316(a)), and (2) making representations about the efficiency of those products or equipment (42 U.S.C. 6293(c); 42 U.S.C. 6314(d)). Similarly, DOE must use these test procedures to determine whether the products or equipment complies with relevant standards promulgated under EPCA. (42 U.S.C. 6295(s); 42 U.S.C. 6316 (a))

Under 42 U.S.C. 6293 and 6314, EPCA sets forth the criteria and procedures DOE is required to follow when prescribing or amending test procedures for covered products and equipment. EPCA requires that test procedures must be reasonably designed to produce test results that reflect energy efficiency, energy use or estimated annual operating cost of a covered product or covered equipment during a representative average use cycle or period of use and requires that test procedures not be unduly burdensome to conduct (42 U.S.C. 6293(b)(3); 42 U.S.C. 6314(a)(2)). DOE's regulations provide that upon receipt of a petition, DOE will grant a waiver from the test procedure requirements if DOE determines either that the basic model for which the waiver was requested contains a design characteristic that prevents testing of the basic model according to the prescribed test procedures, or that the prescribed test procedures evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 430.27(a)(1) and 10 CFR 431.401(f)(2). DOE may grant the waiver subject to conditions, including adherence to alternate test procedures.

In addition to the full waiver ("decision and order") described above, the waiver process permits parties submitting a petition for waiver to also file an application for interim waiver from the applicable test procedure

requirements. 10 CFR 430.27(a) and 10 CFR 431.401(a). The current regulations specify that, if administratively feasible, DOE will notify the applicant in writing of the disposition of a petition for interim waiver within 30 business days of receipt of the application. The Assistant Secretary will grant an interim waiver if it appears likely that the petition for waiver will be granted, and/or the Assistant Secretary determines that it would be desirable for public policy reasons to grant immediate relief pending a determination of the petition for waiver. 10 CFR 430.27(e)(2) and 10 CFR 430.401(e)(2). Notice of DOE's determination on the petition for interim waiver will also be published in the **Federal Register**. 10 CFR 430.27(e)(1) and 10 CFR 431.401(e)(1). Within one year of issuance of an interim waiver, DOE will either: (i) Publish in the **Federal Register** a determination on the petition for waiver; or (ii) publish in the **Federal Register** a new or amended test procedure that addresses the issues presented in the waiver. 10 CFR 430.27(h)(1) and 10 CFR 431.401(h)(2). When DOE amends the test procedure to address the issues presented in a waiver, the waiver will automatically terminate on the date on which use of that test procedure is required to demonstrate compliance. 10 CFR 430.27(h)(2) and 10 CFR 431.401(h)(2).

## II. Discussion of Proposed Amendments

In this proposed rule, DOE is proposing amendments to its regulations that would reduce manufacturers' burden associated with the interim waiver application process, provide them with greater certainty, and speed the availability of innovative product options to consumers. DOE's proposal responds to stakeholder concerns regarding lengthy waiting times following submission of interim waiver and waiver applications, and the burden that lengthy processing time imposes on manufacturers, who are unable to sell their products or equipment absent an interim waiver or waiver from DOE.<sup>4</sup> This burden may be especially pronounced for manufacturers of seasonal appliances, such as room air conditioners, in cases where interim waiver delays cause a product to miss the applicable seasonal sale window.

Specifically, this proposal is intended to address delays in DOE's current process for considering requests for

interim waivers and waivers from the DOE test method, which in turn can result in significant delays for manufacturers in bringing new and innovative products to market. DOE has in the past incurred delays by not responding to petitions in a timely manner, and this delay has imposed negative consequences for manufacturers who cannot bring their products to market absent a waiver from the Department that allows them to test their products and certify them as compliant with DOE energy conservation standards. Additional information on the length and cost to manufacturers of the delays is described in Section III. DOE's proposal would ensure that manufacturers would need to wait only a maximum of 30 business days before selling products under an approved interim waiver. If the petition for waiver ultimately requires the use of a different test method than that granted under the interim waiver, manufacturers would have an additional grace period of 180 days to begin using the test method required by the waiver.

DOE regulations currently require the Department to notify an applicant in writing of the disposition of a petition for interim waiver within 30 business days of receipt of the application "[i]f administratively feasible." 10 CFR 430.27(e)(1) and 10 CFR 431.401(e)(1). DOE proposes in this notice to amend 10 CFR 430.27(e)(1) and 10 CFR 431.401(e)(1) to require the Department to issue decisions on interim waiver applications within 30 business days, removing the language "[i]f administratively feasible." Under the proposal, an application for interim waiver would be deemed granted, thereby permitting use of the alternate test procedure suggested by the applicant in its application, if DOE fails to notify the applicant in writing of the disposition of an application within 30 business days of receipt of the application. DOE's decision on the interim waiver request will not depend on DOE's view of the sufficiency of the associated petition for waiver, because DOE can work with the petitioner to gather any additional information or conduct any additional analysis deemed necessary to reach a decision on the petition while the manufacturer is able to sell the product or equipment at issue under the interim waiver. DOE's regulations specify that DOE may grant an interim waiver if DOE determines that it would be desirable for public policy reasons to grant immediate relief pending a determination of the petition for waiver. 10 CFR 430.27(e)(2) and 10 CFR 430.401(e)(2).

<sup>3</sup> For editorial reasons, Part C was redesignated as Part A-1 upon codification in the U.S. Code.

<sup>4</sup> See, e.g., <https://energy.gov/sites/prod/files/2018/01/f46/NAFEM%20Regulatory%20Reform%20Roundtable%20Meeting%20Notes%20-%202010.31.17.pdf>.

Because manufacturers may not distribute covered products or equipment in commerce without demonstrating compliance with an applicable energy conservation standard pursuant to testing under the DOE test procedure or a waiver or interim waiver approved by DOE, DOE determines that it is desirable for public policy reasons, including burden reduction on regulated parties and administrative efficiency, to grant immediate relief on each application for interim waiver where DOE has not notified the applicant of its interim waiver decision within the 30-business day period.<sup>5</sup>

This proposal would dovetail with DOE’s proposed amendments to 10 CFR 430.27(h) and 10 CFR 431.401(h), which would specify that an interim waiver remains in effect until the earlier of the following: (1) DOE publishes in the **Federal Register** a determination on the petition for waiver or (2) DOE publishes in the **Federal Register** a new or amended test procedure that addresses the issues presented in the waiver application. Under these proposals, manufacturers would receive a decision on their application from DOE within a reasonable time period and would no longer be precluded from distributing covered products or equipment in commerce while waiting for DOE to conclude its analysis, which often stretches significantly beyond 30 business days (see section III, Discussion of Data).

DOE’s intent in issuing these proposals is to provide certainty to regulated entities while reducing

regulatory burden and achieving cost savings for manufacturers by reducing the delay in revenue from products pending an interim waiver. Manufacturers who cannot test their products under the DOE test procedure or for whom use of the test procedure produces results that do not reflect the energy consumption of their products cannot sell their products absent an interim waiver or waiver from DOE. To the extent that DOE previously has issued interim waiver decisions in excess of 30 business days after receipt of petitions, the time saved under this proposal is expected to significantly reduce the costs imposed on these manufacturers who cannot sell their products during the time it takes DOE to process an application for interim waiver or waiver request. Additionally, the certainty of a prescribed period prior to the issuance of a decision by the Department should provide manufacturers better information with which to plan for testing requirements. Manufacturers would also be able to proceed with distribution under the interim waiver pending any decision on a waiver application or publication of a new or amended test procedure by the Department. The expected cost savings from this proposed rule, if adopted, are discussed in Section III of this document.

DOE also proposes that if DOE ultimately denies the petition for waiver or grants the petition with a different alternate test procedure than specified in the interim waiver, DOE will provide a grace period of 180 days for the

manufacturer to begin to use the alternate test procedure specified in the decision and order on the petition. This is consistent with the EPCA provision providing 180 days from issuance of a new or amended test procedure for manufacturers to begin using the test procedure for representations of energy efficiency. *See* 42 U.S.C. 6293(c)(2).

*Issue:* DOE requests comment on its proposal to specify that an interim waiver would remain in effect until the earlier of the following: A waiver decision is published or DOE publishes a new or amended test procedure that addresses the issues presented in the waiver.

**III. Discussion of Data**

DOE has reviewed data on the time lags between receipt of an application for interim waiver and issuance of an interim waiver. To the extent that this proposed change would deem as granted interim waiver applications that would be eventually granted under DOE’s current process for granting waivers, DOE anticipates cost savings to accrue to manufacturers and consumer surplus to accrue to consumers who benefit from the timely availability of desired products.

Between 2016 and 2018, DOE received 40 waiver applications, 33 of which also included a request for an interim waiver. Of these, two waivers were withdrawn and one waiver was delayed pending ongoing litigation. DOE presents data on the remaining 37 waiver applications below.<sup>6</sup>

**TOTAL WAIVERS REQUESTED 2016–2018**

Waivers requested .....	40
% of waivers concluded in under 1 year .....	69
% of waivers concluded in over 1 year .....	31
Interim waivers requested .....	32
% of interim waivers concluded in under 100 days .....	20
% of interim waivers concluded in more than 100 days .....	80

Although DOE regulations specify that, if administratively feasible, DOE will notify the applicant in writing of the disposition of a petition for interim waiver within 30 business days of receipt of the application, only one of

the interim waiver requests in this dataset met this timeframe; one-fifth of interim waiver requests were resolved in under 100 days. On average, interim waiver requests received in 2016 took 162 days to resolve; those received in

2017 took 202 days on average, and those received in 2018 took on average 208 days.<sup>7</sup> This significantly exceeds DOE’s objective of turning around interim waiver petitions within 30 business days, or approximately 45

<sup>5</sup> DOE notes that granting an interim waiver application, as proposed, is not a final agency action as contemplated by the Administrative Procedure Act (APA). The APA defines an “agency action” as including “the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act.” 5 U.S.C. 551(13). The Supreme Court has explained that to be “final,” an agency action must “mark the consummation of the agency’s decision making process, and must either determine rights or obligations or occasion legal consequences.” *Alaska*

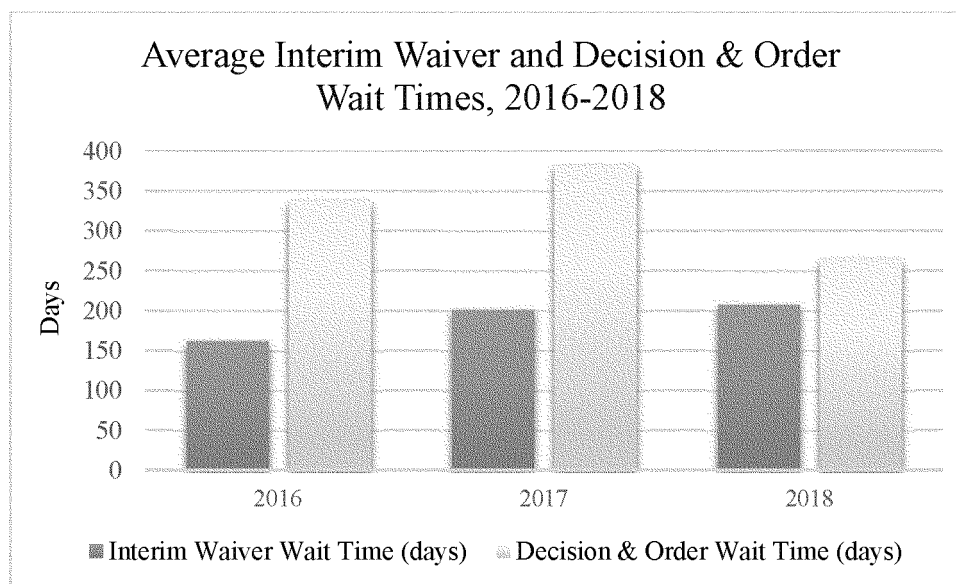
*Dep’t of Env’tl. Conservation v. EPA*, 540 U.S. 461, 482 (2004) (quotation omitted); *see Bennett v. Spear*, 520 U.S. 154, 178 (1997). In this case, interim waivers do not represent the consummation of the Department’s decision making process. Indeed, while manufacturers would be able to test and distribute their products or equipment in commerce if granted an interim waiver under the proposal, DOE regulations still contemplate issuance of a final decision on the associated petition for waiver, or a final rule amending the test procedure. Either of these actions could have rights

or obligations, or consequences, that differ from those provided temporarily under an interim waiver.

<sup>6</sup> In 2016, five of the applications for waiver, four of which included a request for an interim waiver, were addressed in a single final rule amending the test procedures for central air conditioners and heat pumps (81 FR 36991). DOE did not act on the four requests for interim waiver, and there is no accompanying data on the time lag associated with these interim waiver requests.

days. In 2017 alone, four requests for interim waiver took longer than 350 days each to resolve.

interim waiver took longer than 350 days each to resolve.



This time lag between submission of waiver and interim waiver requests and DOE's decision on interim waivers would be somewhat less significant if waiver decisions and orders were issued in a timely manner. However, on average it took DOE nearly one year to issue decisions and orders on waiver petitions submitted in 2016 and 2017.<sup>8</sup> As of this writing, DOE had one outstanding petition for waiver from 2016 and 3 outstanding petitions submitted in 2017, and has yet to reach a decision on 90% of the petitions for waiver received in 2018. These data illustrate the need for issuance of a timely interim waiver while the full waiver application is pending. Enhancing the efficiency of DOE's interim waiver approval process has the potential to reduce uncertainty for manufacturers and provide consumers with more options.

*Issue:* DOE requests comment on the length of time manufacturers have previously waited for DOE to provide notification of the disposition of applications for interim waiver (or final decisions on waiver petitions), and the correlated extent of cost savings and any other benefits they expect to realize as a result of the proposal to specify in the regulations that if the Department fails to issue an interim waiver decision within 30 business days following

receipt of an application, the application is deemed granted. DOE seeks, in particular, comment on whether interim waiver delays have affected the availability of seasonal products during peak season, and the effects of these delays on manufacturers and consumers.

#### IV. Procedural Requirements

##### A. Review Under Executive Order 12866 and 13563

This regulatory action has been determined to be "significant" under Executive Order 12866, "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Accordingly, this action was subject to review under that Executive Order by the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB).

DOE has also reviewed this proposed regulation pursuant to Executive Order 13563, issued on January 18, 2011 (76 FR 3281, Jan. 21, 2011). E.O. 13563 is supplemental to and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, agencies are required by Executive Order 13563 to: (1) Propose or adopt a regulation only upon a reasoned determination

that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public. DOE concludes that this proposed rule is consistent with these principles. The proposed amendments to DOE's regulations are intended to expedite DOE's processing of test procedure interim waiver applications, thereby reducing financial and administrative burdens for all manufacturers; as such, the proposed

<sup>7</sup> Fifty percent of the requests for interim waiver received in 2018 were still pending resolution as of this writing; as a result, totals for 2018 will continue to increase until these requests are concluded.

<sup>8</sup> 2018 data is omitted here as only one decision and order has yet been issued for waivers requested in 2018 and all remaining requests are still pending. Multiple requests for waiver received in 2017 were also still pending as of this writing; as a result,

totals for 2017 and 2018 will continue to increase until these requests are concluded.

rule satisfies the criteria in Executive Order 13563.

*B. Review Under Executive Orders 13771 and 13777*

On January 30, 2017, the President issued Executive Order 13771, “Reducing Regulation and Controlling Regulatory Costs.” That Order stated the policy of the executive branch is to be prudent and financially responsible in the expenditure of funds, from both public and private sources. The Order stated that it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations. DOE considers this proposed rule to be an E.O. 13771 deregulatory action, resulting in expected cost savings to manufacturers.

Additionally, on February 24, 2017, the President issued Executive Order 13777, “Enforcing the Regulatory Reform Agenda.” The Order required the head of each agency designate an agency official as its Regulatory Reform Officer (RRO). Each RRO shall oversee the implementation of regulatory reform initiatives and policies to ensure that agencies effectively carry out regulatory reforms, consistent with applicable law. Further, E.O. 13777 requires the establishment of a regulatory task force at each agency. The regulatory task force will make recommendations to the agency head regarding the repeal, replacement, or modification of existing regulations, consistent with applicable law. At a minimum, each regulatory reform task force shall attempt to identify regulations that:

- (i) Eliminate jobs, or inhibit job creation;
- (ii) Are outdated, unnecessary, or ineffective;
- (iii) Impose costs that exceed benefits;
- (iv) Create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies;
- (v) Are inconsistent with the requirements of Information Quality Act, or the guidance issued pursuant to that Act, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; or
- (vi) Derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.

As noted, this proposed rule is deregulatory, and is expected to reduce both financial and administrative burdens on regulated parties. Specifically, the proposed amendments to DOE’s regulations discussed in the proposal should improve upon current waiver regulations, which potentially are inhibiting job creation; are ineffective in creating certainty for manufacturers with respect to business decisions; and impose costs that exceed benefits. Specifically, the length of time manufacturers have previously waited for DOE to provide notification of the disposition of applications for interim waiver (or final decisions on waiver petitions), made possible by the open-ended nature of the current regulations, would be significantly shortened by the current proposal. As noted above, the cost savings and other benefits manufacturers should realize by waiting no more than 30 days for an interim waiver should create cost savings, as manufacturers would be able to introduce their products and equipment into commerce in a timely fashion. These cost savings may lead to increased job creation, and create other potentially significant economic benefits.

*i. National Cost Savings and Foregone Benefits*

The primary anticipated cost saving is from reducing the number of days by which manufacturer revenues are delayed for affected products. This value is monetized using the interest that a manufacturer might have earned on product revenue if an interim waiver were approved within 30 business days (approximately 45 days). On average, between 2016 and 2018, DOE concluded interim waivers after 185 days, or 140 days beyond the 30 business days specified in DOE’s regulations. DOE uses 7% interest per the Office of Management and Budget’s Circular A–4,<sup>9</sup> and calculates the foregone interest that could have accrued for each affected product during the 140 day delay period.

DOE monetized the scope of delay using average prices for products in

interim waiver petitions and the proportion of affected shipments, based on the proportion of basic models listed in interim waiver petitions relative to the total number of basic models within each product category. A full list of petitions for interim waiver can be accessed at <https://www.energy.gov/eere/buildings/current-test-procedure-waivers>. This list indicates how many interim waiver petitions were received for each product category. Each petition for interim waiver also lists the number of affected basic models, which DOE used to assess the proportion of shipments affected by each petition. Total numbers of basic models per product category are accessible via the DOE’s Compliance Certification Database.<sup>10</sup>

Between 2016 and 2018, 5,322 basic models of 12 residential and commercial products were affected by interim waiver delays, totaling 1.31 million in estimated annual shipments and \$1.76 billion in annual sales. The affected products are outlined in Table IV.B.1 below.<sup>11</sup> While all affected shipments are represented in Table IV.B.1 below, DOE monetized the cost of delay only for those basic models for which manufacturers would be unable to test or certify absent an interim waiver. For one petition, the manufacturer was unable to test or certify half of the basic models requested absent a waiver; the estimated cost of delay is proportionate to those models. DOE calculated the interest that could have been earned on this revenue over the 140-day average delay period and multiplied the average cost of delay per petition by 11, the average number of interim waiver requests received per year, to reach an annual cost of delay. In undiscounted terms, DOE expects that this proposal will result in \$17.3 million in annual cost savings. DOE assumes that these sales are delayed rather than foregone.

<sup>9</sup> “The 7 percent rate is an estimate of the average before-tax rate of return to private capital in the U.S. economy. It is a broad measure that reflects the returns to real estate and small business capital as well as corporate capital.” <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>.

<sup>10</sup> [https://www.regulations.doe.gov/certification-data/#q=Product\\_Group\\_s%3A\\*](https://www.regulations.doe.gov/certification-data/#q=Product_Group_s%3A*).

<sup>11</sup> Walk-in Coolers and Freezers (WICF) are counted as a single affected product. However, Table IV.B.1. breaks out which petitions concerned which WICF components, as their annual shipments and prices vary accordingly.

TABLE IV.B.1—SHIPMENTS AND AVERAGE PRICES OF PRODUCTS/EQUIPMENT AFFECTED BY INTERIM WAIVER DELAYS 2016–2018

Product/equipment	Affected shipments	Average price (2016\$) <sup>12</sup>	Estimated product sales	Cost of delay
<b>Residential</b>				
Battery Chargers .....	74,694	\$7.92	\$591,738	\$16,569
Ceiling Fans .....	48,397	110.43	5,344,688	149,651
Central Air Conditioners & Heat Pumps .....	481,200	3,086.07	1,371,615,829	38,405,243
Clothes Washers .....	31,780	700.24	22,253,510	623,098
Dishwashers .....	24,912	301.92	7,521,486	210,602
Refrigerators .....	40,968	655.30	26,846,375	751,699
<b>Commercial</b>				
Commercial Refrigeration Equipment .....	22,036	3,902.71	85,998,189	2,407,949
Walk-in Coolers & Freezers—Doors .....	190,950	585.60	111,821,271	3,097,477
Walk-in Coolers & Freezers—Systems .....	700	2,681.82	1,876,011	52,528
Total .....				45,714,816
Average Cost of Delay per Petition (29 petitions total) .....				1,576,373
Average Cost of Delay per Year (11 petitions/year) .....				17,340,103

Note that totals may not add due to rounding.

Foregone Benefits

To the extent that this policy would cause DOE to automatically grant interim waiver requests that it would not have granted in the status quo, this proposal may result in foregone benefits to consumers or the environment. Based on historical data, these effects are anticipated to be relatively small. Of 21 concluded interim waiver petitions, DOE granted 18 in full and granted the

remaining 3 with modifications. Of the modified interim waivers, one was granted in part, one was granted with minor modifications, and one was granted with a different alternative test measure than proposed. DOE estimated the foregone environmental benefits and energy savings of granting the petitions as received, rather than as modified by the Department.

All foregone benefits and savings are annual, rather than one-time, and are

projected in the table below using a perpetual time horizon and discounted to 2016. DOE expects these changes to result in \$457.7 million or \$204.4 million in total cost savings, discounted at 3% and 7%, respectively. In annualized terms, DOE expects \$13.7 million in net cost savings, discounted at 3%, or \$14.3 million in net cost savings discounted at 7%.

TABLE IV.B.2—COST IMPACT OF PROPOSED INTERIM WAIVER RULE (2016\$)

	Costs or (Savings)	Costs or (Savings) millions
Annual Cost Savings of Reduced Delay .....	(\$17,340,000)	(\$17.34)
Annual Foregone Energy Savings .....	\$164,000	\$0.16
Annualized Carbon Emissions (SCC), 3% † .....	\$1,764,000	\$1.76
Annualized Carbon Emissions (SCC), 7% † .....	\$827,000	\$0.83
Net Present Value at 3% .....	(\$457,763,000)	(\$457.76)
Net Present Value at 7% .....	(\$204,428,000)	(\$204.43)
Annualized Costs or (Savings) at 3% .....	(\$13,733,000)	(\$13.73)
Annualized Costs or (Savings) at 7% .....	(\$14,310,000)	(\$14.31)

† Undiscounted annual SCC values are not available for comparison.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires that a Federal agency prepare an initial regulatory flexibility analysis for any regulation for which a general notice of proposed rulemaking is required, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial

number of small entities (5 U.S.C. 605(b)).

This proposed rule would impose a requirement on the Department that it must make a decision on interim waiver applications within 30 business days after receipt of a petition. An interim waiver would remain in effect until a waiver decision is published or until DOE publishes a new or amended test procedure that addresses the issues

presented in the waiver, whichever is earlier.

The proposed rule would not impose any new requirements on any manufacturers, including small businesses. The proposed rule would provide greater certainty to manufacturers applying for interim waivers that their petitions would be considered and adjudicated promptly, allowing them, upon DOE grant of an interim waiver, to distribute their

<sup>12</sup> Average price is generally the base case average MSP of equipment from the life-cycle cost year in

the most recently published technical support document. This represents a shipment-weighted

average across efficiency distribution and across all product classes.

products or equipment in commerce while the Department considered its final decision on the petition for waiver. No additional requirements with respect to the waiver application process would be imposed.

For these reasons, DOE certifies that this proposed rule, if promulgated, would not have a significant economic impact on a substantial number of small entities, and therefore, no regulatory flexibility analysis has been prepared. DOE's certification and supporting statement of factual basis will be provided to the Chief Counsel of Advocacy of the SBA pursuant to 5 U.S.C. 605(b).

#### *D. Review Under the Paperwork Reduction Act*

Manufacturers of covered products and equipment must certify to DOE that their products or equipment comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products and equipment 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. 76 FR 12422 (March 7, 2011); 80 FR 5099 (Jan. 30, 2015). 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 30 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.

#### *E. Review Under the National Environmental Policy Act*

DOE has concluded that promulgation of this proposed rule falls into a class of actions that would not individually or cumulatively have a significant impact on the human environment, as determined by DOE's regulations implementing the National Environmental Policy Act of 1969 (42

U.S.C. 4321 *et seq.*). Specifically, this proposed rule amends existing regulations without changing the environmental effect of the regulations being amended, and, therefore, is covered under the Categorical Exclusion in paragraph A5 of appendix A to subpart D, 10 CFR part 1021. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

#### *F. Review Under Executive Order 12988*

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform" (61 FR 4729, February 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; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. Section 3(b)(2) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any, to be given to the regulation; (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, to be given to the regulation; (5) 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 Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of the standards. DOE has completed the required review and determined that, to the extent permitted by law, this proposed rule meets the relevant standards of Executive Order 12988.

#### *G. Review Under Executive Order 13132*

Executive Order 13132, "Federalism" (64 FR 43255, August 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. DOE has examined this

proposed rule and has determined that it would not preempt State law and would not have a substantial direct effect on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. No further action is required by Executive Order 13132.

#### *H. Review Under Executive Order 13175*

Under Executive Order 13175 (65 FR 67249, November 6, 2000) on "Consultation and Coordination with Indian Tribal Governments," DOE may not issue a discretionary rule that has "tribal" implications and imposes substantial direct compliance costs on Indian tribal governments. DOE has determined that the proposed rule would not have such effects and concluded that Executive Order 13175 does not apply to this proposed rule.

#### *I. 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 regulatory actions 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)) 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 "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 them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. (This policy is also available at <http://energy.gov/gc/office-general-counsel>.) DOE examined this proposed rule according to UMRA and its statement of policy and has tentatively determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure by State, local, and Tribal government, in the aggregate, or by the private sector, of \$100 million or

more in any year. Accordingly, no further assessment or analysis is required under UMRA.

#### J. 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 the 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 Executive Order 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. This regulatory action would not have a significant adverse effect on the supply, distribution, or use of energy and is therefore not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

#### K. 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 proposed rule that may affect family well-being. The 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.

#### L. Review Under the Treasury and General Government Appropriations Act, 2001

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 (February 22, 2002), and DOE's guidelines were published at 67

FR 62446 (October 7, 2002). 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.

### V. Public Participation

#### A. Submission of information

DOE will accept comments, data and information regarding this proposed rule before or after the public hearings, but no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested individuals are invited to participate in this proceeding by submitting data, views, or arguments with respect to this proposed rule using any of the methods described in the **ADDRESSES** section at the beginning of this proposed rule. To help the Department review the submitted comments, commenters are requested to reference the paragraph(s), e.g., § 835.3(a), to which they refer where possible.

1. *Submitting comments via <http://www.regulations.gov>.* The <http://www.regulations.gov> web page will require you to provide your name and contact information. Your contact information will be viewable to DOE's Office of Energy Efficiency and Renewable Energy 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 itself 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. Otherwise, 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 <http://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 <http://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 <http://www.regulations.gov> before posting them. 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 <http://www.regulations.gov> provides after you have successfully uploaded your comment.

2. *Submitting comments via email, mail or hand delivery/courier.* Comments and documents submitted via email, mail, or hand delivery/courier, also will be posted to <http://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 in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. 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. If you submit via mail or hand delivery/courier, please provide all items on a CD or USB flash drive, if feasible. It is not necessary to submit printed copies. No facsimiles (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, that are written in English, and that are 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.

3. *Confidential Business Information.* Pursuant to the provisions of 10 CFR 1004.11, anyone submitting information or data he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail two well-marked copies: one copy of the document marked "CONFIDENTIAL BUSINESS INFORMATION" including all the information believed to be confidential, and one copy of the document marked "NO CONFIDENTIAL BUSINESS



INFORMATION” with the information believed to be confidential deleted. Submit these documents via email or CD, if feasible. DOE will make its own determination as to the confidentiality of the information and treat it accordingly. Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

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).

4. *Campaign form letters.* Please submit campaign form letters by the originating organization in batches of between 50 to 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.

#### *B. Issues on Which DOE Seeks Information*

1. DOE requests comment on the length of time manufacturers have previously waited for DOE to provide notification of the disposition of applications for interim waiver (or final decisions on waiver petitions), and the correlated extent of cost savings and any other benefits they expect to realize as a result of the proposal to specify in the regulations that if the Department fails to issue an interim waiver decision within 30 business days following receipt of an application, the application is deemed granted. DOE also requests comment on its proposal to specify that an interim waiver would remain in effect until the earlier of the following: a waiver decision is published or DOE publishes a new or amended test procedure that addresses the issues presented in the waiver.

## **VI. Approval of the Office of the Secretary**

The Secretary of Energy has approved publication of this proposed rule.

### **List of Subjects**

#### *10 CFR Part 430*

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by Reference, Intergovernmental relations, Small businesses.

#### *10 CFR Part 431*

Administrative practice and procedure, Confidential business information, Test procedures, Incorporation by reference, Reporting and recordkeeping requirements.

Signed in Washington, DC, on April 24, 2019.

**Daniel R. Simmons,**

*Assistant Secretary, Energy Efficiency and Renewable Energy.*

For the reasons set forth in the preamble, the Department of Energy proposes to amend parts 430 and 431 of Chapter II, Subchapter D, of Title 10 of the 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. Section 430.27 is amended by revising paragraphs (e)(1) and (h)(1) to read as follows:

#### **§ 430.27 Petitions for waiver and interim waiver.**

\* \* \* \* \*

(e) *Provisions specific to interim waivers—(1) Disposition of application.*

(i) DOE will notify the applicant in writing of the disposition of the petition for interim waiver within 30 days of receipt of the application. If DOE does not notify the applicant in writing of the disposition of the petition for interim waiver within 30 business days of receipt of the application, the interim waiver, as requested in the application, is deemed granted. Notice of DOE’s determination on the petition for interim waiver will be published in the **Federal Register**.

(ii) A waiver is considered received on the date it is received by the Department through the Department’s established email box for receipt of waiver or, if delivered by mail, on the

date the waiver is stamped as received by the Department.

(iii) If DOE ultimately denies the petition for waiver or grants the petition with a different alternate test procedure than specified in the interim waiver, DOE will provide a grace period of 180 days for the manufacturer to begin to use the DOE test procedure or the alternate test procedure specified in the decision and order on the petition to make representations of energy efficiency.

\* \* \* \* \*

(h) *Duration.* (1) Interim waivers remain in effect until the earlier of the following:

(i) DOE publishes a decision on a petition for waiver in the **Federal Register** pursuant to paragraph (f) of this section; or

(ii) DOE publishes in the **Federal Register** a new or amended test procedure that addresses the issues presented in the waiver.

\* \* \* \* \*

### **PART 431—ENERGY EFFICIENCY PROGRAM FOR CERTAIN COMMERCIAL AND INDUSTRIAL EQUIPMENT**

■ 3. The authority citation for part 431 continues to read as follows:

**Authority:** 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

■ 4. Section 431.401 is amended by revising paragraphs (e)(1) and (h)(1) to read as follows:

#### **§ 431.401 Petitions for waiver and interim waiver.**

\* \* \* \* \*

(e) *Provisions specific to interim waivers—(1) Disposition of application.*

(i) DOE will notify the applicant in writing of the disposition of the petition for interim waiver within 30 business days of receipt of the application. If DOE does not notify the applicant in writing of the disposition of the petition for interim waiver within 30 business days of receipt of the application, the interim waiver, as requested in the application, is deemed granted. Notice of DOE’s determination on the petition for interim waiver will be published in the **Federal Register**.

(ii) A waiver is considered received on the date it is received by the Department through the Department’s established email box for receipt of waiver or, if delivered by mail, on the date the waiver is stamped as received by the Department.

(iii) If DOE ultimately denies the petition for waiver or grants the petition with a different alternate test procedure than specified in the interim waiver,

DOE will provide a grace period of 180 days for the manufacturer to begin to use the DOE test procedure or the alternate test procedure specified in the decision and order on the petition to make representations of energy efficiency.

\* \* \* \* \*

(h) *Duration.* (1) Interim waivers remain in effect until the earlier of the following:

(i) DOE publishes a decision on a petition for waiver pursuant to paragraph (f) of this section in the **Federal Register**; or

(ii) DOE publishes in the **Federal Register** a new or amended test procedure that addresses the issues presented in the waiver.

\* \* \* \* \*

[FR Doc. 2019-08699 Filed 4-30-19; 8:45 am]

BILLING CODE 6450-01-P

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-495]

#### Schedules of Controlled Substances: Temporary Placement of *N*-Ethylhexedrone, $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-Chloro- $\alpha$ -PVP in Schedule I

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Proposed amendment; notice of intent.

**SUMMARY:** The Acting Administrator of the Drug Enforcement Administration is issuing this notice of intent to publish a temporary order to schedule the synthetic cathinones, *N*-ethylhexedrone; *alpha*-pyrrolidinohexanophenone (trivial name:  $\alpha$ -PHP); 4-methyl-*alpha*-ethylaminopentiphenone (trivial name: 4-MEAP); 4'-methyl-*alpha*-pyrrolidinoheptiphenone (trivial name: MPHP); *alpha*-pyrrolidinoheptaphenone (trivial name: PV8); and 4-chloro-*alpha*-pyrrolidinovalerophenone (trivial name: 4-chloro- $\alpha$ -PVP), in schedule I. When it is issued, the temporary scheduling order will impose regulatory requirements under the Controlled Substances Act (CSA) on the manufacture, distribution, reverse distribution, possession, importation, exportation, research, conduct of instructional activities, and chemical analysis of these synthetic cathinones, as well as administrative, civil, and criminal remedies with respect to persons who fail to comply with such

requirements or otherwise violate the CSA with respect to these substances.

**DATES:** May 1, 2019.

**FOR FURTHER INFORMATION CONTACT:** Lynnette M. Wingert, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

**SUPPLEMENTARY INFORMATION:** This notice of intent contained in this document is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug Enforcement Administration (DEA) intends to issue a temporary scheduling order (in the form of a temporary amendment) placing *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-chloro- $\alpha$ -PVP in schedule I of the Controlled Substances Act (CSA).<sup>1</sup> The temporary scheduling order will be published in the **Federal Register** on or after May 31, 2019.

#### Legal Authority

Section 201 of the Controlled Substances Act (CSA), 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b), if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance permanently are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

#### Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the

<sup>1</sup> Though DEA has used the term "final order" with respect to temporary scheduling orders in the past, this notice of intent adheres to the statutory language of 21 U.S.C. 811(h), which refers to a "temporary scheduling order." No substantive change is intended.

Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I of the CSA.<sup>2</sup> The Acting Administrator transmitted notice of his intent to place *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-chloro- $\alpha$ -PVP in schedule I on a temporary basis to the Assistant Secretary for Health of HHS by letter dated March 9, 2018. The Acting Assistant Secretary responded to this notice of intent by letter dated March 27, 2018, and advised that based on a review by the Food and Drug Administration (FDA), there were currently no approved new drug applications or active investigational new drug applications for *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-chloro- $\alpha$ -PVP. The Acting Assistant Secretary also stated that the HHS had no objection to the temporary placement of *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-chloro- $\alpha$ -PVP in schedule I of the CSA. *N*-Ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-chloro- $\alpha$ -PVP are not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-chloro- $\alpha$ -PVP under section 505 of the FDCA, 21 U.S.C. 355.

In order to find that placing a substance temporarily in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States,

<sup>2</sup> As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.