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Contents

Federal Register

Vol. 86, No. 49

Tuesday, March 16, 2021

Agriculture Department

See Animal and Plant Health Inspection Service

NOTICES

Request for Comments:

Executive Order on Tackling the Climate Crisis at Home and Abroad, 14403–14404

Animal and Plant Health Inspection Service

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

National Animal Health Monitoring System; On-Farm Monitoring of Antimicrobial Use and Resistance in U.S. Broiler Production Study, 14404–14405

Bureau of Consumer Financial Protection

RULES

Equal Credit Opportunity (Regulation B):

Discrimination on the Bases of Sexual Orientation and Gender Identity, 14363–14366

Census Bureau

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Census Employment Application; Additional Applicant Information Form, 14405–14406

Children and Families Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Annual Statistical Report on Children in Foster Homes and Children in Families Receiving Payment in Excess of the Poverty Income Level From a State Program Funded Under the Social Security Act, 14431

Social Services Block Grant Post-Expenditure Report, Pre-Expenditure Report, and Intended Use Plan, 14432–14433

Meetings:

Community-Based Family Resource and Support Grants, 14431–14432

Coast Guard

PROPOSED RULES

Security Zone:

North Atlantic Ocean, Approaches to Ocean City, MD, 14389–14392

Commerce Department

See Census Bureau

See Foreign-Trade Zones Board

See International Trade Administration

See National Oceanic and Atmospheric Administration

Drug Enforcement Administration

NOTICES

Bulk Manufacturer of Controlled Substances Application: Cambridge Isotope Lab; Correction, 14471

Importer of Controlled Substances Application:

Purisys, LLC, 14471–14472

Education Department

RULES

Final Priority and Definitions:

American Indian Vocational Rehabilitation Training and Technical Assistance Center, 14374–14379

NOTICES

Applications for New Awards:

American Indian Vocational Rehabilitation Training and Technical Assistance Center, 14414–14420

Election Assistance Commission

NOTICES

Agency Organization, Procedure, and Practice:

New Agency Seal, 14420

Energy Department

See Federal Energy Regulatory Commission

Environmental Protection Agency

PROPOSED RULES

Air Quality State Implementation Plans; Approvals and Promulgations:

Rescission of the Source-Specific Federal Implementation Plan for Navajo Generating Station, Navajo Nation, 14392–14396

Texas; Revisions to the Texas Diesel Emissions Reduction Incentive Program, 14396–14398

Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under the Toxic Substances Control Act, 14398–14401

Federal Aviation Administration

RULES

Airworthiness Directives:

Bell Textron Canada Limited Helicopters, 14366–14370

PROPOSED RULES

Special Conditions:

Haeco Cabin Solutions, Boeing Commercial Airplanes Model 737–800 Airplane; Structure-Mounted Airbags, 14387–14389

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

High Density Traffic Airports; Slot Allocation and Transfer Methods, 14515–14516

Petition for Exemption; Summary:

Airlines for America, 14514, 14516

Federal Communications Commission

PROPOSED RULES

Television Broadcasting Services:

Augusta, GA; Correction, 14401

NOTICES

Privacy Act; Matching Program, 14426–14428, 14430–14431

Privacy Act; Systems of Records, 14428–14430

Federal Energy Regulatory Commission

NOTICES

Application:

Kinet, Inc., 14420–14421, 14424–14425

Sandy Hollow Hydroelectric Co., Inc., 14423–14424

Combined Filings, 14423, 14425–14426

Effectiveness of Exempt Wholesale Generator Status:
 Wolf Ridge Wind Energy, LLC; Blue Summit I Wind,
 LLC; Dickerson Power, LLC; et al., 14424
 Meetings; Sunshine Act, 14421–14423
 Surrender of Preliminary Permit:
 BM Energy Park, LLC, 14421

Federal Motor Carrier Safety Administration

NOTICES

Drug and Alcohol Clearinghouse Pre-Employment Full
 Query; Exemption Applications:
 Controlled Substances and Alcohol Use and Testing:
 FirstGroup plc., 14516–14518
 Qualification of Drivers; Exemption Applications:
 Vision, 14518–14521

Federal Railroad Administration

NOTICES

Petition for Waiver of Compliance, 14521–14523

Food and Drug Administration

NOTICES

Agency Information Collection Activities; Proposals,
 Submissions, and Approvals:
 Current Good Manufacturing Practice, Hazard Analysis,
 and Risk-Based Preventive Controls for Human and
 Animal Food, 14436–14440
 Empirical Study of Promotional Implications of
 Proprietary Prescription Drug Names, 14440–14445
 Food and Cosmetic Export Certificate Application
 Process, 14452–14454
 Request for Samples and Protocols, 14448–14450
 Survey on the Occurrence of Foodborne Illness Risk
 Factors in Selected Retail and Foodservice Facility
 Types, 14433–14436
 Determination of Regulatory Review Period for Purposes of
 Patent Extension:
 Hintermann Series H3 Total Ankle Replacement System,
 14445–14447
 OCS Lung System, 14455–14456
 Guidance:
 Best Practices in Developing Proprietary Names for
 Human Nonprescription Drug Products, 14454–14455
 Meetings:
 Potential Medication Error Risks With Investigational
 Drug Container Labels, 14457–14459
 Request for Comments:
 Listing of Patent Information in the Orange Book, 14450–
 14451
 Withdrawal of Approval of New Drug Applications:
 Bristol-Meyers Squibb Co., et al., 14447–14448
 Withdrawal of Drug Products From Sale for Reasons Other
 Than Safety or Effectiveness:
 NIPRIDE RTU (Sodium Nitroprusside), 10 Milligrams/50
 Milliliters (0.2 Milligrams/Milliliters), 14451–14452

Foreign-Trade Zones Board

NOTICES

Proposed Production Activity:
 Zoetis Services, LLC, Foreign-Trade Zone 59, Lincoln,
 NE, 14406

Health and Human Services Department

See Children and Families Administration
 See Food and Drug Administration
 See Health Resources and Services Administration
 See National Institutes of Health

NOTICES

Declaration Under the Public Readiness and Emergency
 Preparedness Act for Medical Countermeasures Against
 COVID-19, 14462–14468

Health Resources and Services Administration

NOTICES

Agency Information Collection Activities; Proposals,
 Submissions, and Approvals:
 Voluntary Partner Surveys To Implement Executive Order
 12862 in the Health Resources and Services
 Administration, 14462
 National Vaccine Injury Compensation Program:
 List of Petitions Received, 14459–14461

Homeland Security Department

See Coast Guard

See U.S. Citizenship and Immigration Services

Housing and Urban Development Department

RULES

Adjustment of Civil Monetary Penalty Amounts for 2021,
 14370–14374

NOTICES

Section 8 Housing Assistance Payments Program:
 Fiscal Year 2021 Inflation Factors for Public Housing
 Agency Renewal Funding, 14470–14471

International Trade Administration

NOTICES

Antidumping or Countervailing Duty Investigations, Orders,
 or Reviews:
 Cast Iron Soil Pipe Fittings From the People's Republic of
 China, 14407
 Pentafluoroethane (R-125) From the People's Republic of
 China, 14406–14407

Justice Department

See Drug Enforcement Administration

National Credit Union Administration

NOTICES

Meetings; Sunshine Act, 14472

National Institutes of Health

NOTICES

Meetings:
 National Institute of Dental and Craniofacial Research,
 14468

National Oceanic and Atmospheric Administration

RULES

Fisheries off West Coast States:
 Magnuson-Stevens Act Provisions; Pacific Coast
 Groundfish Fishery; 2021–2022 Biennial
 Specifications and Management Measures;
 Correction, 14379–14386

PROPOSED RULES

Fisheries Off West Coast States:
 Coastal Pelagic Species Fisheries; Amendment 18 to the
 Coastal Pelagic Species Fishery Management Plan,
 14401–14402

NOTICES

Endangered and Threatened Species:
 Southern Oregon and Northern California Coastal Spring-
 Run Chinook Salmon; 90-Day Finding on Petition To
 List as Threatened or Endangered, 14407–14414

National Transportation Safety Board**NOTICES**

Meetings; Sunshine Act, 14472

Nuclear Regulatory Commission**NOTICES**

Exemption; Issuance:

Exelon Generation Co., LLC; TMI-2 Solutions, LLC;
Three Mile Island Nuclear Station, Units 1 and 2,
14472–14478

Securities and Exchange Commission**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 14484, 14493–14494,
14502–14503

Meetings; Sunshine Act, 14494

Self-Regulatory Organizations; Proposed Rule Changes:

Cboe Exchange, Inc., 14494–14500

Fixed Income Clearing, Corp., 14503–14506

ICE Clear Europe, Ltd., 14478–14482

Long-Term Stock Exchange, Inc., 14511–14513

Nasdaq ISE, LLC, 14482–14484

National Securities Clearing Corp., 14506–14508

The Depository Trust Co., 14500–14502

The Nasdaq Stock Market, LLC, 14484–14493, 14508–
14511

Trade Representative, Office of United States**NOTICES**

Modification of Section 301 Action:

Enforcement of United States World Trade Organization
Rights in the Large Civil Aircraft Dispute, 14513–
14514

Transportation Department

See Federal Aviation Administration

See Federal Motor Carrier Safety Administration

See Federal Railroad Administration

U.S. Citizenship and Immigration Services**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:

Application for Action on an Approved Application or
Petition, 14469–14470

Interagency Alien Witness and Informant Record, 14468–
14469

Veterans Affairs Department**NOTICES**

Meetings:

Advisory Committee on Homeless Veterans, 14523

Reader Aids

Consult the Reader Aids section at the end of this issue for
phone numbers, online resources, finding aids, and notice
of recently enacted public laws.

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CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

12 CFR

1002.....14363

14 CFR

39.....14366

Proposed Rules:

25.....14387

24 CFR

28.....14370

30.....14370

87.....14370

180.....14370

3282.....14370

33 CFR**Proposed Rules:**

165.....14389

34 CFR

Ch. III.....14374

40 CFR**Proposed Rules:**

49.....14392

52 (2 documents)14392,

14396

751.....14398

47 CFR**Proposed Rules:**

73.....14401

50 CFR

660.....14379

Proposed Rules:

660.....14401

Rules and Regulations

Federal Register

Vol. 86, No. 49

Tuesday, March 16, 2021

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1002

Equal Credit Opportunity (Regulation B); Discrimination on the Bases of Sexual Orientation and Gender Identity

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Interpretive rule.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau) is issuing this interpretive rule to clarify that, with respect to any aspect of a credit transaction, the prohibition against sex discrimination in the Equal Credit Opportunity Act (ECOA) and Regulation B, which implements ECOA, encompasses sexual orientation discrimination and gender identity discrimination, including discrimination based on actual or perceived nonconformity with sex-based or gender-based stereotypes and discrimination based on an applicant's associations.

DATES: This interpretive rule is effective on March 16, 2021.

FOR FURTHER INFORMATION CONTACT: Pavy Bacon, Senior Counsel, Office of Regulations at 202-435-7700. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Bureau is responsible for administering and enforcing ECOA¹ and its implementing Regulation B.² ECOA makes it “unlawful for any creditor to discriminate against any applicant, with respect to any aspect of a credit transaction,” on several enumerated bases, including “on the basis of . . . sex”³ Likewise,

Regulation B prohibits a creditor from discriminating against an applicant on a prohibited basis (including “sex”⁴) “regarding any aspect of a credit transaction,” and from making “any oral or written statement to applicants or prospective applicants that would discourage on a prohibited basis a reasonable person from making or pursuing an application.”⁵

On June 15, 2020, in *Bostock v. Clayton County, Georgia*, the Supreme Court ruled that the prohibition against sex discrimination in Title VII of the Civil Rights Act of 1964 (Title VII) encompasses sexual orientation discrimination and gender identity discrimination.⁶ The Court relied on three key findings to reach its decision: (1) Sexual orientation discrimination and gender identity discrimination necessarily involve consideration of sex; (2) Title VII’s language requires sex to be a “but for” cause of the injury, but need not be the only cause; and (3) Title VII’s language covers discrimination against individuals, and not merely against groups.⁷

In response to Executive Order 13988, “Preventing and Combatting Discrimination on the Basis of Gender Identity or Sexual Orientation”,⁸ which addresses *Bostock*, Jeanine M. Worden, Acting Assistant Secretary for Fair Housing & Equal Opportunity, released a memorandum directing the Office of Fair Housing and Equal Opportunity of the U.S. Department of Housing and Urban Development to take the actions to administer and fully enforce the Fair Housing Act to prohibit discrimination because of sexual orientation and gender identity.⁹

Before the issuance of the *Bostock* opinion, at least twenty states and the District of Columbia prohibited discrimination on the bases of sexual orientation and/or gender identity either in all credit transactions or in certain (e.g., housing-related) credit

transactions.¹⁰ As such, financial institutions subject to such laws were required to comply with those requirements prior to the issuance of the *Bostock* opinion. Many financial institutions recognize sexual orientation and/or gender identity to be protected classes under State laws¹¹ and may have determined to incorporate practices that prohibit discrimination on these bases.¹²

¹⁰ While not intended to be an all-inclusive list, the State statutes include Cal. Civ. Code secs. 51, 51.5; Cal. Gov’t Code sec. 12955; Colo. Rev. Stat. sec. 24–34–501(3); Colo. Rev. Stat. sec. 5–3–210; Conn. Gen. Stat. secs. 46a–81e, 46a–81f, 46a–98; Del. Code Ann. tit. 6, sec. 4604; D.C. Code sec. 2–1402.21; Haw. Rev. Stat. secs. 515–3, 515–5; 775 Ill. Comp. Stat. sec. 5/1–102(A), 5/1–103(O), (O1), and (Q), 5/4–102, 5/3–102, 5/4–103; Iowa Code secs. 216.8A, 216.10; Me. Rev. Stat. tit. 5, sec. 4553(5–C) and (9–C), 4595 to 4598, 4581 to 4583; Md. Code Ann., State Gov’t secs. 20–705, 20–707, 20–1103; Mass. Gen. Laws ch. 151B, sec. 4(3B), (14); Minn. Stat. secs. 363A.03 (Subd. 44), 363A.09(3), 363A.16 (Subds.1 and 3), 363A.17; N.H. Rev. Stat. Ann. sec. 354–A:10; N.J. Stat. Ann. sec. 10:5–12(i); N.M. Stat. Ann. sec. 28–1–7; N.Y. Civ. Rights Law sec. 40–c(2); N.Y. Exec. Law sec. 296–A; Or. Rev. Stat. secs. 174.100(7), 659A.421; R.I. Gen. Laws secs. 34–37–4(a) through (c), 34–37–4.3, 34–37–5.4; Va. Code Ann. sec. 6.2–501(B)(1); 15.2–853; 15.2–965; Vt. Stat. Ann. tit. 8, sec. 10403; Vt. Stat. Ann. tit. 9, sec. 2362, 2410, 4503(a)(6); Wash. Rev. Code sec. 49.60.030, 49.60.040 (14), (26), and (27), 49.60.175, 49.60.222; Wis. Stat. secs. 106.50, 224.77(1)(o). Also, since *Bostock*, the North Dakota Department of Labor and Human Rights has interpreted the North Dakota statutes against sex discrimination to include sexual orientation and gender identity discrimination. N.D. Dep’t of Lab. and Hum. Rts. (NDDOLHR), *NDDOLHR Now Accepting and Investigating Charges of Discrimination Based on Sexual Orientation and Gender Identity* (June 18, 2020), <https://www.nd.gov/labor/news/nddolhr-now-accepting-and-investigating-charges-discrimination-based-sexual-orientation-and-gender-identity>. There are also a number of municipalities that include sexual orientation and/or gender identity in their credit discrimination ordinances. See, e.g., Austin City Code sec. 5–1–1 *et seq.*; N.Y.C. Admin. Code secs. 8–101, 8–107 *et seq.*; S.F. Police Code, sec. 3304(a) *et seq.*

¹¹ See Consumer Bankers Ass’n (CBA), Comment Letter on Request for Information on the Equal Credit Opportunity Act and Regulation B (RFI), Document No. CFPB–2020–0026–0147 (Dec. 1, 2020) (“Many CBA members currently consider sexual orientation and gender identity to be protected classes under [S]tate laws, therefore, potential post *Bostock* changes to how the Bureau interprets ECOA’s prohibition on discrimination on the basis of sex would likely align with, and would not significantly alter, practices that comply with state laws.”).

¹² See, e.g., Off. of the Comptroller of the Currency, *Interpretive Letter #998* (Mar. 9, 2004), <https://www.occ.gov/topics/charters-and-licensing/interpretations-and-actions/2004/int998.pdf> (“[W]hat would generally be understood to be an ‘anti-discrimination’ law . . . [e.g., laws that prohibit lenders from discriminating on the basis of race, religion, ethnicity, gender, sexual orientation,

Continued

¹ 15 U.S.C. 1691–1691f.

² 12 CFR part 1002.

³ 15 U.S.C. 1691(a)(1).

⁴ 12 CFR 1002.2(z).

⁵ 12 CFR 1002.4(a)–(b).

⁶ *Bostock v. Clayton Cty., Georgia*, 140 S. Ct. 1731, 207 L. Ed. 2d 218 (2020).

⁷ *Id.*

⁸ 86 FR 7023 (Jan. 25, 2021).

⁹ U.S. Dep’t. of Hous. and Urban Dev., *Memorandum, Implementation of Executive Order 13988 on the Enforcement of the Fair Housing Act* (Feb. 11, 2021), https://www.hud.gov/sites/dfiles/PA/documents/HUD_Memo_EO13988.pdf.

The Bureau has previously indicated that legal developments would lead to prohibitions against sex discrimination being interpreted to afford broad protection against discrimination on the bases of sexual orientation and gender identity. In 2016, in response to an inquiry from Services & Advocacy for GLBT Elders (SAGE), the Bureau sent a letter addressing coverage of sex discrimination involving sexual orientation and gender identity under ECOA.¹³ The letter to SAGE concluded that “the current state of the law supports arguments that the prohibition of sex discrimination in ECOA and Regulation B affords broad protection against credit discrimination on the bases of gender identity and sexual orientation, including but not limited to discrimination based on actual or perceived nonconformity with sex-based or gender-based stereotypes as well as discrimination based on one’s associations.”¹⁴ Further, the letter to SAGE stated that the Bureau “will continue to monitor these legal developments closely as we strive to ensure that our interpretation and application of laws and rules under our jurisdiction, including ECOA and Regulation B, appropriately reflect the evolving precedents interpreting sexual discrimination law.”¹⁵ The Bureau also incorporated its views regarding sex discrimination under ECOA and Regulation B into its ECOA brochure and AskCFPB materials.¹⁶

After the Supreme Court issued the *Bostock* opinion, diverse stakeholders asked the Bureau to clarify that ECOA’s and Regulation B’s prohibition of “sex” discrimination includes discrimination on the bases of sexual orientation and/

or gender identity. Many comments to the Bureau’s recent *Request for Information on the Equal Credit Opportunity Act and Regulation B* (RFI)¹⁷ from a variety of stakeholders, including consumer and civil rights advocates, a local government official, an academic institution, and industry representatives, reiterated this request for regulatory clarification.¹⁸ The Bureau is issuing this interpretive rule to address any regulatory uncertainty that may still exist under ECOA and Regulation B as to the term “sex” so as to ensure the fair, equitable, and nondiscriminatory access to credit for both individuals and communities and to ensure that consumers are protected from discrimination.¹⁹ This interpretive rule serves a stated purpose of Regulation B, which is to “promote the availability of credit to all creditworthy applicants without regard to . . . sex”²⁰

II. Discussion

The Bureau interprets the ECOA and Regulation B prohibitions against discrimination on the basis of “sex” to include discrimination based on sexual orientation and/or gender identity. The Bureau’s interpretation is consistent with the Court’s conclusion in *Bostock* regarding sex discrimination under Title VII.²¹

¹⁷ 85 FR 46600 (Aug. 3, 2020).

¹⁸ See, e.g., Nat’l Fair Hous. All., Comment Letter on RFI, Document No. CFPB–2020–0026–0137 (Dec. 1, 2020); City of Houston, City Controller, Comment Letter on RFI, Document No. CFPB–2020–0026–0120 (Dec. 1, 2020); Steven Trovarelli, Comment Letter on RFI, CFPB–2020–0026–0051 (Oct. 1, 2020); Anonymous, Comment Letter on RFI, Document No. CFPB–2020–0026–0064– (Nov. 3, 2020); Consortium for Citizens with Disabilities Fin. Sec. & Poverty Task Force, Comment Letter on RFI, Document No. CFPB–2020–0026–0104– (Dec. 1, 2020); Nat’l Women’s Law Ctr., Comment Letter on RFI, Document No. CFPB–2020–0026–0112–A1 (Dec. 1, 2020); Cmty. Dev. Bankers Ass’n (CDBA), Comment Letter on RFI, Document No. CFPB–2020–0026–0113 (Dec. 1, 2020); Mortg. Bankers Ass’n, Comment Letter on RFI, Document No. CFPB–2020–0026–0115 (Dec. 1, 2020); Nat’l Cmty. Reinvestment Coal., Comment Letter on RFI, Document No. CFPB–2020–0026–0123 (Dec. 1, 2020); LendingClub, Comment Letter on RFI, Document No. CFPB–2020–0026–0126 (Dec. 2, 2020); Nat’l Consumer Law Ctr., Comment Letter on RFI, Document No. CFPB–2020–0026–0129–A1 (Dec. 2, 2020); The Williams Institute, Comment Letter on RFI, Document No. CFPB–2020–0026–0132 (Dec. 2, 2020); Nat’l Disability Rts. Network, Comment Letter on RFI, Document No. CFPB–2020–0026–0139 (Dec. 2, 2020); Serv. & Advocacy for GLBT Elders (SAGE), Comment Letter on RFI, Document No. CFPB–2020–0026–0141 (Dec. 2, 2020); Ctr. for Am. Progress, Comment Letter on RFI, Document No. CFPB–2020–0026–0144 (Dec. 2, 2020); Consumer Bankers Ass’n, Comment Letter on RFI, Document No. CFPB–2020–0026–0147 (Dec. 2, 2020).

¹⁹ 12 U.S.C. 5493(c)(2)(A), 5511(b)(2).

²⁰ 12 CFR 1002.1(b).

²¹ See *Bostock*, 140 S. Ct. 1731.

It is well established that ECOA and Title VII are generally interpreted consistently.²² Like Title VII,²³ ECOA prohibits sex discrimination (among other bases) and does not require that sex (or other protected characteristics) be the sole or primary reason for an action to be discriminatory.²⁴ Like Title VII,²⁵ ECOA applies to sex discrimination against individuals, not just to situations where all men or all women (or any other group of people with a common protected characteristic) are discriminated against

²² See, e.g., Equal Credit Opportunity Act Amendments of 1976, Public Law 94–239, 114 Stat. 246 (1976); S. Rep. 94–589, at 4–5 (1976), *reprinted in* 1976 U.S.C.A.N. 403. (“judicial constructions of anti-discrimination legislation in the employment field . . . are intended to serve as guides in the application of this [Equal Credit Opportunity] Act”); *Mercado-Garcia v. Ponce Fed. Bank*, 979 F.2d 890, 893 (1st Cir. 1992) (applying Title VII standards in interpreting ECOA); *Bhandari v. First Nat’l Bank of Commerce*, 808 F.2d 1082, 1100 (5th Cir. 1987) (same); *Rosa v. Park W. Bank & Tr. Co.*, 214 F.3d 213, 215 (1st Cir. 2000) (“look[ing] to Title VII case law” and reversing the dismissal of a sex discrimination claim filed by a transgender person who alleged being denied a loan application for failing to appear in clothing consistent with the sex reflected on their identification cards). See also *Bostock*, 140 S. Ct. at 1778 (Alito, S., dissenting) (expressing the view that the decision “is virtually certain to have far-reaching consequences” including, specifically, with regard to ECOA).

²³ *Bostock*, 140 S. Ct. at 1734 (holding that under Title VII, “the plaintiff’s sex need not be the sole or primary cause of the employer’s adverse action”).

²⁴ See Official Staff Commentary, 12 CFR part 1002, supp. I, ¶ 4(a)–1 (“Disparate treatment on a prohibited basis is illegal whether or not it results from a conscious intent to discriminate.”); *Saldana v. Citibank, Fed. Sav. Bank*, No. 93 C 4164, 1996 WL 332451, at *2 (N.D. Ill. June 13, 1996) (“To establish a case of lending discrimination under the [Fair Housing Act] or the ECOA, [plaintiff] does not need to prove an actual intent to discriminate on the part of [defendant], but she must show that race played some role in [defendant’s] decision.”). Moreover, the 1994 Interagency Policy Statement on Discrimination in Lending (Policy Statement) provides an illustration of disparate treatment where the applicants’ minority status was not the sole or primary reason for the loan denial since adverse credit information was also a factor in the decision. The illustration states that a nonminority couple applied for an automobile loan. The lender found adverse information in the couple’s credit report. The lender discussed the credit report with them and determined that the adverse information (a judgment against the couple) was incorrect since the judgment had been vacated. The nonminority couple was granted their loan. A minority couple applied for a similar loan with the same lender. Upon discovering adverse information in the minority couple’s credit report, the lender denied the loan application on the basis of the adverse information without giving the couple an opportunity to discuss the report. 59 FR 18266, 18268 (Apr. 15, 1994); Bureau of Consumer Fin. Prot., *Bulletin 2012–04 (Fair Lending)* (Apr. 18, 2012), https://files.consumerfinance.gov/f/201404_cfpb_bulletin_lending_discrimination.pdf (the Bureau expressed its concurrence with the Policy Statement).

²⁵ *Bostock*, 140 S. Ct. at 1734 (finding that “an employer cannot escape liability [under Title VII] by demonstrating that it treats males and females comparably as groups”).

disability, or the like . . . would not be preempted.”) (emphasis in original); Nat’l Cmty. Reinvestment Coal., Comment Letter on RFI, Document No. CFPB–2020–0026–0123 (Dec. 1, 2020) (noting that “defense attorneys have already informed the mortgage industry that as more State laws incorporate this robust definition of sex, they should incorporate it into their policies and procedures”) (citation omitted).

¹³ See Letter from Bureau of Consumer Fin. Prot., to Serv. & Advocacy for GLBT Elders (SAGE), (Aug. 30, 2016), https://files.consumerfinance.gov/f/documents/cfpb_sage-response-letter_2021-02.pdf.

¹⁴ *Id.* at 7.

¹⁵ *Id.*

¹⁶ See Bureau of Consumer Fin. Prot., *Helping consumers understand credit discrimination* (Mar. 2017), https://files.consumerfinance.gov/f/documents/201703_cfpb_handout_ECOA_helping_consumers.pdf; Bureau of Consumer Fin. Prot., *What protections do I have against credit discrimination?*, <https://www.consumerfinance.gov/fair-lending/>. (Both state: “Currently, the law supports arguments that the prohibition against sex discrimination also affords broad protection from discrimination based on a consumer’s gender identity and sexual orientation.”). The Bureau will update these and other materials to reflect this interpretive rule.

categorically.²⁶ Indeed, Regulation B clarifies that ECOA prohibits discrimination based not only on the characteristics of an applicant but also based on the characteristics of a person with whom an applicant associates.²⁷

The Bureau believes that even though the term “sex” is not defined in ECOA or Regulation B, the prohibitions against discrimination on the basis of “sex” under ECOA and Regulation B are correctly interpreted to include discrimination based on sexual orientation and/or gender identity. As explained below and consistent with the Court’s analysis in the *Bostock* opinion, this conclusion can be based on “no more than the straightforward application of legal terms with plain and settled meanings.”²⁸ But, even if it were not so straightforward, the Bureau would still reach the same conclusion based on its expertise in interpreting ECOA and Regulation B. In sum, the Bureau finds that under ECOA and Regulation B: (1) Sexual orientation discrimination and gender identity discrimination necessarily involve consideration of sex; (2) an applicant’s sex must be a “but for” cause of the injury, but need not be the only cause; and (3) discrimination against individuals, and not merely against groups, is covered. The Bureau also clarifies that ECOA’s and Regulation B’s prohibition against sex discrimination encompasses discrimination motivated by perceived nonconformity with sex-based or gender-based stereotypes, as well as discrimination based on an applicant’s associations.

First, under ECOA and Regulation B, as under Title VII, sexual orientation discrimination and gender identity discrimination necessarily involve consideration of sex. For example, if a creditor declines the loan application of

a male applicant on the basis that he is attracted to men, the creditor discriminates against him for traits or actions it tolerates in female applicants; further, this discrimination is motivated, at least partly, by the applicant “failing to fulfill traditional sex stereotypes.”²⁹ Or, if a creditor declines the loan forbearance application of a transgender person who was identified as male at birth but who now identifies as female, but approves the application of an otherwise similarly-situated applicant who was identified as female at birth and now continues to identify as female, the creditor discriminates against a person identified as male at birth for traits or actions that it tolerates in an applicant identified as female at birth. In these examples, the individual applicant’s “sex plays an unmistakable and impermissible role”³⁰ in the credit decisions and thus constitutes discrimination on the basis of sex in violation of ECOA and Regulation B. The Bureau’s interpretation is consistent with the Supreme Court’s conclusion in *Bostock* that “it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex.”³¹

Second, under ECOA and Regulation B, as under Title VII, sex does not have to be the sole or primary reason for an action to be discriminatory.³² For example, when a creditor rejects an applicant on the basis of their being gay or transgender, two causal factors may be in play—both the individual’s sex and something else (the sex to which the individual is attracted or with which the individual identifies).³³ Under ECOA and Regulation B, if a creditor would not have rejected a credit applicant or discouraged a prospective applicant but for that individual’s sex, the causation standards are met, and liability may attach.³⁴

Third, ECOA and Regulation B, like Title VII, apply to sex discrimination against individuals, not just to situations where all men or all women are discriminated against

categorically.³⁵ Further, ECOA and Regulation B, like Title VII, work to protect individuals of all sexes from discrimination, and do so equally.³⁶ For example, a creditor who rejects an application from a woman because the loan officer regards her as insufficiently feminine, and also rejects an application from a man because the loan officer regards him as being insufficiently masculine, may treat men and women as groups more or less equally. But in both scenarios, the creditor has discriminated against an applicant in violation of ECOA and Regulation B by rejecting an individual applicant in part because of sex. Instead of avoiding ECOA exposure, this creditor “doubles it.”³⁷ It is no defense for a creditor to argue that it is equally happy to reject male and female applicants who are gay or transgender because each instance of discriminating against an individual applicant because of that individual’s sex is an independent violation of ECOA and Regulation B.³⁸

Last, the Bureau interprets the ECOA and Regulation B prohibition against discrimination on the basis of “sex” to also include discrimination motivated by perceived nonconformity with sex-based or gender-based stereotypes, including those related to gender identity and/or sexual orientation, as well as discrimination based on an applicant’s associations. An example of discriminatory sex-based or gender-based stereotyping occurs if a small business lender discourages a small business owner appearing at its office from applying for a business loan and tells the prospective applicant to go home and change because, in the view of the creditor, the small business customer’s attire does not accord with the customer’s gender.³⁹ The Bureau’s interpretation regarding discriminatory stereotyping is consistent with multiple court decisions⁴⁰ and with the Court’s *Bostock* decision.⁴¹ The Bureau’s

²⁶ While Title VII prohibits discrimination against “any individual,” 42 U.S.C. 2000e–2(a)(1), and ECOA prohibits discrimination against “any applicant,” 15 U.S.C. 1691(a), both statutes refer to a singular person or applicant rather than a group. ECOA defines an “applicant” as “any person who applies to a creditor directly for an extension, renewal, or continuation of credit or applies to a creditor indirectly by use of an existing credit plan for an amount exceeding a previously established credit limit.” 15 U.S.C. 1691a(b). Regulation B defines an “applicant” as “any person who requests or who has received an extension of credit from a creditor, and includes any person who is or may become contractually liable regarding an extension of credit.” 12 CFR 1002.2(e).

²⁷ 12 CFR part 1002, supp. I, ¶ 2(z)–1 (providing that “prohibited basis refers not only to characteristics—the race, color, religion, national origin, sex, marital status, or age—of an applicant (or officers of an applicant in the case of a corporation) but also to the characteristics of individuals with whom an applicant is affiliated or with whom the applicant associates”).

²⁸ *Bostock*, 140 S. Ct. at 1743.

²⁹ *Id.* at 1742.

³⁰ *Id.* at 1741–42.

³¹ *Id.* at 1741. Notwithstanding differences in the ways that Title VII and ECOA phrase their prohibition against sex discrimination, the Bureau interprets ECOA and Regulation B to incorporate the *Bostock* principles and reasoning with respect to the recognition of sexual orientation discrimination and gender identity discrimination as sex discrimination under ECOA and Regulation B.

³² *See id.* at 1744; 59 FR 18266, 18268 (Apr. 15, 1994).

³³ *See id.* at 1742.

³⁴ *See id.* at 1742; *see also Rosa*, 214 F.3d at 215.

³⁵ *See Bostock*, 140 S. Ct. at 1740–41; *see also Rosa*, 214 F.3d at 215 (finding a potential ECOA claim where the plaintiff “did not receive the loan application because he was a man, whereas a similarly situated woman would have received the loan application”).

³⁶ *See Bostock*, 140 S. Ct. at 1741.

³⁷ *See id.* at 1741.

³⁸ *See id.* at 1742–43.

³⁹ *See, e.g., Rosa*, 214 F.3d at 214–15.

⁴⁰ *See EEOC v. Boh Bros. Constr. Co.*, 731 F.3d 444, 457–58 (5th Cir. 2013) (en banc); *Glenn v. Brumby*, 663 F.3d 1312, 1314, 1320–21 (11th Cir. 2011); *Barnes v. City of Cincinnati*, 401 F.3d 729, 735–37 (6th Cir. 2005); *Nichols v. Azteca Rest. Enterprises, Inc.*, 256 F.3d 864, 870, 874–75 (9th Cir. 2001); *Rosa*, 214 F.3d at 215.

⁴¹ *See Bostock*, 140 S. Ct. at 1742–43 (stating that an employer who fires employees “for failing to fulfill traditional sex stereotypes doubles rather

interpretation regarding associational discrimination is similarly consistent with the Court's reasoning in *Bostock* regarding how discrimination based on the sex, including sexual orientation and/or gender identity, of the persons with whom the individual associates is prohibited under Title VII.⁴² A creditor engages in such associational discrimination if it, for example, requires a person applying for credit who is married to a person of the same-sex to provide different documentation of the marriage than a person applying for credit who is married to a person of the opposite sex. The Bureau's interpretation is consistent with the principle, applied by Federal agencies for decades, that credit discrimination on a prohibited basis includes discrimination against an applicant because of the protected characteristics of individuals with whom they are affiliated or associated (*e.g.*, spouses, domestic partners, dates, friends, coworkers).⁴³ Moreover, the Bureau has previously established that a creditor may not discriminate against an applicant because of that person's personal or business dealings with members of a protected class, because of the protected class of any persons associated with the extension of credit, or because of the protected class of other residents in the neighborhood where the property offered as collateral is located.⁴⁴

For these reasons, the ECOA and Regulation B prohibition against

than eliminates Title VII liability, an employer who fires [employees] for being gay or transgender does the same").

⁴² See *id.* at 1748 ("So, for example, when it comes to homosexual employees, male sex and attraction to men are but-for factors that can combine to get them fired. The fact that female sex and attraction to women can also get an employee fired does no more than show the same outcome can be achieved through the combination of different factors. In either case, though, sex plays an essential but-for role.").

⁴³ See Equal Credit Opportunity; Revision of Regulation B; Official Staff Commentary, 50 FR 48018, 48049 (Nov. 20, 1985) (providing that discrimination on a "prohibited basis refers not only to characteristics—the race, color, religion, national origin, sex, marital status, or age—of an applicant (or officers of an applicant in the case of a corporation) but also to the characteristics of individuals with whom an applicant is affiliated or with whom the applicant associates," or because of the characteristics of people with whom an applicant has "personal or business dealings"); 59 FR 18266, 18268 (Apr. 15, 1994) (stating that "A lender may not discriminate on a prohibited basis because of the characteristics of: [a] person associated with a credit applicant (for example, a co-applicant, spouse, business partner, or live-in-aide); or [t]he present or prospective occupants of the area where property to be financed is located."); 76 FR 79442, 79473 (Dec. 21, 2011); 81 FR 25323, 25325 (Apr. 28, 2016); Official Staff Commentary, 12 CFR part 1002, supp. I, ¶ 2(z)–1).

⁴⁴ Official Staff Commentary, 12 CFR part 1002, supp. I, ¶ 2(z)–1).

discrimination on the basis of "sex" includes discrimination or discouragement based on sexual orientation and/or gender identity, including but not limited to discrimination based on actual or perceived nonconformity with sex-based or gender-based stereotypes and discrimination based on an applicant's associations.

III. Legal Authority

This interpretive rule is issued under the Bureau's authority to interpret the ECOA and Regulation B, including under section 1022(b)(1) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, which authorized guidance as may be necessary or appropriate to enable the Bureau to administer and carry out the purposes and objectives of Federal consumer financial laws.⁴⁵

By operation of the ECOA section 706(e), no provision of ECOA sections 701(a), 704(b), 706(a), or 706(b) imposing any liability applies to any act done or omitted in good faith in conformity with this interpretive rule, notwithstanding that after such act or omission has occurred, the rule is amended, rescinded, or determined by judicial or other authority to be invalid for any reason.⁴⁶

IV. Effective Date

Because this rule is solely interpretive, it is not subject to the 30-day delayed effective date for substantive rules under section 553(d) of the Administrative Procedure Act.⁴⁷ Therefore, this rule is effective on March 16, 2021, the same date that it is published in the **Federal Register**.

V. Regulatory Matters

As an interpretive rule, this rule is exempt from the notice-and-comment rulemaking requirements of the Administrative Procedure Act.⁴⁸ Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis.⁴⁹ The Bureau also has determined that this interpretive rule does not impose any new or revise any existing recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring approval by the Office of

Management and Budget under the Paperwork Reduction Act.⁵⁰

Pursuant to the Congressional Review Act,⁵¹ the Bureau will submit a report containing this interpretive 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 the rule's published effective date. The Office of Information and Regulatory Affairs has designated this interpretive rule as not a "major rule" as defined by 5 U.S.C. 804(2).

Dated: March 5, 2021.

David Uejio,

Acting Director, Bureau of Consumer Financial Protection.

[FR Doc. 2021–05233 Filed 3–15–21; 8:45 am]

BILLING CODE 4810-AM-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0144; Project Identifier MCAI–2021–00255–R; Amendment 39–21473; AD 2021–06–06]

RIN 2120-AA64

Airworthiness Directives; Bell Textron Canada Limited Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding Emergency Airworthiness Directive (AD) 2021–05–52 which applied to certain Bell Textron Canada Limited (Bell) Model 505 helicopters. Emergency AD 2021–05–52 required a one-time visual inspection of the pilot collective stick and grip assembly (pilot collective stick), a fluorescent penetrant inspection (FPI) if no crack was found during the visual inspection, and depending on the inspection results, removing the pilot collective stick from service and reporting certain information to Bell. Emergency AD 2021–05–52 also prohibited installing any pilot collective stick on any helicopter unless the inspections had been accomplished. This AD removes the visual inspection of the pilot collective stick, requires repetitive FPIs of the pilot collective stick, and requires revising the existing Rotorcraft Flight Manual (RFM) for your helicopter. This AD retains the reporting requirement

⁴⁵ 12 U.S.C. 5512(b)(1). The relevant provisions of the ECOA and Regulation B form part of Federal consumer financial law. 12 U.S.C. 5481(12)(D), (14).

⁴⁶ 15 U.S.C. 1691(e).

⁴⁷ 75 U.S.C. 553(d).

⁴⁸ 5 U.S.C. 553(b).

⁴⁹ 5 U.S.C. 603(a), 604(a).

⁵⁰ 44 U.S.C. 3501–3521.

⁵¹ 5 U.S.C. 801 *et seq.*

and expands the prohibition. This AD was prompted by the determination that visual inspections do not adequately detect a crack and additional findings that a crack may occur sooner than previously expected. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective March 31, 2021.

The Director of the Federal Register approved the incorporation by reference of certain documents listed in this AD as of March 31, 2021.

The FAA must receive comments on this AD by April 30, 2021.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to <https://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* (202) 493-2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, contact Bell Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437-2862 or (800) 363-8023; fax (450) 433-0272; or at <https://www.bellcustomer.com>. You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110. It is also available at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0144.

Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0144; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the Transport Canada AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA National Headquarters, 950 L'Enfant Plaza N SW,

Washington, DC 20024; telephone (202) 267-9167; email hal.jensen@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

On February 22, 2021, the FAA issued Emergency AD 2021-05-52 (Emergency AD 2021-05-52), which was made immediately effective to all known U.S. owners and operators of Bell Model 505 helicopters, serial numbers 65011 and subsequent. Emergency AD 2021-05-52 required, before further flight, removing the pilot collective stick from the jackshaft assembly, cleaning it, and then visually inspecting the complete circumference of certain areas for a crack. If the visual inspection did not reveal a crack, Emergency AD 2021-05-52 required performing an FPI for a crack. Removing from service any cracked pilot collective stick was required before further flight, and if a crack was discovered, reporting certain information to Bell was required within 10 days.

Emergency AD 2021-05-52 was prompted by Canadian Emergency AD CF-2021-05, dated February 21, 2021 (Canadian AD CF-2021-05), issued by Transport Canada, which is the aviation authority for Canada, to correct an unsafe condition for Bell Model 505 helicopters, serial numbers 65011 and subsequent. Transport Canada advised of a report that a pilot collective stick cracked above the cabin floor at the junction with the collective jackshaft. This finding occurred prior to engine start during the pilot pre-flight check of flight controls for travel. The exact cause of the crack was still under investigation, and Transport Canada advised that the unsafe condition, if not addressed, could result in failure of the pilot collective stick and subsequent loss of control of the helicopter.

Accordingly, Canadian AD CF-2021-05 required a one-time visual inspection and as applicable, an FPI of the pilot collective stick to detect cracking. If the pilot collective stick was found to be unserviceable, Canadian AD CF-2021-05 required replacing the collective stick with a serviceable part prior to further flight. Transport Canada advised that a serviceable collective stick is a new collective stick or a collective stick with no crack found during the visual inspection or FPI required by its AD. Transport Canada considered Canadian AD CF-2021-05 an interim action and stated that further AD action may follow.

Actions Since Emergency AD 2021-05-52 was Issued

Since the FAA issued Emergency AD 2021-05-52, Bell has twice revised its

service information. The service information was first revised to remove the procedures for a visual inspection and instead specify recurring FPIs, and Transport Canada superseded Canadian AD CF-2021-05 accordingly with Emergency AD CF-2021-05R1, dated February 26, 2021 (Canadian AD CF-2021-05R1). Canadian AD CF-2021-05R1 advised that examination of a pilot collective stick and another cracked pilot collective stick by Bell revealed fatigue cracking. Based on these findings, Bell determined that a visual inspection is not adequate for detecting smaller cracks. Accordingly, Canadian AD CF-2021-05R1 required an initial FPI for cracks before further flight and then at intervals not to exceed 25 hours time-in-service (TIS). Canadian AD CF-2021-05R1 also contained a ferry flight provision that specifies that ferry flights are permitted to a maintenance base to carry out the FPI, provided that the helicopter is flown from the copilot seat only. Transport Canada considered Canadian AD CF-2021-05R1 an interim action and stated that further AD action may follow.

Bell then again revised its service information to specify inserting a temporary revision (TR) into the RFM that prohibits single pilot operations from the right crew seat. Transport Canada again superseded its AD accordingly with Emergency AD CF-2021-05R2, dated March 4, 2021 (Canadian AD CF-2021-05R2). Canadian AD CF-2021-05R2 specifies that subsequent to the issuance of Canadian AD CF-2021-05R1, additional FPI findings showed that cracking of the pilot collective stick could occur at very low flight hours. As a result, Bell published revised service information to introduce TRs to the RFMs to prohibit single pilot operations from the right crew seat. Transport Canada considers Canadian AD CF-2021-05R2 an interim action as well and states that further AD action may follow to mandate further corrective actions to modify the pilot collective stick to prevent cracking and subsequent failure.

FAA's Determination

These helicopters have been approved by the aviation authority of Canada and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with Canada, Transport Canada, its technical representative, has notified the FAA of the unsafe condition described in its AD. The FAA is issuing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop

on other helicopters of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Bell Alert Service Bulletin 505–21–20, Revision B, dated March 3, 2021 (ASB 505–21–20 Rev B). ASB 505–21–20 Rev B provides instructions for an initial and recurring FPIs for cracks in the pilot collective stick and grip assembly part number M207–20M478–041/–043/–047 on Bell Model 505 helicopters, serial numbers 65011 and subsequent. ASB 505–21–20 Rev B also specifies inserting TRs into the RFMs that prohibit single pilot operations from the right crew seat until further notice. Finally, ASB 505–21–20 Rev B specifies that if the right crew seat pilot collective stick assembly was previously confirmed serviceable following an FPI in accordance with Bell Alert Service Bulletin 505–21–20, Revision A, dated February 26, 2021 (ASB 505–21–20 Rev A), which is not incorporated by reference in this AD, then the 25 flight hour recurring FPI of the right crew seat pilot collective stick assembly is no longer required provided that the helicopter is only operated single pilot in command (PIC) from the left crew seat. If conducting dual pilot operations, ASB 505–21–20 Rev B specifies a 25 flight hour recurring FPI of the right crew seat pilot collective stick assembly.

The FAA also reviewed Bell 505 RFM TR for Pilot Collective (ASB 505–21–20), BHT–505–FM–1, Temporary Revision (TR–6) (BHT–505–FM–1, TR–6) and Bell 505 RFM TR for Pilot Collective (ASB 505–21–20), BHT–505–FM–2, Temporary Revision (TR–1), each dated March 3, 2021. These TRs specify changes to Section 1 of the RFM Limitations Section that the minimum flight crew consists of one pilot that shall operate from the left crew seat and that dual operation is approved provide that the PIC occupies the left crew seat. BHT–505–FM–1, TR–6 also prohibits use of SPLIT–COM mode.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

The FAA reviewed Bell ASB 505–21–20, dated February 20, 2021 (ASB 505–21–20) and ASB 505–21–20 Rev A. ASB 505–21–20 specifies a one-time inspection for cracks of the pilot collective stick and grip assembly. ASB 505–21–20 Rev A removes the visual inspection and adds a repetitive FPI.

AD Requirements

This AD requires, before further flight, revising Section 1, the Limitations section of the existing RFM for your helicopter to prohibit single pilot operations from the right crew seat, require the pilot in command to occupy the left crew seat for dual pilot operations, and depending on configuration, prohibiting the use of SPLIT–COM mode. This AD also requires, before further flight and thereafter at intervals not to exceed 25 hours TIS, removing the pilot collective stick from the jackshaft assembly, cleaning it as specified in ASB 505–21–20 Rev B, and performing an FPI for a crack as specified in ASB 505–21–20 Rev B. Removing from service any cracked pilot collective stick is required before further flight. In addition, this AD requires, within 10 days after the discovery of any crack, reporting certain information to Bell. This AD also prohibits installing any pilot collective stick and grip assembly on any helicopter unless it has successfully passed the FPI inspection requirements of this AD. Lastly, this AD prohibits relief under any Master Minimum Equipment List or Minimum Equipment List for the Audio Panel when the aircraft is operated with a single pilot.

Differences Between This AD and the Transport Canada

This AD prohibits relief under any Master Minimum Equipment List or Minimum Equipment List for the Audio Panel when the aircraft is operated with a single pilot, whereas Canadian AD CF–2021–05R2 does not. Canadian AD CF–2021–05R2 requires the repetitive FPI if the aircraft is not flown solely from the left crew seat whereas this AD requires FPI regardless.

Interim Action

The FAA considers this AD to be an interim action and acknowledges that the requirement to revise the existing RFM for your helicopter to require the pilot in command to occupy the left crew seat, and, depending on configuration, prohibit the use of SPLIT–COM mode may impact seat-dependent training for some helicopters operating under Part 135. However, the unsafe condition requires the FAA to mandate these requirements for continued operational safety. The inspection reports that are required by this AD will enable the FAA to obtain better insight into the cause of the cracking, and eventually develop final action to address the unsafe condition. Once final action has been identified,

the FAA might consider further rulemaking.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for “good cause,” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule because certain requirements must be accomplished before further flight. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forego notice and comment.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include “Docket No. FAA–2021–0144; Project Identifier MCAI–2021–00255–R” at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to <https://www.regulations.gov>, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA National Headquarters, 950 L'Enfant Plaza N SW, Washington, DC 20024; telephone (202) 267-9167; email hal.jensen@faa.gov. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without prior notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 88 helicopters of U.S. Registry. Labor rates are estimated at \$85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Removing, cleaning, performing the FPI of the pilot collective stick, and installing a serviceable pilot collective stick takes about 3 work-hours for an estimated cost of \$255 per helicopter and \$22,440 for the U.S. fleet per inspection cycle. A replacement pilot collective stick costs about \$1,979 per helicopter. If required, reporting information takes about 1 work-hour for an estimated cost of \$85 per instance.

Revising the existing RFM for your helicopter takes about 0.5 work-hour for an estimated cost of \$43 per helicopter.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some of the costs of this AD may be covered under

warranty, thereby reducing the cost impact on affected operators.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 1 hour 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. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177-1524.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will 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.

For the reasons discussed, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866, and

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2021-06-06 Bell Textron Canada Limited:
Amendment 39-21473; Docket No. FAA-2021-0144; Project Identifier MCAI-2021-00255-R.

(a) Effective Date

This airworthiness directive (AD) is effective March 31, 2021.

(b) Affected ADs

This AD replaces Emergency AD 2021-05-52, Project Identifier MCAI-2021-00217-R, dated February 22, 2021.

(c) Applicability

This AD applies to Bell Textron Canada Limited Model 505 helicopters, serial numbers 65011 and subsequent, certificated in any category.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6710, Main Rotor Control.

(e) Unsafe Condition

This AD was prompted by a report of a cracked pilot collective stick. The FAA is issuing this AD to detect a cracked pilot collective stick which, if not corrected, could result in failure of the pilot collective stick and subsequent loss of control of the helicopter.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) Before further flight after the effective date of this AD, revise the Limitations section of the existing Rotorcraft Flight Manual (RFM) for your helicopter by inserting Bell 505 RFM Temporary Revision (TR) for Pilot

Collective (ASB 505–21–20), BHT–505–FM–1, Temporary Revision (TR–6) or Bell 505 RFM TR for Pilot Collective (ASB 505–21–20), BHT–505–FM–2, Temporary Revision (TR–1), each dated March 3, 2021, as applicable to your helicopter. Using a different document with information identical to the information for the “Flight Crew” and “Configuration,” as applicable to your helicopter, in the RFM TR specified in this paragraph for your helicopter is acceptable for compliance with the requirements of this paragraph. This action may be performed by the owner/operator (pilot) holding at least a private pilot certificate and must be entered into the aircraft records showing compliance with this AD in accordance with § 43.9(a)(1) through (4) and § 91.417(a)(2)(v). The record must be maintained as required by § 91.417, § 121.380, or § 135.439.

(2) Before further flight after the effective date of this AD, and thereafter at intervals not to exceed 25 hours time-in-service:

(i) Remove the pilot collective stick and grip assembly from the jackshaft assembly and clean the areas specified in Figure 2 of Bell Alert Service Bulletin 505–21–20, Revision B, dated March 3, 2021 (ASB 505–21–20 Rev B) with a clean cloth C–516C or equivalent moistened with dry cleaning solvent C–304 or equivalent.

(ii) Perform a fluorescent penetrant inspection (FPI) for a crack by following the Accomplishment Instructions, paragraph 5. (but not paragraphs 5.a. and b.) of ASB 505–21–20 Rev B. Perform this FPI in the areas specified in Figure 2 of ASB 505–21–20 Rev B. If there is a crack, before further flight, remove the pilot collective stick and grip assembly from service.

(3) Within 10 days after the discovery of any crack, report the information specified in paragraph 5.a. of ASB 505–21–20 Rev B to Bell Product Support Engineering at productsupport@bellflight.com.

(4) As of the effective date of this AD, do not install any pilot collective stick and grip assembly on any helicopter unless the actions required by paragraphs (g)(2)(i) and (ii) have been accomplished.

(5) As of the effective date of this AD, relief under any Master Minimum Equipment List or Minimum Equipment List for the Audio Panel is prohibited when the aircraft is operated with a single pilot.

(h) Credit for Previous Actions

If you performed an FPI of the pilot collective stick and grip assembly before the effective date of this AD using Bell Alert Service Bulletin 505–21–20, dated February 20, 2021, or Bell Alert Service Bulletin 505–21–20, Revision A, dated February 26, 2021, you met the before further flight FPI requirement of paragraph (g)(2) of this AD.

(i) Special Flight Permits

A special flight permit to a maintenance facility may be granted provided that:

- (1) There are no passengers on-board,
- (2) The helicopter is flown from the copilot seat only, and
- (3) The GMA (intercom) is operative.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation office, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Related Information

(1) Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA National Headquarters, 950 L'Enfant Plaza N SW, Washington, DC 20024; telephone (202) 267–9167; email hal.jensen@faa.gov.

(2) The subject of this AD is addressed in Transport Canada Emergency AD CF–2021–05R2, dated March 4, 2021. You may view the Transport Canada AD on the internet at <https://www.regulations.gov> in Docket No. FAA–2021–0144.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Bell Alert Service Bulletin 505–21–20, Revision B, dated March 3, 2021.

(ii) Bell 505 Rotorcraft Flight Manual Temporary Revision for Pilot Collective (ASB 505–21–20), BHT–505–FM–1, Temporary Revision (TR–6), dated March 3, 2021.

(iii) Bell 505 Rotorcraft Flight Manual Temporary Revision for Pilot Collective (ASB 505–21–20), BHT–505–FM–2, Temporary Revision (TR–1), dated March 3, 2021.

(3) For service information identified in this AD, contact Bell Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; or at <https://www.bellcustomer.com>.

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: fedreg.legal@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on March 10, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–05513 Filed 3–12–21; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 28, 30, 87, 180, and 3282

[Docket No. FR–6252–F–01]

Adjustment of Civil Monetary Penalty Amounts for 2021

AGENCY: Office of the General Counsel, HUD.

ACTION: Final rule.

SUMMARY: This rule provides for 2021 inflation adjustments of civil monetary penalty amounts required by the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

DATES: Effective April 15, 2021.

FOR FURTHER INFORMATION CONTACT:

Aaron Santa Anna, Associate General Counsel for Legislation and Regulations, Office of the General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20024; telephone number 202–402–5138 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) (Pub. L. 114–74, Sec. 701), which further amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410), requires agencies to make annual adjustments to civil monetary penalty (CMP) amounts for inflation “notwithstanding section 553 of title 5, United States Code.” Section 553 refers to the Administrative Procedure Act, which provides for advance notice and public comment during the rulemaking process. However, as explained in Section III below, HUD has determined that advance notice and public comment on this final rule is unnecessary.

This annual adjustment is for 2021. The annual adjustment is based on the percent change between the U.S. Department of Labor’s Consumer Price

Index for All Urban Consumers (“CPI–U”) for the month of October preceding the date of the adjustment, and the CPI–U for October of the prior year (28 U.S.C. 2461 note, section (5)(b)(1)). Based on that formula, the cost-of-living adjustment multiplier for 2021 is 1.01182.¹ Pursuant to the 2015 Act, adjustments are rounded to the nearest dollar.²

II. This Final Rule

This final rule makes the required 2021 inflation adjustment of HUD’s civil

money penalty amounts. Since HUD is not applying these adjustments retroactively, the 2021 increases apply to violations occurring on or after this rule’s effective date. HUD provides a table showing how, for each component, the penalties are being adjusted for 2021 pursuant to the 2015 Act. In the first column (“Description”), HUD provides a description of the penalty. In the second column (“Statutory Citation”), HUD provides the United States Code statutory citation providing for the

penalty. In the third column (“Regulatory Citation”), HUD provides the Code of Federal Regulations citation under Title 24 for the penalty. In the fourth column (“Previous Amount”), HUD provides the amount of the penalty pursuant to the rule implementing the 2020 adjustment (85 FR 13041, April 06, 2020). In the fifth column (“2021 Adjusted Amount”), HUD lists the penalty after applying the 2021 inflation adjustment.

Description	Statutory citation	Regulatory citation (24 CFR)	Previous amount	2021 adjusted amount
False Claims	Omnibus Budget Reconciliation Act of 1986 (31 U.S.C. 3802(a)(1)).	\$28.10(a)	\$11,665	\$11,803.
False Statements	Omnibus Budget Reconciliation Act of 1986 (31 U.S.C. 3802(a)(2)).	\$28.10(b)	\$11,665	\$11,803.
Advance Disclosure of Funding	Department of Housing and Urban Development Act (42 U.S.C. 3537a(c)).	\$30.20	\$20,489	\$20,731.
Disclosure of Subsidy Layering	Department of Housing and Urban Development Act (42 U.S.C. 3545(f)).	\$30.25	\$20,489	\$20,731.
FHA Mortgagees and Lenders Violations.	HUD Reform Act of 1989 (12 U.S.C. 1735f–14(a)(2)).	\$30.35	Per Violation: \$10,245; Per Year: \$2,048,915.	Per Violation: \$10,366; Per Year: \$2,073,133.
Other FHA Participants Violations	HUD Reform Act of 1989 (12 U.S.C. 1735f–14(a)(2)).	\$30.36	Per Violation: \$10,245; Per Year: \$2,048,915.	Per Violation: \$10,366; Per Year: \$2,073,133.
Indian Loan Mortgagees Violations	Housing Community Development Act of 1992 (12 U.S.C. 1715z–13a(g)(2)).	\$30.40	Per Violation: \$10,245; Per Year: \$2,048,915.	Per Violation: \$10,366; Per Year: \$2,073,133.
Multifamily & Section 202 or 811 Owners Violations.	HUD Reform Act of 1989 (12 U.S.C. 1735f–15(c)(2)).	\$30.45	\$51,222	\$51,827
Ginnie Mae Issuers & Custodians Violations.	HUD Reform Act of 1989 (12 U.S.C. 1723i(a)).	\$30.50	Per Violation: \$10,245; Per Year: \$2,048,915.	Per Violation: \$10,366; Per Year: \$2,073,133.
Title I Broker & Dealers Violations	HUD Reform Act of 1989 (12 U.S.C. 1703).	\$30.60	Per Violation: \$10,245; Per Year: \$2,048,915.	Per Violation: \$10,366; Per Year: \$2,073,133.
Lead Disclosure Violation	Title X—Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. 4852d(b)(1)).	\$30.65	\$18,149	\$18,364.
Section 8 Owners Violations	Multifamily Assisted Housing Reform and Affordability Act of 1997 (42 U.S.C. 1437z–1(b)(2)).	\$30.68	\$39,811	\$40,282.
Lobbying Violation	The Lobbying Disclosure Act of 1995 (31 U.S.C. 1352).	\$87.400	Min: \$20,489; Max: \$204,892	Min: \$20,731; Max: \$207,314.
Fair Housing Act Civil Penalties	Fair Housing Act (42 U.S.C. 3612(g)(3)).	\$180.671(a)	No Priors: \$21,410; One Prior: \$53,524; Two or More Priors: \$107,050.	No Priors: \$21,663; One Prior: \$54,157; Two or More Priors: \$108,315.
Manufactured Housing Regulations Violation.	Housing Community Development Act of 1974 (42 U.S.C. 5410).	\$3282.10	Per Violation: \$2,976; Per Year: \$3,719,428.	Per Violation: \$3,011; Per Year: \$3,763,392.

III. Justification for Final Rulemaking for the 2021 Adjustments

HUD generally publishes regulations for public comment before issuing a rule for effect, in accordance with its own regulations on rulemaking in 24 CFR part 10. However, part 10 provides for exceptions to the general rule if the agency finds good cause to omit advanced notice and public participation. The good cause requirement is satisfied when prior public procedure is “impractical,

unnecessary, or contrary to the public interest” (see 24 CFR 10.1). As discussed, this final rule makes the required 2021 inflation adjustment, which HUD does not have discretion to change. Moreover, the 2015 Act specifies that a delay in the effective date under the Administrative Procedure Act is not required for annual adjustments under the 2015 Act. HUD has determined, therefore, that it is unnecessary to delay the effectiveness of

the 2021 inflation adjustments to solicit public comments.

Section 7(o) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(o)) requires that any HUD regulation implementing any provision of the Department of Housing and Urban Development Reform Act of 1989 that authorizes the imposition of a civil money penalty may not become effective until after the expiration of a public comment period of not less than 60 days. This rule does not authorize

¹ Office of Management and Budget, M–21–10, Memorandum for the Heads of Executive Departments and Agencies, Implementation of Penalty Inflation Adjustments for 2021, Pursuant to

the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. (<https://www.whitehouse.gov/wp-content/uploads/2020/12/>

M-21-10.pdf). (October 2020 CPI–U (260.388)/ October 2019 CPI–U (257.346) = 1.01182.)

² 28 U.S.C. 2461 note.

the imposition of a civil money penalty—rather, it makes a standard inflation adjustment to penalties that were previously authorized. As noted above, the 2021 inflation adjustments are made in accordance with a statutorily prescribed formula that does not provide for agency discretion. Accordingly, a delay in the effectiveness of the 2021 inflation adjustments in order to provide the public with an opportunity to comment is unnecessary because the 2015 Act exempts the adjustments from the need for delay, the rule does not authorize the imposition of a civil money penalty, and, in any event, HUD would not have the discretion to make changes as a result of any comments.

IV. Findings and Certifications

Regulatory Review—Executive Orders 12866 and 13563

Under Executive Order 12866 (Regulatory Planning and Review) (58 FR 51735), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulations and Regulatory Review) (76 FR 3821) directs executive agencies to analyze regulations that are “outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.” Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. As discussed above in this preamble, this final rule adjusts existing civil monetary penalties for inflation by a statutorily required amount. HUD determined that this rule was not significant under Executive Order 12866 and Executive Order 13563.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Because HUD has determined that good cause exists to issue this rule without prior public comment, this rule is not subject to the

requirement to publish an initial or final regulatory flexibility analysis under the RFA as part of such action.

Unfunded Mandates Reform

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA)³ requires that an agency prepare a budgetary impact statement before promulgating a rule that includes 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 in any one year. If a budgetary impact statement is required, section 205 of UMRA also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule.⁴ However, the UMRA applies only to rules for which an agency publishes a general notice of proposed rulemaking. As discussed above, HUD has determined, for good cause, that prior notice and public comment is not required on this rule and, therefore, the UMRA does not apply to this final rule.

Executive Order 13132, Federalism

Executive Order 13132 (entitled “Federalism”) (64 FR 43255) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This rule will not have federalism implications and would not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive order.

Environmental Review

This final rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern, or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this final rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

³ 2 U.S.C. 1532.

⁴ 2 U.S.C. 1535.

List of Subjects

24 CFR Part 28

Administrative practice and procedure, Claims, Fraud, Penalties.

24 CFR Part 30

Administrative practice and procedure, Grant programs—housing and community development, Loan programs—housing and community development, Mortgage insurance, Penalties.

24 CFR Part 87

Government contracts, Grant programs, Loan programs, Lobbying, Penalties, Reporting and recordkeeping requirements.

24 CFR Part 180

Administrative practice and procedure, Aged, Civil rights, Fair housing, Persons with disabilities, Investigations, Mortgages, Penalties, Reporting and recordkeeping requirements.

24 CFR Part 3282

Administrative practice and procedure, Consumer protection, Intergovernmental relations, Manufactured homes, Reporting and recordkeeping requirements.

Accordingly, for the reasons described in the preamble, HUD amends 24 CFR parts 28, 30, 87, 180, and 3282 to read as follows:

PART 28—IMPLEMENTATION OF THE PROGRAM FRAUD CIVIL REMEDIES ACT OF 1986

■ 1. The authority citation for part 28 continues to read as follows:

Authority: 28 U.S.C. 2461 note; 31 U.S.C. 3801–3812; 42 U.S.C. 3535(d).

■ 2. In § 28.10, revise paragraphs (a)(1) introductory text and (b)(1) introductory text to read as follows:

§ 28.10 Basis for civil penalties and assessments.

(a) * * *. (1) A civil penalty of not more than \$11,803 may be imposed upon any person who makes, presents, or submits, or causes to be made, presented, or submitted, a claim that the person knows or has reason to know:

* * * * *

(b) * * *. (1) A civil penalty of not more than \$11,803 may be imposed upon any person who makes, presents, or submits, or causes to be made, presented, or submitted, a written statement that:

* * * * *

PART 30—CIVIL MONEY PENALTIES: CERTAIN PROHIBITED CONDUCT

■ 3. The authority citation for part 30 continues to read as follows:

Authority: 12 U.S.C. 1701q–1, 1703, 1723i, 1735f–14, and 1735f–15; 15 U.S.C. 1717a; 28 U.S.C. 1 note and 2461 note; 42 U.S.C. 1437z–1 and 3535(d).

■ 4. In § 30.20, revise paragraph (b) to read as follows:

§ 30.20 Ethical violations by HUD employees.

* * * * *

(b) Maximum penalty. The maximum penalty is \$20,731 for each violation.

■ 5. In § 30.25, revise paragraph (b) to read as follows:

§ 30.25 Violations by applicants for assistance.

* * * * *

(b) Maximum penalty. The maximum penalty is \$20,731 for each violation.

■ 6. In § 30.35, revise the first sentence in paragraph (c)(1) to read as follows:

§ 30.35 Mortgagees and lenders.

* * * * *

(c)(1) * * * The maximum penalty is \$10,366 for each violation, up to a limit of \$2,073,133 for all violations committed during any one-year period.

* * * * *

■ 7. In § 30.36, revise the first sentence in paragraph (c) to read as follows:

§ 30.36 Other participants in FHA programs.

* * * * *

(c) * * * The maximum penalty is \$10,366 for each violation, up to a limit of \$2,073,133 for all violations committed during any one-year period.

* * *

■ 8. In § 30.40, revise the first sentence in paragraph (c) to read as follows:

§ 30.40 Loan guarantees for Indian housing.

* * * * *

(c) * * * The maximum penalty is \$10,366 for each violation, up to a limit of \$2,073,133 for all violations committed during any one-year period.

* * *

■ 9. In § 30.45, revise paragraph (g) to read as follows:

§ 30.45 Multifamily and section 202 or 811 mortgagors.

* * * * *

(g) *Maximum penalty.* The maximum penalty for each violation under paragraphs (c) and (f) of this section is \$51,827.

* * * * *

■ 10. In § 30.50, revise the first sentence in paragraph (c) to read as follows:

§ 30.50 GNMA issuers and custodians.

* * * * *

(c) * * * The maximum penalty is \$10,366 for each violation, up to a limit of \$2,073,133 during any one-year period.

■ 11. In § 30.60, revise paragraph (c) to read as follows:

§ 30.60 Dealers or sponsored third-party originators.

* * * * *

(c) *Amount of penalty.* The maximum penalty is \$10,366 for each violation, up to a limit for any particular person of \$2,073,133 during any one-year period.

■ 12. In § 30.65, revise paragraph (b) to read as follows:

§ 30.65 Failure to disclose lead-based paint hazards.

* * * * *

(b) *Amount of penalty.* The maximum penalty is \$18,364 for each violation.

■ 13. In § 30.68, revise paragraph (c) to read as follows:

§ 30.68 Section 8 owners.

* * * * *

(c) *Maximum penalty.* The maximum penalty for each violation under this section is \$40,282.

* * * * *

PART 87—NEW RESTRICTIONS ON LOBBYING

■ 14. The authority citation for part 87 continues to read as follows:

Authority: 28 U.S.C. 1 note; 31 U.S.C. 1352; 42 U.S.C. 3535(d).

■ 15. In § 87.400, revise paragraphs (a), (b), and (e) to read as follows:

§ 87.400 Penalties.

(a) Any person who makes an expenditure prohibited herein shall be subject to a civil penalty of not less than \$20,731 and not more than \$207,314 for each such expenditure.

(b) Any person who fails to file or amend the disclosure form (see appendix B of this part) to be filed or amended if required herein, shall be subject to a civil penalty of not less than \$20,731 and not more than \$207,314 for each such failure.

* * * * *

(e) First offenders under paragraphs (a) or (b) of this section shall be subject to a civil penalty of \$20,731, absent aggravating circumstances. Second and subsequent offenses by persons shall be subject to an appropriate civil penalty between \$20,731 and \$207,314 as

determined by the agency head or his or her designee.

* * * * *

PART 180—CONSOLIDATED HUD HEARING PROCEDURES FOR CIVIL RIGHTS MATTERS

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

Authority: 28 U.S.C. 1 note; 29 U.S.C. 794; 42 U.S.C. 2000d–1, 3535(d), 3601–3619, 5301–5320, and 6103.

■ 17. In § 180.671, revise paragraphs (a)(1) through (3) to read as follows:

§ 180.671 Assessing civil penalties for Fair Housing Act cases.

(a) * * *

(1) \$21,663, if the respondent has not been adjudged in any administrative hearing or civil action permitted under the Fair Housing Act or any state or local fair housing law, or in any licensing or regulatory proceeding conducted by a federal, state, or local governmental agency, to have committed any prior discriminatory housing practice.

(2) \$54,157, if the respondent has been adjudged in any administrative hearing or civil action permitted under the Fair Housing Act, or under any state or local fair housing law, or in any licensing or regulatory proceeding conducted by a federal, state, or local government agency, to have committed one other discriminatory housing practice and the adjudication was made during the 5-year period preceding the date of filing of the charge.

(3) \$108,315, if the respondent has been adjudged in any administrative hearings or civil actions permitted under the Fair Housing Act, or under any state or local fair housing law, or in any licensing or regulatory proceeding conducted by a federal, state, or local government agency, to have committed two or more discriminatory housing practices and the adjudications were made during the 7-year period preceding the date of filing of the charge.

* * * * *

PART 3282—MANUFACTURED HOME PROCEDURAL AND ENFORCEMENT REGULATIONS

■ 18. The authority citation for part 3282 continues to read as follows:

Authority: 15 U.S.C. 2967; 42 U.S.C. 3535(d), 5403, and 5424.

■ 19. Revise § 3282.10 to read as follows:

§ 3282.10 Civil and criminal penalties.

Failure to comply with these regulations may subject the party in question to the civil and criminal penalties provided for in section 611 of the Act, 42 U.S.C. 5410. The maximum amount of penalties imposed under section 611 of the Act shall be \$3,011 for each violation, up to a maximum of \$3,763,392 for any related series of violations occurring within one year from the date of the first violation.

Damon Smith,

Principal Deputy General Counsel.

[FR Doc. 2021-04817 Filed 3-15-21; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF EDUCATION**34 CFR Chapter III**

[Docket ID ED-2020-OSERS-0063]

**Final Priority and Definitions—
American Indian Vocational
Rehabilitation Training and Technical
Assistance Center**

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education.

ACTION: Final priority and definitions.

SUMMARY: The Department of Education (Department) announces a priority and definitions to fund an American Indian Vocational Rehabilitation Training and Technical Assistance Center (AIVRTTAC), Assistance Listing Number 84.250Z. The Department may use the priority and definitions for competitions in fiscal year (FY) 2021 and later years. We take this action to improve employment outcomes and raise expectations for American Indians with disabilities and to fund training and technical assistance (TA) activities to support the American Indian Vocational Rehabilitation Services (AIVRS) projects. We intend the AIVRTTAC to provide training and TA to the AIVRS project personnel, especially vocational rehabilitation (VR) counselors, to improve their capacity to implement innovative and effective VR services and employment strategies and practices to increase the number and quality of employment outcomes for American Indians with disabilities served through the AIVRS program.

Awards will be made to State, local, or Tribal governments, non-profit organizations, or institutions of higher education that have experience in the operation of AIVRS programs.

DATES: This priority and definitions are effective April 15, 2021.

FOR FURTHER INFORMATION CONTACT: Jerry Elliott, U.S. Department of Education, 400 Maryland Avenue SW, Room 5097, Potomac Center Plaza, Washington, DC 20202-2800. Telephone: (202) 245-7335. Email: jerry.elliott@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

Purpose of Program: The purpose of the AIVRTTAC program is to provide training and TA to governing bodies of Indian Tribes, or consortia of those governing bodies, that have received an AIVRS grant under section 121(a) of the Rehabilitation Act of 1973, as amended (Act). Under section 121(c)(2) of the Act, the Commissioner of the Rehabilitation Services Administration (RSA) makes grants to, or enters into contracts or other cooperative agreements with, entities that have experience in the operation of AIVRS projects to provide such training and TA on developing, conducting, administering, and evaluating these projects.

Program Authority: 29 U.S.C. 741(c).

Applicable Program Regulations: 34 CFR part 371.

We published a notice of proposed priorities and definitions (NPP) for this program in the **Federal Register** on September 10, 2020 (85 FR 55802). That notice contained background information and our reasons for proposing the particular priorities and definitions.

Except for minor editorial and technical revisions for grammar and clarity, and one substantive change explained in the discussion of the comments that follow, there are no differences between Proposed Priority 1 and the proposed definitions and the final priority and final definitions. We have not included Proposed Priority 2 in the final priorities.

Public Comment: In response to our invitation in the NPP, five parties submitted comments on the proposed priorities and definitions.

Generally, we do not address technical and other minor changes, or suggested changes the law does not authorize us to make. In addition, we do not address general comments that raise concerns not directly related to the proposed priorities or definitions.

Analysis of Comments and Changes: An analysis of the comments and of any changes in the priorities and definitions since publication of the NPP follows.

Comment: Two commenters noted that American Indians, just like other groups, deserve rehabilitation and

disability assistance services. The commenters believe that the AIVRS program is a great way to help this group. The commenters believe that Proposed Priority 1 would help.

Discussion: The Department agrees with the commenters that Proposed Priority 1 is important in helping the AIVRS projects to deliver AIVRS services to American Indians with disabilities served by the AIVRS projects.

Changes: None.

Comment: One commenter discussed the need to build internal capacity within AIVRS projects to deliver benefits counseling to AIVRS project participants. The commenter noted that benefits counseling is a proven approach that not only helps individuals understand the benefits of work but also leads to more employment outcomes. The commenter stated that benefits counseling provided within Tribal programs will be more welcome and better accepted than benefits counseling provided by “outsiders” who provide counseling and then leave. Specifically, the commenter recommended that the AIVRTTAC institute a plan to provide AIVRS consumers with benefits planning services by training Tribal members to provide these services and build expert capacity within the Tribal nations so that consumers can learn and understand the process and complex rules of government programs.

Discussion: The Department agrees with the commenter that benefits counseling services are important services to provide to AIVRS consumers as they work to develop their career goals and their individualized plan for employment (IPE). Benefits counseling is a commonly provided VR service. The Department agrees that the AIVRTTAC should be able to provide TA to Tribes seeking to build resources to provide these services and will address it in the cooperative agreement once the applicant is selected, but the priority addresses broader requirements for training such as development of the IPE, which looks at all VR services, of which benefits counseling is one. The Department does not believe that the one-size-fits-all approach suggested by the commenter—to require the AIVRTTAC to train all AIVRS grantees on benefits counseling—is the best approach given the diversity of the AIVRS grantees. Many small AIVRS projects may not have the capacity to devote staff time to this complicated issue and would need TA to establish relationships with other sources to address this need. Also, there may be local services available that have proven

effective, or there may be collaborative approaches with other Tribal programs or external programs that could address this need. The Department believes that the specific method of providing benefits counseling services is best left to the specific AIVRS project and Tribal organizations to determine, with the AIVRTTAC providing TA as appropriate and as requested by the AIVRS project.

Changes: None.

Comment: One commenter advocated that any TA provided that results in the successful attainment of a certificate be offered only for academic credit and that certificates of a non-academic nature be only offered as incremental steps that would ultimately result in academic credit, resulting in a terminal degree in American Indian Vocational Rehabilitation Services. The commenter stated that when an individual self-identifies as an American Indian VR professional, the individual should be striving to be on a career-long learning endeavor to perform at their highest potential for the clients they serve. AIVRS agencies need personnel who choose this work as a career option, and academic degrees are an avenue whereby an individual makes these career choices.

Discussion: The Department agrees with the commenter that an academic credit option needs to be available for the courses offered for completion of a certificate in American Indian Vocational Rehabilitation Services. Proposed Priority 1 allows VR professionals from the AIVRS projects to decide to take certificate courses for no academic credit if they so choose. The Department will modify the priority to require that the AIVRTTAC offer an academic option in addition to a non-academic option and allow the applicant to determine the designation and requirements for each.

In addition, the Department will revise the proposed priority to encourage but not require an academic path whereby certificate courses taken for academic credit could lead to a degree in vocational rehabilitation or a closely related field. While an academic path leading to a degree is important, the Department does not agree that an academic path should be the only option. AIVRS projects hire staff at different levels in the organization, and certificate course knowledge could be helpful to staff at all levels of the organization. In addition, there may be individuals who bring great cultural or work experience to the AIVRS project but may not be, for various reasons, able to pursue a degree. The knowledge gained through a certificate class would nevertheless be helpful to the employee

and benefit the AIVRS consumers the employee serves, even if the class is not taken for academic credit.

Changes: We have revised Proposed Priority 1 to require that the AIVRTTAC provide an academic credit option for courses offered that lead to a certificate in AIVRS and added language to encourage the inclusion of an academic path that allows certificate courses taken for academic credit to lead to a degree.

Comment: Regarding Proposed Priority 2, one commenter stated that the match requirement should be the smallest percentage possible and that foregone indirect funds should be allowable as an in-kind match because the commenter's organization within a university structure is funded by grant and contract revenue and has only limited other funds that could be used for match purposes. The commenter also stated that potential applicants, such as small colleges and Tribal entities, have limited funds available for match and that a match requirement will limit the diversity of applicants.

Discussion: The Department agrees that requirements in the proposed priority that would limit the potential applicant pool are not desirable. In particular, there are a number of institutions of higher education (IHEs) operated by Tribes that would bring cultural relevance and practical experience in the operation of workforce related programs in Tribal areas. While Tribal IHEs vary in size, funding, and location, it is possible that a match requirement would deter a Tribal IHE from becoming an applicant or a partner in an application. Applications with multiple partners generally require the participating organizations to furnish the matching funds for the portion of the grant they receive. Thus, a match requirement could discourage participation even as a partner in an application.

The Department also recognizes that the COVID-19 pandemic is not abating, especially in Tribal communities, and that the impact of the pandemic is causing revenue challenges for State and Tribal governments and State and Tribal IHEs, making the provision of matching funds even more difficult.

The proposed matching requirement is not required by statute. Because the Department wishes to invite applications from the broadest range of applicants, and because most of the eligible applicant pool is also economically affected by the COVID-19 pandemic, the Department has determined that the concerns raised by the commenter and the others recognized by the Department outweigh

the value that a matching requirement might otherwise generate through greater institutional investment in the grant activity.

Changes: We have removed Proposed Priority 2.

Final Priority

American Indian Vocational Rehabilitation Services—Training and Technical Assistance Program

This priority funds a five-year cooperative agreement to establish an American Indian Vocational Rehabilitation Training and Technical Assistance Center (AIVRTTAC) to provide four types of training and technical assistance (TA) for the personnel of the American Indian Vocational Rehabilitation Services (AIVRS) projects awarded under section 121(a) of the Rehabilitation Act of 1973, as amended (Act), to the governing bodies of Indian Tribes and consortia of those governing bodies. The four types of training and TA are: (1) Intensive training and TA; (2) targeted training and TA; (3) universal training and TA; and (4) capacity-building for AIVRS project personnel through training modules that build foundational skills for the delivery of VR services to AIVRS project participants. The AIVRTTAC will develop and provide these types of training and TA for AIVRS projects in the following topic areas:

(a) Applicable laws and regulations governing the AIVRS program.

(b) Promising practices for providing VR services to American Indians with disabilities.

(c) The delivery of VR services to American Indians with disabilities, including the determination of eligibility, case management, case record documentation, assessment, development of the individualized plan for employment, and placement into competitive integrated employment.

(d) Knowledge of assistive technology (AT), including the definition of AT, how to evaluate the need for AT and what types of AT are available, use of AT, and access to AT.

(e) Implementing professional development practices to ensure effective project coordination, administration, and management.

(f) Implementing appropriate financial and grant management practices to ensure compliance with OMB's Uniform Guidance (2 CFR part 200) and the Education Department General Administrative Regulations.

(g) Evaluating project performance, including data collection, data analysis, and reporting.

Specific subjects for training and TA in each of these topic areas will be

identified on an annual basis and in coordination with RSA.

Project Activities

To be considered for funding under this priority, applicants must conduct the following activities, or a subset of the following activities as determined by the Department, in a culturally appropriate manner:

(a) Maintain and build upon the 12 training modules and the fiscal tool kit developed by the Tribal Vocational Rehabilitation Institute (the Institute) during Federal fiscal years (FFYs) 2015–2021, including maintaining the series of seven training modules that build foundational skills that, when satisfactorily completed, lead to a VR certificate to be awarded by the AIVRTTAC. To satisfy this activity requirement, the grantee—

(i) Must develop both academic and non-academic options for completing courses leading to the VR certificate, the requirements for obtaining a certificate including the specific requirements for academic credit for courses included in the certificate when applicable, and how the certificate may be used by the participants who earn it;

(ii) May offer the series of training modules in a traditional classroom setting, through distance learning, through week-long institutes, at regional trainings throughout the country as an extension of national conferences, and through other delivery methods, as appropriate, to meet the needs of the targeted audience;

(iii) May use grant funds to provide reasonable financial assistance for the cost of tuition, fees, and training materials and to offset costs associated with travel for participants who may be in remote areas of the country;

(iv) Must conduct an assessment before and after providing training for each participant in order to assess strengths and specific areas for improvement, educational attainment, and application of skills, and any issues or challenges to be addressed post-training to ensure improved delivery of VR services to American Indians with disabilities;

(v) Must provide follow-up TA to participants to address any issues or challenges that are identified post-training and to ensure that the training they received is applied effectively in their work setting, and such follow-up may be conducted as part of the provision of targeted training and TA or intensive training and TA as determined by the needs of the specific AIVRS project;

(vi) Must conduct an evaluation to obtain feedback on the training and

follow-up TA and to determine whether this training and TA contributed to increased employment outcomes for American Indians with disabilities;

(vii) Are encouraged to develop a path by which courses offered for academic credit lead to a degree in Rehabilitation or a related field; and

(viii) May develop additional training modules as negotiated through the cooperative agreement.

(b) Maintain and build upon the topics and tools the current AIVRTTAC has developed to provide intensive training and TA. To satisfy this activity requirement, the grantee must—

(i) Develop and provide intensive training and TA to a minimum of three AIVRS projects in the first year. For future years, the minimum number of AIVRS projects to receive intensive training and TA will be negotiated through the cooperative agreement;

(ii) Develop and implement training and TA consistent with AIVRS project activities and tailored to the specific needs and challenges of the AIVRS project receiving the intensive training and TA;

(iii) Provide training and TA under an agreement with each AIVRS project receiving intensive training and TA that, at a minimum, details the purpose of the training and TA, intended outcomes, and requirements for the subsequent evaluation of the training and TA; and

(iv) Assess the results of the training and TA 90 days after its completion to ensure that the recipient is able to apply effectively the training and TA, identify any issues or challenges in its implementation, and provide additional training and TA, either virtually or on-site, as needed.

(c) Maintain and build upon the topics and tools the current AIVRTTAC has developed to provide a range of targeted training and TA in the topic areas described in this priority based on needs common to multiple AIVRS projects. The grantee must follow up with the recipients of targeted training and TA it provides to determine the effectiveness of the training and TA;

(d) Maintain and build upon the topics and tools the current AIVRTTAC has developed to provide universal training and TA in the topic areas in this priority;

(e) Provide a minimum of two webinars or video conferences in each of the topic areas in this priority to describe and disseminate up-to-date information, guides, examples, and emerging and promising practices in each area;

(f) Develop new information technology (IT) platforms and systems,

or modify existing platforms and systems, as follows:

(i) Develop or modify, and maintain, a state-of-the-art IT platform capable and reliable enough to support webinars, teleconferences, video conferences, and other virtual methods of dissemination of information and TA;

(ii) Develop or modify, and maintain, a state-of-the-art archiving and dissemination system that is open and available to all AIVRS projects and that provides a central location for all AIVRS training and TA products for later use, including course curricula, audiovisual materials, webinars, examples of promising practices related to the topic areas in this priority, the primary areas identified through the annual surveys completed by AIVRS projects, other topics identified by RSA, and other relevant TA products (the possibility of collaborating with the National Clearinghouse of Rehabilitation Training Materials will be considered with the grantee and included in the cooperative agreement, as appropriate);

(iii) Ensure that all products produced by the AIVRTTAC meet government and industry-recognized standards for accessibility; and

(iv) Ensure that all products, resources, and materials developed by the AIVRTTAC are widely disseminated across the AIVRS projects and reflect the AIVRS population and diversity among its communities to the maximum extent possible.

(g) Establish a community of practice (or communities of practice) that will serve as a vehicle for communication, an exchange of information among AIVRS projects, and a forum for sharing the results of training and TA projects that are in progress or have been completed;

(h) Conduct outreach to AIVRS projects so that they are aware of, and can participate in, training and TA activities; and

(i) Conduct an evaluation to determine the quality, relevance, and usefulness of the AIVRTTAC's training and TA, including the impact of the AIVRTTAC's activities on the ability of AIVRS projects to effectively manage their projects and improve the delivery of VR services to American Indians with disabilities.

Project Requirements

To be funded under this priority, applicants must meet the project requirements in this priority. RSA encourages innovative approaches to meet these requirements, which are—

(a) Demonstrate in the narrative section of the application under

“Significance of the Proposed Project” how the proposed project will—

(1) Use the applicant’s knowledge and experience in the operation of AIVRS projects to provide training and TA for these projects;

(2) Address the AIVRS projects’ capacity to effectively implement an AIVRS project. To meet this requirement, the applicant must—

(i) Demonstrate knowledge of emerging and promising practices in the topic areas in this priority;

(ii) Demonstrate knowledge of current RSA guidance and Federal initiatives designed to improve the functioning of grant projects in general and grant projects for American Indian Tribes in particular; and

(iii) Present information about the difficulties that AIVRS grantees have encountered in implementing effective AIVRS projects;

(b) Demonstrate in the narrative section of the application under “Quality of Project Design” how the proposed project will—

(1) Achieve its goals, objectives, and intended outcomes. To meet this requirement, the applicant must provide—

(i) Measurable intended project outcomes;

(ii) A plan for how the proposed project will achieve its intended outcomes;

(iii) A plan for communicating and coordinating with RSA and key personnel of AIVRS projects; and

(iv) A draft training module or outline for a targeted training and TA presentation or an outline for intensive training and TA activities for one of the topic areas in this priority to demonstrate how participants would be trained in that area. The module or outline is a required attachment in the application and must include, at a minimum, the following:

(A) The goals and objectives of this training module, targeted training and TA activity, or intensive training and TA activities;

(B) A specific list of what participants should know and be able to do as a result of successfully completing the module, targeted training and TA activity, or intensive training and TA activities;

(C) Up-to-date resources, publications, applicable laws and regulations, and other materials that may be used to develop the module, targeted training and TA activity, or intensive training and TA activities;

(D) Exercises that will provide an opportunity for application of the subject matter;

(E) A description of how participant knowledge, skills, and abilities will be measured; and

(F) In the case of an intensive training and TA intervention, how the outcomes and impact of the intensive training and TA intervention will be measured;

(2) Use a logic model to develop project plans and activities that includes, at a minimum, the goals, activities, outputs, and outcomes of the proposed project;

(3) Be based on current research and make use of emerging and promising practices, and evidence-based practices, where available. To meet this requirement the applicant must describe—

(i) The current research on the emerging and promising practices in the topic areas in this priority; and

(ii) How the AIVRTTAC will incorporate current research and promising and evidence-based practices, including research about adult learning principles and implementation science, in the development and delivery of its products and services;

(4) Develop products and provide services that are of high quality and of sufficient intensity and duration to achieve the intended outcomes of the proposed project. To address this requirement the applicant must describe—

(i) Its proposed approach to universal training and TA;

(ii) Its proposed approach to targeted training and TA, which must identify—

(A) The intended recipients of the products and services under this approach, including the categories of personnel that would be receiving the training and TA;

(B) Its proposed methods for providing targeted training and TA; and

(C) Its proposed methodology for determining topics for the targeted training and TA;

(iii) Its proposed approach to intensive training and TA, which must identify—

(A) Its proposed approach to identifying recipients for intensive training and TA;

(B) Its proposed methodology for providing intensive training and TA to recipients; and

(C) Its proposed approach to assessing the training and TA needs of recipients, including their ability to respond effectively to the training and TA; and

(iv) Its proposed approach to maintaining and building upon capacity-building modules, which must identify—

(A) Its proposed approach to maintaining the 12 training modules and the fiscal tool kit developed by the

Institute in FFYs 2015–2021, including maintaining the series of seven training modules that build foundational skills that, when satisfactorily completed, lead to a VR certificate to be awarded by the grantee; and

(B) Its proposed approach to identifying, developing, and delivering new capacity-building modules; and

(5) Develop products and implement services to maximize the proposed project’s efficiency. To address this requirement, the applicant must describe—

(i) How the proposed project will use technology to achieve the intended project outcomes;

(ii) With whom the proposed project will collaborate and the intended outcomes of this collaboration; and

(iii) In particular, how the proposed project will coordinate and collaborate with other RSA-funded technical assistance centers to exchange and adapt relevant products and materials to avoid duplication and make effective use of grant funds to better manage the AIVRTTAC project and its available resources to improve service delivery to AIVRS projects;

(c) Demonstrate in the narrative section of the application under “Adequacy of Project Resources” how—

(1) The applicant and any key partners possess adequate resources to carry out the proposed activities; and

(2) The proposed costs are reasonable in relation to the anticipated results and benefits;

(d) Demonstrate in the narrative section of the application under “Quality of Project Personnel” how—

(1) The proposed project will encourage applications for employment from persons who are members of groups that have historically been underrepresented based on race, color, national origin, gender, age, or disability, as appropriate; and

(2) The proposed key project personnel, consultants, and subcontractors have the qualifications and experience to provide training and TA to AIVRS projects in each of the topic areas in this priority and to achieve the project’s intended outcomes, including how the proposed project personnel have a high degree of knowledge and understanding of cultural factors that will be sufficient to ensure the delivery of training and TA in a culturally appropriate manner;

(e) Demonstrate in the narrative section of the application under “Quality of the Management Plan” how the proposed management plan will ensure that the project’s intended outcomes will be achieved on time and within budget. To address this

requirement, the applicant must describe—

(1) Clearly defined roles and responsibilities for at least two full-time key project personnel designated to the AIVRTTAC through the entire project period and for consultants and subcontractors, as applicable;

(2) Timelines and milestones for accomplishing the project tasks;

(3) Using a personnel loading chart, detailed project activities through the entire project period, key personnel and any consultants or subcontractors that will be allocated to each activity, and the designated level of effort for each of those activities;

(4) How the personnel allocations in the personnel loading chart are appropriate and adequate to achieve the project's intended outcomes, including an assurance that all personnel will communicate with stakeholders and RSA in a timely way;

(5) How the proposed management plan will ensure that the training and TA products developed through this cooperative agreement are complete, accurate, and of high quality; and

(6) How the proposed project will benefit from a diversity of perspectives, including AIVRS projects and consumers, State VR agencies, TA providers, and policy makers, in its development and operation; and

(f) Demonstrate in the narrative section of the application under "Quality of the Evaluation Plan" how the applicant proposes to collect and analyze data on specific and measurable goals, objectives, and intended outcomes of the project, including the effectiveness of the training and TA provided. To address this requirement, the applicant must describe—

(i) Its proposed evaluation methodologies, including instruments, data collection methods, and analyses;

(ii) Its proposed standards or targets for determining effectiveness;

(iii) How it will use the evaluation results to examine the effectiveness of its implementation and its progress toward achieving the intended outcomes; and

(iv) How the methods of evaluation will produce quantitative and qualitative data that demonstrate whether the project and individual training and TA activities achieved their intended outcomes.

Types of Priorities

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a

notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Final Definitions: We establish the following definitions for use in any competition in which the final priority is used:

Intensive training and technical assistance (TA) means training and TA provided to the governing bodies of Indian Tribes that have received an AIVRS grant and to the current personnel of the AIVRS projects primarily on-site over an extended period. Intensive training and TA is based on an ongoing relationship between the training and TA center staff and the governing bodies of Indian Tribes that have received an AIVRS grant and the current personnel of the AIVRS projects under the terms of a signed intensive training and TA agreement.

Targeted training and technical assistance means training and TA based on needs common to one or more governing bodies of Indian Tribes that have received an AIVRS grant and to the current personnel of the AIVRS projects on a time-limited basis and with limited commitment of training and technical assistance center resources. Targeted training and TA are delivered through virtual or in-person methods tailored to the identified needs of the participating governing bodies of Indian Tribes that have received an AIVRS grant and to the current personnel of the AIVRS projects.

Universal training and technical assistance means training and TA broadly available to governing bodies of Indian Tribes that have received an AIVRS grant and to the current personnel of the AIVRS projects and other interested parties through their own initiative, resulting in minimal interaction with training and technical assistance center staff. Universal

training and TA includes generalized presentations, products, and related activities available through a website or through brief contacts with the training and technical assistance center staff.

This document does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This document does *not* solicit applications. In any year in which we choose to use the priority and definitions we invite applications through a notice in the **Federal Register**.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, OMB must determine whether this regulatory action is "significant" and, therefore, subject to the requirements of the Executive order and subject to review by OMB. Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of \$100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities in a material way (also referred to as an "economically significant" rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This final regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this final regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and

taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select 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 the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency “to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.” The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include “identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.”

We are issuing this final priority and definitions only on a reasoned determination that their benefits justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

In accordance with these Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department’s programs and activities. The costs would include the time and effort in responding to the priority for entities that choose to respond.

In addition, we have considered the potential benefits of this regulatory action and have noted these benefits in the background section of this document. The benefits include continuing to provide both TA and a structured training program focused on

the VR process and practices and the unique skills and knowledge necessary to improve employment outcomes for American Indians with disabilities.

Intergovernmental Review: This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Regulatory Flexibility Act Certification: The Secretary certifies that this regulatory action will not have a significant economic impact on a substantial number of small entities. The U.S. Small Business Administration Size Standards define proprietary institutions as small businesses if they are independently owned and operated, are not dominant in their field of operation, and have total annual revenue below \$7,000,000. Nonprofit institutions are defined as small entities if they are independently owned and operated and not dominant in their field of operation. Public institutions are defined as small organizations if they are operated by a government overseeing a population below 50,000.

The small entities that this regulatory action will affect are public or private nonprofit agencies and organizations, including Indian Tribes and institutions of higher education that may apply. We believe that the costs imposed on an applicant by the priority and definitions will be limited to paperwork burden related to preparing an application and that the benefits of the priority and definitions will outweigh any costs incurred by the applicant. There are very few entities that could provide the type of training and TA required under the final priority. For these reasons the priority and definitions will not impose a burden on a significant number of small entities.

Paperwork Reduction Act of 1995: The priority and definitions contain information collection requirements that are approved by OMB under OMB control number 1820–0018; the priority and definitions do not affect the currently approved data collection.

Accessible Format: On request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, Braille, large print, audiotope, or compact disc, or other accessible format.

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David Cantrell,

Deputy Director, Office of Special Education Programs. Delegated the authority to perform the functions and duties of the Assistant Secretary for the Office of Special Education and Rehabilitative Services.

[FR Doc. 2021–05430 Filed 3–11–21; 4:15 pm]

BILLING CODE 4000–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 210308–0049]

RIN 0648–BJ74

Magnuson-Stevens Act Provisions; Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; 2021–2022 Biennial Specifications and Management Measures; Correction

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

ACTION: Final rule; correcting amendment.

SUMMARY: This action contains corrections to the final rule for the 2021–2022 Biennial Harvest Specifications and Management Measures for groundfish harvested in the U.S. exclusive economic zone off the coasts of Washington, Oregon, and California published on December 11, 2020. This action corrects: the Rockfish Conservation Area (RCA) waypoints for the 100 fathom depth contour, the other flatfish gear restrictions in the RCA, language describing the boundary lines for the depth contours, and the boundaries of the non-groundfish RCA for California halibut, sea cucumber, and ridgeback prawns south of 34°27′ N. lat. These corrections are necessary so the regulations accurately implement the Pacific Fishery Management

Council's intent and are consistent with what was anticipated by participants in the groundfish fishery.

DATES: This correction is effective March 16, 2021.

FOR FURTHER INFORMATION CONTACT:

Karen Palmigiano at karen.palmigiano@noaa.gov or 206-526-4491.

SUPPLEMENTARY INFORMATION: NMFS published a final rule on December 11, 2020, (85 FR 79880), that implemented the 2021–2022 harvest specifications and management measures for groundfish harvested in the U.S. exclusive economic zone off the coasts of Washington, Oregon, and California. That final rule was effective January 1, 2021. After publication of the final rule, NMFS noted the need for four corrections.

Corrections

The final rule for the 2021–2022 groundfish harvest specifications and management measures (85 FR 79880; December 11, 2020) inadvertently deleted the final waypoint for the line approximating the 100-fathom depth contour coast-wide at the U.S. and Mexico border. This waypoint, known as point #322, at 32°34.22' North latitude (N lat.), 117°21.20' West longitude (W. long.) was part of the regulations in 2020 and the Pacific Fishery Management Council (Council) did not recommend to remove it through the 2021–2022 harvest specifications. This final rule will add point #322 back into the list of waypoints for the 100-fathom line. Without this point identified in the regulations, it is difficult for members of industry to use their plotters to identify the boundaries of the non-trawl RCA. Additionally, the waypoint must be reinstated into the regulations in order for law enforcement to correctly enforce the boundaries of the non-trawl RCA. This correcting amendment would revise the regulations to reinstate the missing waypoint.

In order to make the description of the depth contours off of California consistent with the description used for Oregon and Washington, the final rule noted in section “V. Changes From the Proposed Rule” that the language describing the boundary lines in § 660.360(3)(i)(A)(1) and (2) would be changed from . . . is prohibited seaward of the 30 fm (55m) depth contour . . . to . . . is prohibited seaward of the boundary line approximating the 30 fm (55m) depth contour However, the final rule inadvertently did not change the regulatory text to include the updated description. This correcting amendment

would revise the language in § 660.360(3)(i)(A)(1) and (2) to include the correct description of the depth contours consistent with the intent of the 2021–2022 harvest specifications final rule and the Council's intent. This clarification is needed to provide consistency among sections in the regulations so that the description of the depth contours for recreational closed areas are consistent between the three states.

The final rule implemented the Council recommendation to remove the gear restrictions for the limited-entry fixed-gear (LEFG) and open-access (OA) fishery targeting stocks in the “Other Flatfish” complex south of 42° N lat. by removing the hook-and-line gear restriction language from the LEFG and OA trip limit tables. However, NMFS inadvertently did not remove the gear restriction from other sections of the regulatory text. Specifically, the requirement to use no more than 12 hooks, Number 2 or smaller, which measure no more than 11 mm (0.44 inches) point to shank and up to two 1-lb (0.45 kg) weights per line should have been removed in all places it appears in the regulatory text and replaced with hook and line gear only. This final rule would remove the gear restriction specifying the type and number of hooks from the regulations so that the regulations are consistent and follow the intent of the action. This correction is needed to reduce confusion and inconsistencies in the regulatory text as to what gears are allowed to be used inside the non-trawl RCA.

The final rule included a typographical error in the description of the boundary lines south of 34°27' N lat. for the non-groundfish trawl RCA for California halibut, sea cucumber, and ridgeback prawns in Table 3 (South) to Subpart F. Instead of stating the fathom lines of the boundary, the boundaries are stated as 01/01/2021+A108:P133. This final rule will correct the boundary from the 100 fm line to the 150 fm line. This correction is needed to enforce the boundaries of this non-groundfish trawl RCA and also to reduce confusion about the boundaries among members of industry.

All of these corrections are consistent with the Council action for the 2021–2022 groundfish harvest specifications and the public expects the regulations to be written as in the correction. These are minor corrections to correctly implement the Council's intent in their final action taken in June 2020.

Classification

NMFS is issuing this rule pursuant to 305(d) of the Magnuson-Stevens Act. In

a previous action taken pursuant to section 304(b), the Council designed the Pacific Coast Groundfish Fishery Management Plan (FMP) to authorize NMFS to take this action pursuant to MSA section 305(d). See 50 CFR 660. The NMFS Assistant Administrator has determined that this final rule is consistent with the FMP and other applicable law.

Pursuant to 5 U.S.C. 553(b)(B), the Assistant Administrator for Fisheries (AA) finds there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be unnecessary and contrary to public interest. Notice and comment are unnecessary and contrary to the public interest because this action corrects inadvertent errors related to the December 11, 2020 final rule (85 FR 79880). Immediate correction of the errors is necessary to prevent confusion among participants in the fishery due to conflicting gear restrictions and lack of waypoints to define boundary lines that could result in issues with enforcement. To effectively correct the errors, the changes in this action must be effective upon publication as the fishery has already begun. Thus, there is not sufficient time for notice and comment. In addition, notice and comment is unnecessary because this notice makes only minor changes to correct inadvertent errors related to the December 11, 2020 final rule (85 FR 79880). These corrections will not affect the results of analyses conducted to support management decisions in the Pacific Coast groundfish fishery. These corrections are consistent with the Council's intent for regulations and the public expects the regulations to be written as in the correction. No change in operating practices in the fishery is required.

For the same reasons stated above, the AA has determined good cause exists to waive the 30-day delay in effectiveness pursuant to 5 U.S.C. 553(d). This notice makes only minor corrections to the final rule which was effective January 1, 2021. Delaying effectiveness of these corrections would result in conflicts in the regulations and confusion among fishery participants. Because prior notice and an opportunity for public comment are not required to be provided for this rule by 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are not applicable. Accordingly, no Regulatory Flexibility Analysis is required for this rule and none has been prepared.

This final rule is not significant under Executive Order 12866.

This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, and Indian fisheries.

Dated: March 10, 2021.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 660 is corrected by making the following correcting amendments:

PART 660—FISHERIES OFF WEST COAST STATES

- 1. The authority citation for 50 CFR part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*, 16 U.S.C. 773 *et seq.*, and 16 U.S.C. 7001 *et seq.*

- 2. In § 660.73, add paragraph (a)(322) to read as follows:

§ 660.73 Latitude/longitude coordinates defining the 100 fm (183 m) through 150 fm (274 m) depth contours.

* * * * *

(a) * * *

(322) 32°34.22' N lat., 117°21.20' W long.

* * * * *

- 3. In § 660.230, revise paragraph (d) introductory text, add paragraph (d)(10)(i), and revise paragraphs (d)(11)(iv) and (d)(12) and (13) to read as follows:

§ 660.230 Fixed gear fishery—management measures.

* * * * *

(d) *Groundfish conservation areas.* GCAs are defined by coordinates expressed in degrees of latitude and longitude. The latitude and longitude coordinates of the GCA boundaries are specified at §§ 660.70 through 660.74. A vessel that is authorized by this paragraph to fish within a GCA (*e.g.*, fishing for “other flatfish” with hook and line gear only), may not simultaneously have other gear on board the vessel that is unlawful to use for fishing within the GCA. The following GCAs apply to vessels participating in the limited entry fixed gear fishery.

* * * * *

(10) * * *

(i) Fishing for “other flatfish” is permitted within the CCAs with hook and line gear only; and provided a valid declaration report as required at § 660.13(d), subpart C, has been filed with NMFS OLE.

* * * * *

(11) * * *

(iv) It is lawful to fish within the nontrawl RCA with limited entry fixed gear using hook and line gear only when trip limits authorize such fishing, and provided a valid declaration report as required at § 660.13(d), subpart C, has been filed with NMFS OLE.

(12) *Farallon Islands.* Under California law, commercial fishing for all groundfish is prohibited between the shoreline and the 10 fm (18 m) depth contour around the Farallon Islands. An exception to this prohibition is that commercial fishing for “other flatfish” is allowed around the Farallon Islands using hook and line gear only. (See Table 2 (South) of this subpart.) For a definition of the Farallon Islands, see § 660.70, subpart C.

(13) *Cordell Banks.* Commercial fishing for groundfish is prohibited in waters of depths less than 100 fm (183 m) around Cordell Banks, as defined by specific latitude and longitude coordinates at § 660.70, subpart C. An exception to this prohibition is that commercial fishing for “other flatfish” is allowed around Cordell Banks using hook and line gear only.

* * * * *

- 4. Revise Table 2 (North) and Table 2 (South) to part 660, subpart E, to read as follows:

BILLING CODE 3510-22-P

Table 2 (North) to Part 660, Subpart E—Non-Trawl Rockfish Conservation Areas and Trip Limits for Limited Entry Fixed Gear North of 40°10' N.

Table 2 (North) to Part 660, Subpart E -- Non-Trawl Rockfish Conservation Areas and Trip Limits for Limited Entry Fixed Gear North of 40°10' N. lat.

Other limits and requirements apply -- Read §§660.10 through 660.399 before using this table

2/16/2021

	JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC
Rockfish Conservation Area (RCA)^{1/}:						
¹ North of 46° 16' N. lat.	shoreline - 100 fm line ^{1/}					
² 46° 16' N. lat. - 40° 10' N. lat.	40 fm line ^{1/} - 100 fm line ^{1/}					
	30 fm line ^{1/} - 40 fm line ^{1/2/}					
See §§660.60 and 660.230 for additional gear, trip limit and conservation area requirements and restrictions. See §§660.70-660.74 and §§660.76-660.79 for State trip limits and seasons may be more restrictive than Federal trip limits or seasons, particularly in waters off Oregon and California.						
⁴ Minor Slope Rockfish^{3/} & Darkblotched rockfish	8,000 lb/ 2 month					
⁵ Pacific ocean perch	3,600 lb/ 2 months					
⁶ Sablefish	1,700 lb week, not to exceed 5,100 lbs / 2 months					
⁷ Longspine thornyhead	10,000 lb/ 2 months					
⁸ Shortspine thornyhead	2,000 lb/ 2 months					
⁹ Dover sole, arrowtooth flounder, petrale sole, English sole, starry flounder, Other Flatfish^{4/5/}	10,000 lbs/ month					
¹² Whiting	10,000 lb/ trip					
¹³ Minor Shelf Rockfish^{3/}	800 lbs / month					
¹⁴ Shortbelly Rockfish	200 lbs / month					
¹⁵ Widow rockfish	4,000 lb/ 2 month					
¹⁶ Yellowtail rockfish	3,000 lb/ month					
¹⁷ Canary rockfish	3,000 lb/ 2 months					
¹⁸ Yelloweye rockfish	CLOSED					
¹⁹ Minor Nearshore Rockfish, Oregon black/blue/deacon rockfish & CA black rockfish^{6/}						
²⁰ North of 42°00' N. lat.	5,000 lb/ 2 months, no more than 1,200 lb of which may be species other than black rockfish or blue/deacon rockfish ^{4/}					
²¹ 42°00' N. lat. - 40°10' N. lat.	7,000 lb/ 2 months, no more than 2,000 lb of which may be species other than black rockfish					
²² Lingcod^{6/}						
²³ North of 42°00' N. lat.	4,000 lb/ 2 months					
²⁴ 42°00' N. lat. - 40°10' N. lat.	2,000 lb/2 months					
²⁵ Pacific cod	1,000 lb/ 2 months					
²⁶ Spiny dogfish	200,000 lb / 2months	150,000 lb / 2months		100,000 lb / 2months		
²⁷ Longnose skate	Unlimited					
²⁸ Other Fish^{7/} & Cabezon in California	Unlimited					
²⁹ Oregon Cabezon/Kelp Greenling	Unlimited					
³⁰ Big skate	Unlimited					

^{1/} The Rockfish Conservation Area is an area closed to fishing by particular gear types, bounded by lines specifically defined by latitude and longitude coordinates set out at §§ 660.71-660.74. This RCA is not defined by depth contours (with the exception of the 20-fm depth contour boundary south of 42° N. lat.), and the boundary lines that define the RCA may close areas that are deeper or shallower than the depth contour. Vessels that are subject to RCA restrictions may not fish in the RCA, or operate in the RCA for any purpose other than transiting.

^{2/} Between 46°16' N. lat. and 40°10' N. lat. and the 30 fm and 40 fm lines, fishing is only allowed with hook-and-line gear except bottom longline and dinglebar gear, as defined in §660.11

^{3/} Bocaccio, chilipepper and cowcod are included in the trip limits for Minor Shelf Rockfish and splinose rockfish is included in the trip limits for Minor Slope Rockfish.

^{4/} "Other flatfish" are defined at § 660.11 and include butter sole, curfin sole, flathead sole, Pacific sandbar, rex sole, rock sole, and sand sole.

^{5/} For black rockfish north of Cape Alava (48°09.50' N. lat.), and between Destruction Is. (47°40' N. lat.) and Leadbetter Pt. there is an additional limit of 100 lb or 30 percent by weight of all fish on board, whichever is greater, per vessel, per fishing trip.(46°38.17' N. lat.).

^{6/} The minimum size limit for lingcod is 22 inches (56 cm) total length North of 42° N. lat. and 24 inches (61 cm) total length South of 42° N. lat.

^{7/} "Other Fish" are defined at § 660.11 and include kelp greenling off California and leopard shark.

^{8/} LEFG vessels are allowed to fish inside groundfish conservation areas using hook and line only. See section 660.230 (d) of the regulations for more information.

To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

TABLE 2 (North)

TABLE 2 (North)

^{1/} The Rockfish Conservation Area is an area closed to fishing by particular gear types, bounded by lines specifically defined by latitude and longitude coordinates set out at §§ 660.71-660.74. This RCA is not defined by depth contours (with the exception of the 20-fm depth contour boundary south of 42° N. lat.), and the boundary lines that define the RCA may close areas that are deeper or shallower than the depth contour. Vessels that are subject to RCA restrictions may not fish in the RCA, or operate in the RCA for any purpose other than transiting.

^{2/} Between 46°16' N. lat. and 40°10' N. lat. and the 30 fm and 40 fm lines, fishing is only allowed with hook-and-line gear except bottom longline and danglebar gear, as defined in §660.11

^{3/} Bocaccio, chilipepper and cowcod are included in the trip limits for Minor Shelf Rockfish and spltnose rockfish is included in the trip limits for Minor Slope Rockfish.

^{4/} "Other flatfish" are defined at § 660.11 and include butter sole, curfin sole, flathead sole, Pacific sanddab, rex sole, rock sole, and sand sole.

^{5/} For black rockfish north of Cape Alava (48°09.50' N. lat.), and between Destruction Is. (47°40' N. lat.) and Leadbetter Pt. there is an additional limit of 100 lb or 30 percent by weight of all fish on board, whichever is greater, per vessel, per fishing trip.(46°38.17' N. lat.).

^{6/} The minimum size limit for lingcod is 22 inches (56 cm) total length North of 42° N. lat. and 24 inches (61 cm) total length South of 42° N. lat.

^{7/} "Other Fish" are defined at § 660.11 and include kelp greenling off California and leopard shark.

^{8/} LEFG vessels are allowed to fish inside groundfish conservation areas using hook and line only. See section 660.230 (d) of the regulations for more information.

To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

Table 2 (South) to Part 660, Subpart E—Non-Trawl Rockfish Conservation Areas and Trip Limits for Limited Entry Fixed Gear South of 40°10' N.

Table 2 (South) to Part 660, Subpart E -- Non-Trawl Rockfish Conservation Areas and Trip Limits for Limited Entry Fixed Gear South of 40°10' N. lat.									
Other limits and requirements apply -- Read §§660.10 through 660.399 before using this table									
		JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT		NOV-DEC	2/16/2021
Rockfish Conservation Area (RCA)^{1/}:									
1	40°10' N. lat. - 38°57.5' N. lat.				40 fm line ^{1/} - 125 fm line ^{1/}				
2	38°57.5' N. lat. - 34°27' N. lat.				50 fm line ^{1/} - 125 fm line ^{1/}				
3	South of 34°27' N. lat.				100 fm line ^{1/} - 125 fm line ^{1/} (also applies around islands)				
See §§660.60 and 660.230 for additional gear, trip limit and conservation area requirements and restrictions. See §§660.70-660.74 and §§660.76-660.79 for State trip limits and seasons may be more restrictive than Federal trip limits or seasons, particularly in waters off Oregon and California.									
3	Minor Slope rockfish^{2/} & Splitside rockfish				40,000 lb/ 2 months, of which no more than 6,000 lb may be blackgill rockfish				
5	Sablefish				40,000 lb/ 2 months				
6	40°10' N. lat. - 36°00' N. lat.				1,700 lb/week, not to exceed 5,100 lbs / 2 months				
7	South of 36°00' N. lat.				2,500 lb/ week				
8	Longspine thornyhead				10,000 lb/ 2 months				
9	Shortspine thornyhead								
10	40°10' N. lat. - 34°27' N. lat.				2,000 lb/ 2 months			2,500 lb/ 2 months	
11	South of 34°27' N. lat.				3,000 lb/ 2 months				
12	Dover sole, arrowtooth flounder, petrale sole, English sole, starry flounder, Other Flatfish^{3/8/}				10,000 lb/ month				
18	Whiting				10,000 lb/ trip				
	Minor Shelf Rockfish^{2/}								
	40°10' N. lat. - 34°27' N. lat.				8,000 lbs. / 2 months, of which no more than 500 lbs. may be vermillion				
	South of 34°27' N. lat.				5,000 lbs. / 2 months, of which no more than 3,000lbs. may be vermillion				
	Widow								
	40°10' N. lat. - 34°27' N. lat.				10,000 lbs. / 2 months				
	South of 34°27' N. lat.				8,000 lbs. / 2 months				
21	Chilipepper								
	40°10' N. lat. - 34°27' N. lat.				10,000 lbs. / 2 months				
	South of 34°27' N. lat.				8,000 lbs. / 2 months				
	Shortbelly Rockfish								
	South of 40°10' N. lat.				200 lb/ month				
22	Canary rockfish				3,500 lbs/ 2 months				
23	Yelloweye rockfish				CLOSED				
24	Cowcod				CLOSED				
25	Bronzespotted rockfish				CLOSED				
26	Bocaccio				6,000 lbs/ 2 months				
27	Minor Nearshore Rockfish								
	Shallow nearshore ^{4/}				2,000 lbs/ 2 months				
	Deeper nearshore ^{5/}				2,000 lbs/ 2 months				
30	California Scorpionfish				3,500 lbs/ 2 months				
	Lingcod^{6/}				1,600 lbs / 2 months				
32	Pacific cod				1,000 lb/ 2 months				
33	Spiny dogfish	200,000 lb/ 2 months		150,000 lb/ 2 months				100,000 lb/ 2 months	
34	Longnose skate				Unlimited				
35	Other Fish^{7/} & Cabezon in California				Unlimited				
36	Big Skate				Unlimited				

1/ The Rockfish Conservation Area is an area closed to fishing by particular gear types, bounded by lines specifically defined by latitude and longitude coordinates set out at §§ 660.71-660.74. This RCA is not defined by depth contours (with the exception of the 20-fm depth contour boundary south of 42° N. lat.), and the boundary lines that define the RCA may close areas that are deeper or shallower than the depth contour. Vessels that are subject to RCA restrictions may not fish in the RCA, or operate in the RCA for any purpose other than transiting.

2/ POP is included in the trip limits for Minor Slope Rockfish. Blackgill rockfish have a species specific trip sub-limit within the Minor Slope Rockfish cumulative limit. Yellowtail rockfish are included in the trip limits for Minor Shelf Rockfish. Bronzespotted rockfish have a species specific trip limit.

3/ "Other Flatfish" are defined at § 660.11 and include butter sole, curfin sole, flathead sole, Pacific sanddab, rex sole, rock sole, and sand sole.

4/ "Shallow Nearshore" are defined at § 660.11 under "Groundfish" (7)(i)(B)(1).

5/ "Deeper Nearshore" are defined at § 660.11 under "Groundfish" (7)(i)(B)(2).

6/ The commercial minimum size limit for lingcod is 24 inches (61 cm) total length South of 42° N. lat.

7/ "Other Fish" are defined at § 660.11 and include kelp greenling off California and leopard shark.

8/ LEFG vessels are allowed to fish inside groundfish conservation areas using hook and line only. See section 660.230 (d) of the regulations for more information.

To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

TABLE 2 (South)

BILLING CODE 3510-22-C

■ 5. In § 660.330, revise paragraphs (d) introductory text, (d)(11)(i), (d)(12)(iv), and (d)(14) and (15) to read as follows:

§ 660.330 Open access fishery—management measures.

* * * * *

(d) *Groundfish conservation areas (GCAs)*. GCAs, a type of closed area, are defined at § 660.11 and with latitude and longitude coordinates at §§ 660.70 through 660.74. A vessel that is authorized by this paragraph to fish within a GCA (e.g., fishing for "other flatfish" using hook and line gear only),

may not simultaneously have other gear on board the vessel that is unlawful to use for fishing within the GCA. The following GCAs apply to vessels participating in the open access groundfish fishery.

* * * * *

(11) * * *

(i) Fishing for "other flatfish" is allowed within the CCAs with hook and line gear only; and provided a valid declaration report as required at § 660.13(d), has been filed with NMFS OLE.

* * * * *

(12) * * *

(iv) Fishing for "other flatfish" off California (between 42° N lat. south to the U.S./Mexico border) is allowed within the nontrawl RCA with hook and line gear only; and provided a valid declaration report as required at § 660.13(d), has been filed with NMFS OLE.

* * * * *

(14) *Farallon Islands*. Under California law, commercial fishing for all groundfish is prohibited between the shoreline and the 10 fm (18 m) depth contour around the Farallon Islands. An

exception to this prohibition is that commercial fishing for “other flatfish” is allowed around the Farallon Islands using hook and line gear only. (See Table 2 (South) of this subpart.) For a definition of the Farallon Islands, see § 660.70, subpart C.

(15) *Cordell Banks*. Commercial fishing for groundfish is prohibited in waters of depths less than 100-fm (183-m) around Cordell Banks, as defined by specific latitude and longitude coordinates at § 660.70, subpart C. An exception to this prohibition is that commercial fishing for “other flatfish”

is allowed around Cordell Banks using hook and line gear only.

* * * * *

■ 6. Revise Table 3 (North) and Table 3 (South) to part 660, subpart F, to read as follows:

BILLING CODE 3510-22-P

Table 3 (North) to Part 660, Subpart F—Non-Trawl Rockfish Conservation Areas and Trip Limits for Open Access Gears North of 40°10' N. lat.

Table 3 (North) to Part 660, Subpart F – Non-Trawl Rockfish Conservation Areas and Trip Limits for Open Access Gears North of 40°10' N. lat.						
Other limits and requirements apply – Read §§660.10 through 660.399 before using this table						2/16/2021
	JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC
Rockfish Conservation Area (RCA)^{1/}:						
1 North of 46°16' N. lat.						shoreline - 100 fm line ^{1/}
2 46°16' N. lat. - 40°10' N. lat.						40 fm line ^{1/} - 100 fm line ^{1/}
						30 fm line ^{1/} - 40 fm line ^{1/2/}
See §§660.60, 660.330 and 660.333 for additional gear, trip limit and conservation area requirements and restrictions. See §§660.70-660.74 and §§660.76-660.79 for conservation area descriptions and coordinates (including RCAs, YRCAs, CCAs, Farallon Islands, Cordell Bank, and EFHCAs).						
State trip limits and seasons may be more restrictive than Federal trip limits or seasons, particularly in waters off Oregon and California.						
4 Minor Slope Rockfish ^{3/} & Darkblotched rockfish						2,000 lbs / months
5 Pacific ocean perch						100 lbs/ month
6 Sablefish						600 lbs. daily, or 1 landing per week up to 2,000 lbs, not to exceed 4,000 lbs/2 months
7 Shortpine thornyheads						50 lb/month
8 Longspine thornyheads						50 lb/month
9 Dover sole, arrowtooth flounder, petrale sole, English sole, starry flounder, Other Flatfish ^{4/8/}						5,000 lbs/ month
12 Whiting						300 lbs/ month
13 Minor Shelf Rockfish ^{3/}						800 lbs / month
14 Widow rockfish						2,000 lb/ 2 months
15 Shortbelly Rockfish						200 lbs / month
16 Yellowtail rockfish						1,500 lbs/ month
17 Canary rockfish						1,000 lbs/ 2 months
18 Yelloweye rockfish						CLOSED
19 Minor Nearshore Rockfish, Oregon black/blue/deacon rockfish & CA black rockfish						
20 North of 42°00' N. lat.						5,000 lb/ 2 months, no more than 1,200 lb of which may be species other than black rockfish or blue/deacon rockfish ^{5/}
21 42°00' N. lat. - 40°10' N. lat.						7,000 lb/ 2 months, no more than 2,000 lb of which may be species other than black rockfish
22 Lingcod ^{6/}						
23 North of 42°00' N. lat.						2,000 lbs/ month
24 42°00' N. lat. - 40°10' N. lat.						1,000 lbs / month
25 Pacific cod						1,000 lbs/ 2 months
26 Spiny dogfish		200,000 lbs/ 2 months		150,000 lbs/ 2 months		100,000 lbs/ 2 months
27 Longnose skate						Unlimited
28 Big skate						Unlimited
29 Other Fish ^{7/} & Cabezon in California						Unlimited
30 Oregon Cabezon/Kelp Greenling						Unlimited
31 SALMON TROLL (subject to RCAs when retaining all species of groundfish, except for yellowtail rockfish and lingcod, as described below)						Salmon trollers may retain and land up to 500 lbs of yellowtail rockfish per month as long as salmon is on board, both within and outside of the RCA. Salmon trollers may retain and land up to 1 lingcod per 5 Chinook per trip, plus 1 lingcod per trip, up to a trip limit of 10 lingcod, on a trip where any fishing occurs within the RCA. The lingcod limit only applies during times when lingcod retention is allowed, and is not “CLOSED.” These limits are within the per month limits described in the table above, and not in addition to those limits. All groundfish species are subject to the open access limits, seasons, size limits and RCA restrictions listed in the table above, unless otherwise stated here.
32 North						
33 PINK SHRIMP NON-GROUNDFISH TRAWL (not subject to RCAs)						
34 North						Effective April 1 - October 31: Groundfish: 500 lbs/day, multiplied by the number of days of the trip, not to exceed 1,500 lbs/trip. The following sublimits also apply and are counted toward the overall 500 lbs/day and 1,500 lbs/trip groundfish limits: lingcod 300 lbs/month (minimum 24 inch size limit); sablefish 2,000 lbs/month; canary, thornyheads and yelloweye rockfish are PROHIBITED. All other groundfish species taken are managed under the overall 500 lbs/day and 1,500 lbs/trip groundfish limits. Landings of these species count toward the per day and per trip groundfish limits and do not have species-specific limits. The amount of groundfish landed may not exceed the amount of pink shrimp landed.

TABLE 3 (North)

1/ The Rockfish Conservation Area is an area closed to fishing by particular gear types, bounded by lines specifically defined by latitude and longitude coordinates set out at §§ 660.71-660.74. This RCA is not defined by depth contours (with the exception of the 20-fm depth contour boundary south of 42° N. lat.), and the boundary lines that define the RCA may close areas that are deeper or shallower than the depth contour. Vessels that are subject to RCA restrictions may not fish in the RCA, or operate in the RCA for any purpose other than transiting.

2/ Between 46°16' N. lat. and 40°10' N. lat. and the 30 fm and 40 fm lines, fishing is only allowed with hook-and-line gear except bottom longline and danglebar gear, as defined in §660.11

3/ Bocaccio, chilipepper and cowcod rockfishes are included in the trip limits for Minor Shelf Rockfish. Splitnose rockfish is included in the trip limits for Minor Slope Rockfish.

4/ “Other flatfish” are defined at § 660.11 and include butter sole, curfin sole, flathead sole, Pacific sanddab, rex sole, rock sole, and sand sole.

5/ For black rockfish north of Cape Alava (48°09.50' N. lat.), and between Destruction Is. (47°40' N. lat.) and Leadbetter Pnt. (46°38.17' N. lat.), there is an additional limit of 100 lbs or 30 percent by weight of all fish on board, whichever is greater, per vessel, per fishing trip.

6/ The minimum size limit for lingcod is 22 inches (56 cm) total length North of 42° N. lat. and 24 inches (61 cm) total length South of 42° N. lat.

7/ “Other fish” are defined at § 660.11 and include kelp greenling off California and leopard shark.

8/ Open access vessels are allowed to fish inside groundfish conservation areas using hook and line only. See section 660.330 (d) of the regulations for more information.

To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

Table 3 (South) to Part 660, Subpart F—Non-Trawl Rockfish Conservation Areas and Trip Limits for Open Access Gears South of 40°10' N. lat.

Table 3 (South) to Part 660, Subpart F—Non-Trawl Rockfish Conservation Areas and Trip Limits for Open Access Gears South of 40°10' N. lat.							2/16/2021
Other limits and requirements apply – Read §§660.10 through 660.399 before using this table							
	JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC	
Rockfish Conservation Area (RCA)^{1/}:							
1 40°10' N. lat. - 38°57.5' N. lat.				40 fm line ^{1/} - 125 fm line ^{1/}			
2 38°57.5' N. lat. - 34°27' N. lat.				50 fm line ^{1/} - 125 fm line ^{1/}			
3 South of 34°27' N. lat.				100 fm line ^{1/} - 150 fm line ^{1/} (also applies around islands)			
See §§660.60 and 660.230 for additional gear, trip limit and conservation area requirements and restrictions. See §§660.70-660.74 and §§660.76-660.79 for State trip limits and seasons may be more restrictive than Federal trip limits or seasons, particularly in waters off Oregon and California.							
4 Minor Slope Rockfish^{2/} & Darkblotched rockfish				10,000 lbs/ 2 months, of which no more than 2,500 lbs may be blackgill rockfish			
5 Splitnose rockfish				200 lbs/ month			
6 Sablefish							
7 40°10' N. lat. - 36°00' N. lat.				600 lbs. daily, or 1 landing per week up to 2,000 lbs., not to exceed 4,000 lbs/2 months			
8 South of 36°00' N. lat.				2,000 lbs/week, not to exceed 6,000 lbs/2 months			
9 Shortpine thornyheads							
10 40°10' N. lat. - 34°27' N. lat.				50lb/ month			
11 Longspine thornyheads							
12 40°10' N. lat. - 34°27' N. lat.				50 lb/ month			
13 Shortpine thornyheads and longspine							
14 South of 34°27' N. lat.				100 lbs/day, no more than 1,000 lbs/ 2 months			
15 Dover sole, arrowtooth flounder, petrale sole, English sole, starry flounder, Other Flatfish^{3/8/}				5,000 lbs/ month			
17 Whiting				300 lbs/ month			
19 Minor Shelf Rockfish^{2/}							
20 40°10' N. lat. - 34°27' N. lat.				4,000 lbs. / 2 months, of which no more than 400 lbs. may be vermilion			
21 South of 34°27' N. lat.				3,000 lbs. / 2 months, of which no more than 1,200lbs. may be vermilion			
22 Widow							
23 40°10' N. lat. - 34°27' N. lat.				6,000 lbs. / 2 months			
24 South of 34°27' N. lat.				4,000 lbs. / 2 months			
25 Chilipepper							
26 40°10' N. lat. - 34°27' N. lat.				6,000 lbs. / 2 months			
27 South of 34°27' N. lat.				4,000 lbs. / 2 months			
28 Shortbelly Rockfish							
29 South of 40°10' N. lat.				200 lb/ month			
22 Canary rockfish				1,500 lbs/ 2 months			
23 Yelloweye rockfish				CLOSED			
24 Cowcod				CLOSED			
25 Bronzespotted rockfish				CLOSED			
26 Bocaccio				4,000 lbs/ 2 months			
30 Minor Nearshore Rockfish							
31 Shallow nearshore ^{4/}				2,000 lbs/ 2 months			
32 Deeper nearshore ^{5/}				2,000 lbs/ 2 months			
33 California Scorpionfish				3,500 lbs/ 2 months			
34 Lingcod^{6/}				700 lbs / months			
35 Pacific cod				1,000 lbs/ 2 months			
36 Spiny dogfish	200,000 lbs/ 2 months		150,000 lbs/ 2		100,000 lbs/ 2 months		
37 Longnose skate				Unlimited			
38 Big skate				Unlimited			
39 Other Fish^{7/} & Cabezon in California				Unlimited			

TABLE 3 (South)

Table 3 (South) Continued							2/16/2021
Other limits and requirements apply -- Read §§660.10 through 660.399 before using this table							
	JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC	
Rockfish Conservation Area (RCA)^{1/}:							
40	40° 10' N. lat. - 38° 57.5' N. lat.		40 fm line ^{1/} - 125 fm line ^{1/}				
41	38° 57.5' N. lat. - 34° 27' N. lat.		50 fm line ^{1/} - 125 fm line ^{1/}				
42	South of 34° 27' N. lat.		100 fm line ^{1/} - 150 fm line ^{1/} (also applies around islands)				
See §§660.60 and 660.230 for additional gear, trip limit and conservation area requirements and restrictions. See §§660.70-660.74 and §§660.76-660.79 for							
43	SALMON TROLL (subject to RCAs when retaining all species of groundfish, except for yellowtail rockfish and lingcod, as described below)						
44	South of 40° 10' N. lat.	Salmon trollers may retain and land up to 1 lbs of yellowtail rockfish for every 2 lbs of Chinook salmon landed, with a cumulative limit of 200 lbs/month, both within and outside of the RCA. This limit is within the 4,000 lbs per 2 month limit for minor shelf rockfish between 40° 10' and 34° 27' N lat., and not in addition to that limit. All groundfish species are subject to the open access limits, seasons, size limits and RCA restrictions listed in the table above, unless otherwise stated here.					
45	RIDGEBACK PRAWN AND, SOUTH OF 38° 57.50' N. LAT., CA HALIBUT AND SEA CUCUMBER NON-GROUNDFISH TRAWL						
46	NON-GROUNDFISH TRAWL Rockfish Conservation Area (RCA) for CA Halibut, Sea Cucumber & Ridgeback Prawn:						
47	40° 10' N. lat. - 38° 00' N. lat.	100 fm line ^{1/} - 200	100 fm line ^{1/} - 150 fm line ^{1/}			100 fm line ^{1/} - 200 fm	
48	38° 00' N. lat. - 34° 27' N. lat.		100 fm line ^{1/} - 150 fm line ^{1/}				
49	South of 34° 27' N. lat.		100 fm line ^{1/} - 150 fm line ^{1/}				
50		Groundfish: 300 lbs/trip. Species-specific limits described in the table above also apply and are counted toward the 300 lbs groundfish per trip limit. The amount of groundfish landed may not exceed the amount of the target species landed, except that the amount of spiny dogfish landed may exceed the amount of target species landed. Spiny dogfish are limited by the 300 lbs/trip overall groundfish limit. The daily trip limits for sablefish coastwide and thornyheads south of Pt. Conception and the overall groundfish "per trip" limit may not be multiplied by the number of days of the trip. Vessels participating in the California halibut fishery south of 38° 57.50' N. lat. are allowed to (1) land up to 100 lbs/day of groundfish without the ratio requirement, provided that at least one California halibut is landed and (2) land up to 3,000 lbs/month of flatfish, no more than 300 lbs of which may be species other than Pacific sanddabs, sand sole, starry flounder, rock sole, curfin sole, or California scorpionfish (California scorpionfish is also subject to the trip limits and closures in line 29).					
51	PINK SHRIMP NON-GROUNDFISH TRAWL GEAR (not subject to RCAs)						
52	South	Effective April 1 - October 31: Groundfish: 500 lbs/day, multiplied by the number of days of the trip, not to exceed 1,500 lbs/trip. The following sublimits also apply and are counted toward the overall 500 lbs/day and 1,500 lbs/trip groundfish limits: lingcod 300 lbs/ month (minimum 24 inch size limit); sablefish 2,000 lbs/ month; canary rockfish, thornyheads and yelloweye rockfish are PROHIBITED. All other groundfish species taken are managed under the overall 500 lbs/day and 1,500 lbs/trip groundfish limits. Landings of all groundfish species count toward the per day, per trip or other species-specific sublimits described here and the species-specific limits described in the table above do not apply. The amount of groundfish landed may not exceed the amount of pink shrimp landed.					
1/ The Rockfish Conservation Area is an area closed to fishing by particular gear types, bounded by lines specifically defined by latitude and longitude coordinates set out at §§ 660.71-660.74. This RCA is not defined by depth contours (with the exception of the 20-fm depth contour boundary south of 42° N. lat.), and the boundary lines that define the RCA may close areas that are deeper or shallower than the depth contour. Vessels that are subject to RCA restrictions may not fish in the RCA, or operate in the RCA for any purpose other than transiting.							
2/ POP is included in the trip limits for minor slope rockfish. Blackgill rockfish have a species specific trip sub-limit within the minor slope rockfish cumulative limits. Yellowtail rockfish is included in the trip limits for minor shelf rockfish. Bronzespotted rockfish have a species specific trip limit.							
3/ "Other flatfish" are defined at § 660.11 and include butter sole, curfin sole, flathead sole, Pacific sanddab, rex sole, rock sole, and sand sole.							
4/ "Shallow Nearshore" are defined at § 660.11 under "Groundfish" (7)(i)(B)(1).							
5/ "Deeper Nearshore" are defined at § 660.11 under "Groundfish" (7)(i)(B)(2).							
6/ The commercial minimum size limit for lingcod is 24 inches (61 cm) total length South of 42° N. lat.							
7/ "Other fish" are defined at § 660.11 and includes kelp greenling off California and leopard shark.							
8/ Open access vessels are allowed to fish inside groundfish conservation areas using hook and line only. See section 660.330 (d) of the regulations for more information.							
To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.							

Table 3 (South) Continued

■ 7. In § 660.360, revise paragraphs (c)(3)(i)(A)(1) and (2) to read as follows:

§ 660.360 Recreational fishery—management measures.

* * * * *

(c) * * *

(3) * * *

(i) * * *

(A) * * *

(1) Between 42° N lat. (California/Oregon border) and 40° 10' N lat. (Northern Management Area), recreational fishing for all groundfish (except petrale sole, starry flounder, and

“Other Flatfish” as specified in paragraph (c)(3)(iv) of this section) is closed from January 1 through April 30; is prohibited seaward of the boundary line approximating the 30 fm (55 m) depth contour along the mainland coast and along islands and offshore seamounts from May 1 through October 31 (shoreward of 30 fm is open); and is open at all depths from November 1 through December 31.

(2) Between 40° 10' N lat. and 38° 57.50' N lat. (Mendocino Management Area), recreational fishing for all groundfish (except petrale sole,

starry flounder, and “Other Flatfish” as specified in paragraph (c)(3)(iv) of this section) is closed from January 1 through April 30; prohibited seaward of the boundary line approximating the 30 fm (55 m) depth contour along the mainland coast and along islands and offshore seamounts from May 1 through October 31 (shoreward of 30 fm is open), and is open at all depths from November 1 through December 31.

* * * * *

[FR Doc. 2021–05359 Filed 3–15–21; 8:45 am]

BILLING CODE 3510–22–C

Proposed Rules

Federal Register

Vol. 86, No. 49

Tuesday, March 16, 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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2021–0228; Notice No. 25–21–01–SC]

Special Conditions: Haeco Cabin Solutions, Boeing Commercial Airplanes Model 737–800 Airplane; Structure-Mounted Airbags

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This action proposes special conditions for the Boeing Commercial Airplanes (Boeing) Model 737–800 airplane. This airplane, as modified by Haeco Cabin Solutions (Haeco), will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. This design feature is structure-mounted airbags designed to protect each occupant from serious head injury in the event of an emergency landing. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: Send comments on or before April 15, 2021.

ADDRESSES: Send comments identified by Docket No. FAA–2021–0228 using any of the following methods:

- *Federal eRegulations 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: Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received without change, to <http://www.regulations.gov/>, including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about this proposal.

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this Notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this Notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and the indicated comments will not be placed in the public docket of this Notice. Send submissions containing CBI to John Shelden, Human Machine Interface, AIR–626, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3214; email John.Shelden@faa.gov. Comments the FAA receives, which are not specifically designated as CBI, will be placed in the public docket for this rulemaking.

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 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: John Shelden, Human Machine Interface, AIR–626, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3214; email John.Shelden@faa.gov.

SUPPLEMENTARY INFORMATION: The substance of these special conditions has been subject to the notice and public comment procedure in several prior instances. Additionally, a delay in design approval would significantly affect the applicant’s installation of the system on the airplane. Therefore, the FAA is shortening the public comment period to 30 days.

Comments Invited

The FAA invites interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

The FAA will consider all comments received by the closing date for comments. The FAA may change these special conditions based on the comments received.

Background

On September 1, 2020, Haeco applied for a supplemental type certificate for structure-mounted airbags in the Boeing Model 737–800 airplane. The Boeing Model 737–800 airplane, which is a derivative of the Boeing Model 737 airplane currently approved under Type Certificate No. A16WE, is a twin-engine, transport-category airplane with seating for 189 passengers and a maximum takeoff weight of 174,200 pounds.

Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.101, Haeco must show that the Boeing Model 737–800 airplane, as changed, continues to meet the applicable provisions of the regulations listed in Type Certificate No. A16WE or the applicable regulations in effect on the date of application for the

change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (e.g., 14 CFR part 25) do not contain adequate or appropriate safety standards for the Boeing Model 737–800 airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Boeing Model 737–800 airplane must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34, and the noise certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The Boeing Model 737–800 airplane will incorporate the following novel or unusual design features:

Airbags mounted to structure to prevent head injury.

Discussion

Haeco proposes to install structure-mounted airbags instead of inflatable lap belts as a means to protect each occupant from serious injury in the event of an emergency landing, as required by § 25.562(c)(5), on 737–800 airplanes.

Such use of airbags to provide injury protection for the occupant is a novel or unusual feature for this airplane model, and the applicable airworthiness regulations do not contain adequate or appropriate airworthiness standards for these design features. Therefore, special conditions are needed to address requirements particular to installation of airbags in this manner.

Special conditions exist for airbags installed on seat belts, known as inflatable lap belts, which have been installed on transport airplane passenger seats. Structure-mounted airbags, although a novel design, were first introduced on Jetstream Aircraft Limited Model 4100 series airplanes, which resulted in issuance of Special Conditions 25–ANM–127 on May 14,

1997. These special conditions supplemented 14 CFR part 25 and, more specifically, §§ 25.562 and 25.785.

The structure-mounted airbag, similar to the inflatable lap belt, is designed to limit occupant forward excursion in the event of an emergency landing. These airbags will reduce the potential for serious injury, including reducing the head-injury criterion measurement defined in part 25. However, structure-mounted airbags function similarly as automotive airbags, where the airbag deploys from furniture located in front of the passenger, relative to the airplane's direction of flight, forming a barrier between the structure and occupant. Also, unlike the inflatable lap belt, the structure-mounted airbag does not move with the occupant. To account for out-of-position and brace-position occupants, the airbag is designed to conform to the curvature of the exposed structure in the head-strike zone.

Because the airbag system is essentially a single-use device, it could deploy under crash conditions that are not sufficiently so severe as to require the injury protection the airbag system provides. Because an actual crash is frequently composed of a series of impacts before the airplane comes to rest, a larger impact following the initial impact could render the airbag system unavailable. This potential situation does not exist with standard upper-torso restraints, which tend to provide continuous protection regardless of impact severity, or number of impacts, in a crash event. Therefore, the airbag system installation should be such that it provides protection, when it is required, by not expending its protection when it is not required. If the airbag deployment threshold is unnecessarily low, the airbag would need to continue to provide protection when an impact requiring protection occurs.

These proposed special conditions are based upon Special Conditions 25–605–SC for the Boeing Model 787–9 airplanes equipped with B/E Aerospace Super-Diamond model business-class passenger seats and associated furniture. Additionally, the special conditions address protection of the occupant's neck and spine for the structure-mounted airbag deployment. When using the HIC15 head-injury method for airbag impacts (calculated in accordance with 49 CFR 571.208) the neck and spine limits are included as part of the allowance. These additional conditions are based on special conditions issued previously on oblique seats. The proposed special conditions contain the additional safety standards that the Administrator considers necessary to

establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Boeing Model 737–800 airplane as modified by Haeco. Should Haeco apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. A16WE to incorporate the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only a certain novel or unusual design features on one model of airplane. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, 44704.

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for Boeing Model 737–800 airplanes, as modified by Haeco Cabin Solutions:

1. The applicant must demonstrate by test that the structure-mounted airbag will deploy and provide protection under crash conditions where it is necessary to prevent serious injury to a 50th percentile occupant, as specified in § 25.562. The means of protection must provide a consistent approach to energy absorption for a range of occupants, from a two-year-old child to a 95th percentile male. In addition, the following situations should be considered:

- The seat occupant is holding an infant.
- The seat occupant is a child in a child restraint device.
- The seat occupant is a child not using a child restraint device.
- The seat occupant is a pregnant woman.

a. Head-Injury Criteria

Compliance with § 25.562(c)(5) is required, except that, if the ATD has no apparent contact with the seat/structure but has contact with an airbag, a head-

injury criterion (HIC) unlimited score in excess of 1000 is acceptable, provided the HIC15 score (calculated in accordance with 49 CFR 571.208) for that contact is less than 700.

b. Body-to-Wall/Furnishing Contact

If a seat is installed aft of structure (e.g., an interior wall or furnishing) that does not provide a homogenous contact surface for the expected range of occupants and yaw angles, then additional analysis or tests may be required to demonstrate that the injury criteria are met for the area that an occupant could contact. For example, if different yaw angles could result in different airbag performance, then additional analysis or separate tests may be necessary to evaluate performance.

c. Neck-Injury Criteria

The seating system must protect the occupant from experiencing serious neck injury. The assessment of neck injury must be conducted with the airbag device activated, unless there is reason to also consider that the neck-injury potential would be higher for impacts below the airbag-device deployment threshold.

(1) The N_{ij} (calculated in accordance with 49 CFR 571.208) must be below 1.0, where $N_{ij} = F_z/F_{zc} + M_y/M_{yc}$, and N_{ij} critical values are:

- (a) $F_{zc} = 1,530$ lb for tension
- (b) $F_{zc} = 1,385$ lb for compression
- (c) $M_{yc} = 229$ lb-ft in flexion
- (d) $M_{yc} = 100$ lb-ft in extension

(2) In addition, peak F_z must be below 937 lb in tension and 899 lb in compression.

(3) Rotation of the head about its vertical axis, relative to the torso, is limited to 105 degrees in either direction from forward-facing.

(4) The neck must not impact any surface that would produce concentrated loading on the neck.

d. ATD and Test Conditions

Longitudinal tests conducted to measure the injury criteria above must be performed with the FAA Hybrid III ATD, as described in SAE 1999-01-1609, "A Lumbar Spine Modification to the Hybrid III ATD for Aircraft Seat Tests." The tests must be conducted with an undeformed floor, at the most-critical yaw cases for injury, and with all lateral structural supports (e.g. armrests or walls) installed.

Note: Applicant must demonstrate that the installation of seats via plinths or pallets meets all applicable requirements. Compliance with the guidance contained in policy memorandum PS-ANM-100-2000-00123, "Guidance for Demonstrating

Compliance with Seat Dynamic Testing for Plinths and Pallets," dated February 2, 2000, is acceptable to the FAA.

2. The structure-mounted airbag must provide adequate protection for each occupant regardless of the number of occupants of the seat assembly.

3. The structure-mounted airbag system must not be susceptible to inadvertent deployment as a result of wear and tear, or inertial loads resulting from in-flight or ground maneuvers (including gusts and hard landings) likely to be experienced in service.

4. The applicant must demonstrate that an inadvertent deployment that could cause injury to a standing or sitting person is improbable. Inadvertent deployment must not cause injury to anyone who may be positioned close to the structure-mounted airbag (e.g., seated in an adjacent seat, or standing adjacent to the airbag installation or the subject seat). Cases where a structure-mounted airbag is inadvertently deployed near a seated occupant or an empty seat must be considered.

5. Inadvertent deployment of the structure-mounted airbag during the most critical part of flight will either not cause a hazard to the airplane or is extremely improbable.

6. Deployment of the structure-mounted airbag must not introduce hazards or injury mechanisms to the seated occupant, including occupants in the brace position. Deployment of the structure-mounted airbag must also not result in injuries that could impede rapid exit from the airplane.

7. Effects of the deflection and deformation of the structure to which the airbag is attached must be taken into account when evaluating deployment and location of the inflated airbag. The effect of loads imposed by airbag deployment, or stowed components where applicable, must also be taken into account.

8. The applicant must demonstrate that the structure-mounted airbag, when deployed, does not impair access to the seatbelt- or harness-release means, and must not hinder evacuation. This will include consideration of adjacent seat places and the aisle.

9. The airbag, once deployed, must not adversely affect the emergency-lighting system, and must not block escape-path lighting to the extent that the light(s) no longer meet their intended function.

10. The structure-mounted airbag must not impede occupants' rapid exit from the airplane 10 seconds after its deployment.

11. Where structure-mounted airbag systems are installed in or close to passenger evacuation routes (other than

for the passenger seat for which the airbag is installed), possibility of impact on emergency evacuation (e.g., hanging in the aisle, potential trip hazard, etc.) must be evaluated.

12. The airbag electronic system must be designed to be protected from lightning per § 25.1316(b), and high-intensity radiated fields per § 25.1317(c).

13. The structure-mounted airbag system must not contain or release hazardous quantities of gas or particulate matter into the cabin.

14. The structure-mounted airbag installation must be protected from the effects of fire such that no hazard to occupants will result.

15. The inflatable bag material must meet the 2.5-inches-per-minute horizontal flammability test defined in 14 CFR part 25, appendix F, part I, paragraph (a)(1)(iv).

16. The design of the structure-mounted airbag system must protect the mechanisms and controls from external contamination associated with that which could occur on or around passenger seating.

17. The structure-mounted airbag system must have a means to verify the integrity of the structure-mounted airbag activation system.

18. The applicant must provide installation limitations to ensure installation compatibility between the seat design and opposing monument or structure.

Issued in Kansas City, MO, on March 10, 2021.

Patrick R. Mullen,

Manager, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2021-05331 Filed 3-15-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2021-0115]

RIN 1625-AA87

Security Zone; North Atlantic Ocean, Approaches to Ocean City, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary security zone encompassing certain waters of the North Atlantic Ocean. The security zone is necessary to prevent waterside threats

before, during and after National Geospatial-Intelligence Agency equipment testing conducted offshore near Ocean City, MD, from April 25, 2021, through May 8, 2021. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Maryland-National Capital Region or his designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before April 15, 2021.

ADDRESSES: You may submit comments identified by docket number USCG–2021–0115 using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email LCDR Samuel M. Danus, Waterways Management Division, U.S. Coast Guard; 410–576–2519, Samuel.M.Danus@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On February 17, 2021, the National Geospatial-Intelligence Agency (NGA) notified the Coast Guard that it will be conducting U.S. Government training and systems testing from 9 a.m. on April 25, 2021, through 10 p.m. on May 8, 2021. The training and testing will take place in two locations offshore of Ocean City, MD. The COTP Maryland-National Capital Region has determined that a security zone is needed for waterborne protection of the public, mitigation of potential terrorist acts, and the enhancing of public and maritime safety and security in order to safeguard life, property, and the environment on or near the navigable waters near Ocean City, MD.

The purpose of this rulemaking is to ensure the security of vessels and government equipment involved in this event by prohibiting vessels from entering the security zone. If a person or vessel has been granted permission to

enter the zone, they must not enter waters within 1,000 yards of the on scene Coast Guard vessel or test equipment being used by Coast Guard personnel. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1232).

III. Discussion of Proposed Rule

The COTP is proposing to establish a security zone from 9 a.m. on April 25, 2021, through 10 p.m. on May 8, 2021. The security zone will be enforced from 9 a.m. to 10 p.m. on April 25, 2021, and those same hours on April 26, 2021, April 27, 2021, April 28, 2021, April 29, 2021, April 30, 2021, May 1, 2021, May 2, 2021, May 3, 2021, May 4, 2021, May 5, 2021, May 6, 2021, May 7, 2021 and May 8, 2021. The security zone will cover all waters of the North Atlantic Ocean, from surface to bottom, encompassed by a line connecting the following points beginning at 38°23'56" N, 074°48'06" W, thence south to 38°21'40" N, 074°48'33" W, thence south to 38°17'54" N, 074°49'57" W, thence southwest to 38°15'04" N, 074°51'44" W, thence northwest to 38°18'52" N, 074°54'24" W, thence north to 38°22'55" N, 074°52'44" W, and northeast back to the beginning point. The zone is approximately 9.3 nautical miles in length and 3.6 nautical miles in width. If a person or vessel has been granted permission to enter the zone, they must not enter waters within 1,000 yards of the on scene Coast Guard vessel or test equipment being used by Coast Guard personnel.

The duration of the rule and enforcement of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the Coast Guard vessel and test equipment are being used. All vessels and persons must obtain permission from the COTP Maryland-National Capital Region or his designated representative before entering the security zone. Equipment testing operations may occur anywhere within the security zone during the enforcement periods. Vessels and persons will not be permitted to enter the security zone within 1,000 yards of the Coast Guard vessel or test equipment. While this 1,000 yards area lies within the security zone, its exact location within the security zone may change. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking.

Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This NPRM has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on location and duration of the security zone. This security zone will be enforced 182 hours over the course of a two week period. Vessels will be able to safely transit around the security zone, which impacts a small area of the North Atlantic Ocean, where vessel traffic is normally low. Additionally, the Coast Guard will make notifications to the maritime community via marine information broadcasts. The Coast Guard will update such notifications as necessary to keep the maritime community informed of the status of the security zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the security zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement

Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has 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. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect 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. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a security zone lasting only 182 total enforcement hours that will prohibit entry within a small portion of the North Atlantic Ocean. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Documents mentioned in this NPRM as being available in the docket, and public comments, will be in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive. If you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 165.T05–0115 to read as follows:

§ 165.T05–0115 Security Zone; North Atlantic Ocean, Approaches to Ocean City, MD.

(a) *Location.* The following is a security zone: All waters of the North Atlantic Ocean, from surface to bottom, encompassed by a line connecting the following points beginning at 38°23'56" N, 074°48'06" W, thence south to 38°21'40" N, 074°48'33" W, thence south to 38°17'54" N, 074°49'57" W, thence southwest to 38°15'04" N, 074°51'44" W, thence northwest to 38°18'52" N, 074°54'24" W, thence north to 38°22'55" N, 074°52'44" W, and northeast back to the beginning point. All coordinates are based on datum NAD 83.

(b) *Definitions.* As used in this section—

Captain of the Port (COTP) means the Commander, U.S. Coast Guard Sector Maryland-National Capital Region.

Designated representative means the Coast Guard commissioned, warrant, or petty officer operating the on scene Coast Guard vessel designated by or assisting the Captain of the Port Maryland-National Capital Region (COTP) in the enforcement of the security zone.

(c) *Regulations.* (1) Under the general security zone regulations in subpart D of this part, you may not enter the security zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter the security zone described in paragraph (a) of this section, contact the COTP or the COTP's representative by telephone at 410-576-2693 or on Marine Band Radio VHF-FM channel 16 (156.8 MHz). The Coast Guard vessel enforcing this section can be contacted on Marine Band Radio VHF-FM channel 16 (156.8 MHz). Those in the security zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(3) A person or vessel operating in the security zone described in paragraph (a)(1) of this section must not enter waters within 1,000 yards of the on scene Coast Guard vessel or test equipment being used by Coast Guard personnel.

(d) *Enforcement periods.* This section will be enforced 9 a.m. to 10 p.m. on April 25, 2021, and those same hours on April 26, 2021, April 27, 2021, April 28, 2021, April 29, 2021, April 30, 2021, May 1, 2021, May 2, 2021, May 3, 2021, May 4, 2021, May 5, 2021, May 6, 2021, May 7, 2021 and May 8, 2021.

Dated: March 9, 2021.

Joseph B. Loring,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2021-05391 Filed 3-15-21; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 49 and 52

[EPA-R09-OAR-2021-0018; FRL-10020-02-Region 9]

Rescission of the Source-Specific Federal Implementation Plan for Navajo Generating Station, Navajo Nation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to rescind

the federal implementation plan (FIP) that regulates emissions from the Navajo Generating Station (NGS), a coal-fired power plant that was located on the reservation lands of the Navajo Nation near Page, Arizona. NGS permanently ceased operations on November 18, 2019, and the Clean Air Act (CAA or "Act") operating permit for this facility has expired.

DATES: Any comments on this proposal must arrive by April 15, 2021.

ADDRESSES: Submit your comments, identified by Docket ID number EPA-R09-OAR-2021-0018, at <http://www.regulations.gov>. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, or if you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Anita Lee, EPA Region IX, (415) 972-3958, lee.anita@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, "we," "us," and "our" refer to the EPA.

Table of Contents

- I. Background
 - A. Action
 - B. Facility
 - C. Attainment Status
 - D. The EPA's Authority To Promulgate a FIP in Indian Country
 - E. Historical Overview of NGS FIP Actions
- II. Basis for Proposed Action
- III. Solicitation of Comments
- IV. Statutory and Executive Order Reviews

I. Background

A. Action

In this action, the EPA is proposing to rescind the FIP for NGS that we promulgated on October 3, 1991 ("1991 FIP"), March 5, 2010 ("2010 FIP"), and August 8, 2014 ("2014 FIP").¹ The provisions of the 1991 action are codified in the Code of Federal Regulations (CFR) at 40 CFR 52.145(d), the provisions of the 2010 action are codified at 40 CFR 49.5513(a) through (i), and provisions of the 2014 action are codified at 40 CFR 49.5513(j). We refer collectively to the provisions from the 1991, 2010, and 2014 actions as the "FIP" or the "NGS FIP." The NGS FIP includes federally enforceable emissions limitations that apply to the fossil fuel-fired steam generating equipment, designated as Units 1, 2, and 3, equipment associated with the coal and ash handling, and the two auxiliary steam boilers at NGS. These emissions limitations apply to emissions of particulate matter (PM), sulfur dioxide (SO₂), and oxides of nitrogen (NO_x), and opacity. The EPA is proposing to rescind the NGS FIP and remove the provisions of the FIP from 40 CFR 52.145(d) and 40 CFR 49.5513.

B. Facility

NGS was a coal-fired power plant that ceased operation in 2019, located on the reservation lands of the Navajo Nation, just east of Page, Arizona, and approximately 135 miles north of Flagstaff. NGS was co-owned by several entities and operated by Salt River Project Agricultural Improvement and Power District ("SRP").² The facility operated three units, each with a capacity of 750 megawatts (MW) net generation, with a total capacity of 2250 MW. Operations at the facility produced air pollutant emissions, including emissions of SO₂, NO_x, and PM. Existing pollution control equipment at NGS included wet flue gas desulfurization units for SO₂ and PM removal, electrostatic precipitators for PM removal, and low-NO_x burners with separated over-fire air to reduce NO_x formation during the combustion process. Had the facility not ceased operations, the owner or operator of NGS would have taken steps by December 31, 2019 to reduce emissions

¹ 56 FR 50172 (October 3, 1991), 75 FR 10174 (March 5, 2010), and 79 FR 46552 (August 8, 2014).

² The original participants in NGS were the United States Bureau of Reclamation, SRP, Arizona Public Service Company, Tucson Electric Company, NV Energy, and the Los Angeles Department of Water and Power (LADWP). SRP, serves as the facility operator. Prior to the permanent closure of NGS, SRP acquired the LADWP participant share in NGS.

of NO_x further, pursuant to the requirements of the 2014 FIP.

C. Attainment Status

The area around NGS is designated attainment, unclassifiable/attainment, or unclassifiable for all criteria pollutants under the Act.³

D. The EPA's Authority To Promulgate a FIP in Indian Country

When the CAA was amended in 1990, Congress included a new provision, section 301(d), granting the EPA authority to treat tribes in the same manner as states where appropriate.⁴ In 1998, the EPA promulgated regulations known as the Tribal Authority Rule (TAR).⁵ The EPA's promulgation of the TAR clarified, among other things, that state air quality regulations generally do not, under the CAA, apply to facilities located anywhere within the exterior boundaries of Indian reservations.⁶ Prior to the addition of section 301(d) and the promulgation of the TAR, some states had included emission limitations in their state implementation plans (SIPs) that they may have believed could apply under the CAA to private facilities operating on adjacent Indian reservations.

In the preambles to the proposed and final 1998 TAR, the EPA generally discussed the legal basis in the CAA that authorizes the EPA to regulate sources of air pollution in Indian country.⁷ The EPA concluded that the CAA authorizes the EPA to protect air quality throughout Indian country.⁸ The TAR, therefore, provides that the EPA "[s]hall promulgate without unreasonable delay such federal implementation plan provisions as are necessary or appropriate to protect air quality, consistent with the provisions of sections [301](a) and 301(d)(4), if a tribe does not submit a tribal implementation plan meeting the

completeness criteria of 40 CFR part 51, Appendix V, or does not receive EPA approval of a submitted tribal implementation plan."⁹

E. Historical Overview of NGS FIP Actions

On December 2, 1980, EPA issued regulations addressing visibility impairment that is traceable or "reasonably attributable" to a single source or small group of sources.¹⁰ These regulations required a number of states to submit SIPs no later than September 2, 1981. Most states, including Arizona, failed to submit SIPs as called for by the regulations. Accordingly, in 1987, the EPA issued visibility FIPs consisting of general plan requirements and long-term strategies for 29 states including Arizona.¹¹

In 1989, based on a report submitted by the National Park Service, the EPA proposed to find that a portion of the visibility impairment in Grand Canyon National Park was reasonably attributable to NGS.¹² Under the 1991 FIP, NGS was required to phase-in compliance with the SO₂ emissions limit by installing scrubbers in 1997, 1998, and 1999.¹³ In establishing the SO₂ emissions limit for NGS in the final 1991 FIP, the EPA determined that the FIP would provide for greater reasonable progress toward the national visibility goal than implementation of best available retrofit technology (BART).¹⁴

On September 8, 1999, the EPA proposed a source-specific FIP for NGS.¹⁵ The 1999 proposed FIP stated: "Although the facility has been historically regulated by Arizona since its construction, the state lacks jurisdiction over the facility or its owners or operations for CAA compliance or enforcement purposes." The EPA intended for the proposed action in 1999 to "federalize" the

emission limitations that Arizona had erroneously included in its SIP.¹⁶ The EPA received comments on the proposed FIP but did not finalize the proposal.

The EPA published a new proposed rule to promulgate federally enforceable numerical emissions limitations for PM and SO₂ in 2006 and took action to finalize it in 2010.¹⁷ The 2010 FIP also established an opacity limit and a requirement for specific control measures to limit dust emissions. In the 2010 FIP, the EPA determined that the emissions limitations for PM and SO₂ were more stringent than, or at least as stringent as, the emissions limitations that had historically applied at NGS pursuant to an operating permit issued by Arizona. Therefore, the EPA concluded that air quality in this area would be positively impacted by the 2010 FIP.¹⁸

On August 8, 2014, the EPA promulgated a final rule that established emissions limitations for NO_x emissions from NGS under BART provisions of the Regional Haze Rule.¹⁹ We finalized an alternative to BART based on agreed-upon recommendations developed by a group of diverse stakeholders. The 2014 FIP limited emissions of NO_x from NGS by establishing a long-term facility-wide cap on total NO_x emissions from 2009 to 2044 and required the implementation of one of several alternative operating scenarios to ensure that the 2009 to 2044 cap was met.

II. Basis for Proposed Action

In 2017, due to the changing economics of the energy industry, the owners of NGS voted to permanently close the facility at the end of 2019.²⁰ On November 27, 2019, consistent with the reporting requirements in the alternative to BART provisions of the NGS FIP, SRP notified the EPA that it would not implement any of the BART alternatives in the FIP due to the permanent cessation of operations at NGS.²¹ In that letter, SRP noted that Unit 3 permanently ceased operations on September 19, 2019, and that Units 1 and 2 permanently ceased operations on November 18, 2019. This closure

³ 40 CFR 81.303.

⁴ 40 U.S.C. 7601(d).

⁵ 40 CFR parts 9, 35, 49, 50, and 81. See also 63 FR 7254 (February 12, 1998).

⁶ 63 FR 7254 at 7258 (noting that unless a state has explicitly demonstrated its authority and has been expressly approved by the EPA to implement CAA programs in Indian country, the EPA is the appropriate entity to implement CAA programs prior to tribal primacy). *Arizona Public Service Company v. EPA*, 211 F.3d 1280 (D.C. Cir. 2000), cert. denied sub nom, *Michigan v. EPA*, 532 U.S. 970 (2001) (upholding the TAR); see also *Alaska v. Native Village of Venetie Tribal Government*, 533 U.S. 520, 526 n.1 (1998) (primary jurisdiction over Indian country generally lies with federal government and tribes, not with states).

⁷ 59 FR 43956 (August 25, 1994); 63 FR 7253 (February 12, 1998).

⁸ 63 FR 7253 at 7262 (February 12, 1998); 59 FR 43956 at 43960–43961 (August 25, 1994) (citing, among other things, to CAA sections 101(b)(1), 301(a), and 301(d)).

⁹ 63 FR 7273, codified at 40 CFR 49.11(a). In the preamble to the final TAR, the EPA explained that it was inappropriate to treat tribes in the same manner as states with respect to section 110(c) of the Act, which directs the EPA to promulgate a FIP within 2 years after the EPA finds a state has failed to submit a complete state plan or within 2 years after the EPA disapproval of a state plan. Although the EPA is not required to promulgate a FIP within the 2-year period for tribes, the EPA promulgated 40 CFR 49.11(a) to clarify that the EPA will continue to be subject to the basic requirement to issue any necessary or appropriate FIP provisions for affected tribal areas within some reasonable time. See 63 FR 7264–65.

¹⁰ 45 FR 80084 (December 2, 1980), codified at 40 CFR 51.300–51.307.

¹¹ 52 FR 45132 (November 24, 1987).

¹² 56 FR 50172 (October 3, 1991), codified at 40 CFR 52.145.

¹³ 40 CFR 52.145(d)(7).

¹⁴ 56 FR 50172 (October 3, 1991).

¹⁵ 64 FR 48725 (September 8, 1999).

¹⁶ 64 FR 48725, 48727.

¹⁷ 75 FR 10179 (March 5, 2010) codified at 40 CFR 49.24(a) through (i) and redesignated to 40 CFR 49.5513(a) through (i). See 76 FR 23879 (April 29, 2011).

¹⁸ 75 FR 10174 (March 5, 2010).

¹⁹ 79 FR 46514 (August 8, 2014).

²⁰ <https://www.powermag.com/utility-owners-vote-to-shut-down-coal-fired-2-2-gw-navajo-generating-station/>.

²¹ Letter dated November 27, 2019, from Kenneth Joe Frazier, SRP, to Elizabeth Adams, EPA, regarding "Navajo Generating Station—Notification of BART Alternative."

timeframe was consistent with the terms of the NGS Extension Lease agreement between the Navajo Nation and the owners of NGS prohibiting the combustion of coal at NGS after December 22, 2019. After November 18, 2019, the owners and operator of NGS began decommissioning the facility. On November 30, 2020, SRP withdrew its CAA title V operating permit renewal application that it had submitted to the Navajo Nation Environmental Protection Agency (Navajo Nation EPA), and requested that the EPA rescind the NGS FIP.²²

On December 18, 2020, the Navajo Nation EPA notified SRP that effective December 1, 2020, expiration of the title V permit terminated the ability of NGS to be operated.²³ In that letter, the Navajo Nation EPA noted that NGS had been operating under Permit No. NN-ROP-05-06, a title V permit issued on July 7, 2008. The permit was set to expire on July 7, 2013; however, because SRP submitted a timely and complete permit renewal application on March 4, 2013, NGS was able to continue to operate under the existing title V operating permit while awaiting action by the Navajo Nation EPA on the renewal permit application.²⁴ As a complete renewal application is no longer submitted and pending action by the Navajo Nation EPA, withdrawal of the renewal permit application caused Permit No. NN-ROP-05-06 to expire.²⁵ Expiration of the operating permit terminated the facility's right to operate.

In its rescission request, SRP stated that since ceasing operations all equipment permitted to operate under the title V permit, which includes all equipment subject to the NGS FIP, are non-operational and in the process of being removed. In addition, electrical and mechanical equipment had been removed, preventing the combustion of fuel and equipment operation and eliminating sources of air pollutant emissions from the permitted equipment. The Kayenta Mine, which supplied coal to NGS, has permanently

closed, and the dedicated rail line linking the mine to NGS has been dismantled. In addition, the three 775-foot stacks at NGS have been demolished.²⁶

Because NGS has permanently ceased operation and all equipment subject to the NGS FIP is no longer operational, and because the facility no longer holds a valid CAA title V permit to operate, the EPA is proposing to rescind the FIP for NGS at 40 CFR 52.145(d) and 40 CFR 49.5513.

The provisions of the 1991 FIP at 40 CFR 52.145(d) applied to the fossil fuel-fired steam-generating units designated as Units 1, 2, and 3, and NGS and addressed emissions limitations for SO₂, specifications for how compliance with the emissions limitations would be determined, requirements for continuous emissions monitoring, and reporting requirements.²⁷ Because the SO₂ emissions limitations in the 1991 FIP were achievable with the installation and operation of new flue gas desulfurization units, the 1991 FIP also specified compliance dates, schedules of compliance and associated reporting requirements.²⁸ Finally, the 1991 FIP also included various provisions related to equipment operation and maintenance.²⁹

Under 110(l) of the CAA, the EPA shall not approve a revision of an implementation plan if the revision would interfere with any applicable requirements concerning attainment, reasonable further progress, or any other applicable requirement of the CAA. Although this provision does not apply directly to the EPA's revision or rescission of a FIP, we have nonetheless considered whether rescission of the NGS FIP would interfere with any CAA requirements.

The 1991 FIP established emissions limitations for SO₂ emitted from the fossil fuel-fired steam-generating units at NGS, as well as associated compliance, monitoring, and reporting requirements for the flue gas desulfurization units. Because NGS has permanently ceased operation, these provisions are no longer necessary to satisfy any CAA requirements related to regional haze and visibility protection. In addition, because the area surrounding NGS is designated attainment, unclassifiable/attainment, or unclassifiable for all NAAQS, the provisions of the 1991 FIP are not

needed to satisfy requirements concerning attainment or reasonable further progress. Therefore, we propose to find that rescission of the 1991 FIP will not interfere with any applicable CAA requirements.

The provisions of the 2010 FIP at 40 CFR 49.5513(a) through (i) apply to Units 1, 2, and 3, equipment associated with coal and ash handling, and the two auxiliary steam boilers at NGS, and established emissions limitations and associated continuous monitoring, testing and reporting requirements for SO₂, PM, dust, and opacity.³⁰ The 2010 FIP also includes provisions related to compliance certifications, equipment operations, and enforcement.³¹ Although the testing and monitoring requirements at 40 CFR 49.5513(e) generally relate to continuous emissions monitoring and periodic source testing for SO₂, NO_x, and PM emissions from the facility, one provision required SRP to install, maintain and operate non-regulatory ambient monitors at the Glen Canyon Dam for PM, nitrogen dioxide (NO₂), SO₂, and ozone.³² The 2010 FIP did not elucidate the rationale for ambient monitoring but generally stated that "[t]his final action will help to advance the goals of ensuring continued maintenance of the national ambient air quality standards and protecting visibility."³³

Because NGS has permanently ceased operation, the air pollutants regulated under the 2010 FIP are no longer emitted from the facility, and the facility no longer operates the coal handling and storage equipment or the fly ash handling and storage equipment. Therefore, the provisions of the 2010 FIP that regulate emissions of air pollutants from NGS are no longer necessary to satisfy any CAA requirements related to regional haze and visibility protection. In addition, the area surrounding NGS is designated attainment, unclassifiable/attainment, or unclassifiable for all NAAQS, therefore, the provisions of the 2010 FIP are not needed to satisfy requirements concerning attainment or reasonable further progress. The ambient monitors at the Glen Canyon Dam are operated by SRP and are not relied upon by any state, local or tribal agency to satisfy the minimum monitoring requirements in 40 CFR part 58. Furthermore, data from the monitors are not reported to the EPA's Air Quality System. For these reasons, we propose to determine that the 2010 FIP, including the provisions

²² Letters dated November 30, 2020 from Joe Frazier, SRP, to Oliver Whaley, Navajo Nation EPA, regarding "Request to Withdraw the Pending Renewal Application for the Navajo Generating Station Title V Permit to Operate—Permit No. NN-ROP 05-06," and dated November 30, 2020 from Joe Frazier, SRP to John Busterud, EPA Region IX, regarding "Request to Rescind Navajo Generating Station Federal Implementation Plan at 40 CFR 52.145(d) and 49.5513."

²³ Letter dated December 18, 2020, from Ronnie Ben, Delegated Executive Director, Navajo Nation EPA, to Joe Frazier, Director General Engineering, SRP, Subject: "Expiration of Title V Permit to Operate for Navajo Generating Station—Permit No. NN-ROP-05-06."

²⁴ 40 CFR 71.7(c)(3).

²⁵ Condition IX.R of Permit No. NN-ROP-05-06.

²⁶ See, e.g., <https://www.powermag.com/explosions-topple-smokestacks-of-iconic-navajo-generating-station/>, accessed on December 23, 2020.

²⁷ 40 CFR 52.145 (d)(1) through (5).

²⁸ 40 CFR 52.145(d)(6) through (8).

²⁹ 40 CFR 52.145(d)(9) through (13).

³⁰ 40 CFR 49.5513(a) through (f).

³¹ 40 CFR 49.5513(g) through (i).

³² 40 CFR 49.5513(e)(6).

³³ 43 FR 10174, 10175 (March 5, 2010).

requiring operation of ambient monitors operated at the Glen Canyon Dam, is not needed to satisfy requirements related to attainment, reasonable further progress, visibility protection, or any other CAA requirements.

The provision of the 2014 FIP at 40 CFR 49.5513(j) were promulgated to satisfy the BART requirements of the CAA and the Regional Haze Rule and established emissions limitations for NO_x from NGS and associated requirements, including implementation schedules, reporting, monitoring, compliance determinations, recordkeeping, equipment operations, and enforcement.³⁴ Because NGS has permanently ceased operation, the emissions of NO_x regulated under the 2014 FIP have also permanently ceased. Therefore, the provisions of the 2014 FIP, which were intended to satisfy CAA requirements for visibility protection, are no longer necessary. In addition, the area surrounding NGS is designated attainment, unclassifiable/attainment, or unclassifiable for all NAAQS. Therefore, we propose to find that the provisions of the 2014 FIP are not needed to satisfy requirements concerning attainment or reasonable further progress or any other applicable CAA requirements.

III. Solicitation of Comments

As described above, the EPA is proposing the rescind the NGS FIP from 40 CFR 52.145(d) and 40 CFR 49.5513. The EPA solicits comments on this proposed FIP rescission and will accept comments until April 15, 2021.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget for review. This proposed rule applies to only one facility and is therefore not a rulemaking of general applicability.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because this action does not contain any information collection activities.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It 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.

F. Executive Order 13175: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. The Navajo Generating Station is located on the reservation lands of the Navajo Nation, and the EPA recognizes there is significant community and tribal interest in this facility. The facility has already permanently ceased operations and this action simply proposes to rescind previously promulgated requirements applicable to this shuttered facility. In addition, the Navajo Nation EPA has already determined that NGS no longer has the right to operate. This proposed action to rescind the NGS FIP will not have substantial direct effects on any 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. Thus, Executive Order 13175 does not apply to this action. However, on January 7, 2021, we invited the Navajo Nation to consult on this proposed action.³⁵ The Navajo Nation did not request consultation on this proposed FIP rescission.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. The facility has already permanently ceased operations and this action simply proposes to rescind previously promulgated requirements applicable to this shuttered facility. Therefore, the EPA considers this proposed action to rescind the NGS FIP to have no impacts to human health and the environment, and to have no potential disproportionately high and adverse effects on minority, low-income, or indigenous populations.

List of Subjects

40 CFR Part 49

Administrative practice and procedure, Air pollution control, Environmental protection, Incorporation by reference, Indians, Intergovernmental relations, Reporting and recordkeeping requirements.

40 CFR Part 52

Air pollution control, Environmental protection, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements, Visibility.

³⁵ Letter dated January 7, 2021 from Elizabeth J. Adams, EPA Region IX, to Jonathan Nez, President of the Navajo Nation, Re: Invitation to Consult on a Request from the Salt River Project to Rescind the Federal Implementation Plan for the Navajo Generating Station.

³⁴ 40 CFR 49.5513(j)(1) through (11).

Dated: February 22, 2021.

Deborah Jordan,

Acting Regional Administrator, Region IX.

For the reasons stated in the preamble, the Environmental Protection Agency proposes to amend chapter I, title 40, of the Code of Federal Regulations as follows:

PART 49—INDIAN COUNTRY: AIR QUALITY PLANNING AND MANAGEMENT

- 1. The authority citation for part 49 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart L—Implementation plans for tribes—Region IX

§ 49.5513 [Removed and Reserved]

- 2. Remove and reserve § 49.5513.

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

- 3. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart D—Arizona

§ 52.145 [Amended]

- 4. Amend § 52.145 by removing and reserving paragraph (d).

[FR Doc. 2021-04352 Filed 3-15-21; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R06-OAR-2020-0713; FRL-10020-73-Region 6]

Air Plan Approval; Texas; Revisions to the Texas Diesel Emissions Reduction Incentive Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is proposing to approve a revision to the Texas State Implementation Plan (SIP) that pertains to the Texas Diesel Emissions Reduction Incentive Program, submitted on August 13, 2020.

DATES: Written comments must be received on or before April 15, 2021.

ADDRESSES: Submit your comments, identified by Docket No. EPA-R06-OAR-2020-0713, at <https://www.regulations.gov> or via email to

young.carl@epa.gov. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [Regulations.gov](https://www.regulations.gov). The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact Carl Young, 214-665-6645, young.carl@epa.gov. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

Docket: The index to the docket for this action is available electronically at www.regulations.gov. While all documents in the docket are listed in the index, some information may not be publicly available due to docket file size restrictions or content (*e.g.*, CBI).

FOR FURTHER INFORMATION CONTACT: Carl Young, EPA Region 6 Office, Infrastructure and Ozone Section, 214-665-6645, young.carl@epa.gov. Out of an abundance of caution for members of the public and our staff, the EPA Region 6 office will be closed to the public to reduce the risk of transmitting COVID-19. We encourage the public to submit comments via <https://www.regulations.gov>, as there will be a delay in processing mail and no courier or hand deliveries will be accepted. Please call or email the contact listed above if you need alternative access to material indexed but not provided in the docket.

SUPPLEMENTARY INFORMATION:

Throughout this document wherever “we,” “us,” or “our” is used, we mean the EPA.

I. Background

Section 110 of the CAA requires states to develop and submit to the EPA a SIP to ensure that state air quality meets National Ambient Air Quality Standards (NAAQS). These ambient standards currently address six criteria pollutants: Carbon monoxide, nitrogen dioxide, ozone, lead, particulate matter, and

sulfur dioxide. Each federally-approved SIP protects air quality primarily by addressing air pollution at its point of origin through air pollution regulations and control strategies. The EPA approved SIP regulations and control strategies are federally enforceable.

An Economic Incentive Program (EIP) is a program that uses market-based strategies to reduce emissions of air pollutants.¹ The Texas Diesel Emissions Reduction Incentive Program (DERIP) for On-Road and Non-Road Vehicles is part of the Texas Emissions Reduction Program (TERP) that was established by the Texas Legislature in 2001 and approved in the Texas SIP as an economic incentive program (70 FR 48647, August 19, 2005). DERIP provides grants to eligible individuals, businesses, or local governments to reduce emissions from diesel-powered vehicles and equipment in areas designated as nonattainment for a NAAQS or other counties identified by the Texas Legislature.²

In 2019 the Texas Legislature revised the eligibility requirements for DERIP. As a result, the Texas Commission on Environmental Quality (TCEQ) revised the DERIP regulations found in Title 30, Chapter 114 (Control of Air Pollution from Motor Vehicles) of the Texas Administrative Code (30 TAC 114). The revisions were adopted on June 10, 2020 and submitted to the EPA as a SIP revision on August 13, 2020. Specifically, the TCEQ revisions: (1) Changed the minimum required usage for grant-funded vehicles and equipment in the eligible area from 75% to 55% (30 TAC 114.622), and (2) removed Victoria County from the list of counties eligible for DERIP grants (30 TAC 114.629). A copy of the SIP revision submitted to EPA is available in the electronic docket for this action.

II. The EPA's Evaluation

We approved DERIP regulations into the Texas SIP in 2005 (70 FR 48647, August 19, 2005). More recently, we approved updates to DERIP regulations in 2018 (83 FR 50018, October 4, 2018). This SIP revision further updates DERIP regulations. The effect of this update is to: (1) Allow more diesel vehicles and equipment in nonattainment areas or

¹ For more information on EIPs see “Improving Air Quality with Economic Incentive Programs”, EPA-452/R-01-001, January 2001, available at <https://www.epa.gov/sites/production/files/2015-07/documents/eipfin.pdf>.

² For more information on TERP and DERIP please see “Texas Emissions Reduction Plan Biennial Report (2019–2020), Report to the 87th Texas Legislature, December 2020, SFR-079/20”. The document is available at: https://www.tceq.texas.gov/assets/public/comm_exec/pubs/sfr/079-20.pdf.

affected counties to be eligible for grant funding (30 TAC 114.622) and (2) exclude Victoria County from eligibility for DERIP grants (30 TAC 114.629).

Section 110(l) of the CAA requires that EPA shall not approve a SIP revision if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in Section 171 of the CAA) or any other applicable requirements of the CAA. DERIP is a voluntary incentive program for reducing emissions and is not a requirement of the Act. The inclusion of DERIP in the SIP, therefore, is discretionary and as such, revisions can be made as long as they do not contribute to nonattainment or interfere with maintenance. Reductions from the TERP program were part of the emission reductions in SIP revisions relied upon to provide for attainment of (1) the 1997 ozone standard in the Dallas-Fort Worth area (70 FR 15592, March 28, 2005) and (2) the 1-hour ozone standard in the Houston-Galveston-Brazoria area (71 FR 52670, September 6, 2006). The reductions relied upon in these plans have long been achieved through grants and rebates that have already been issued and none of the subsequent ozone attainment plans submitted by the State have relied upon reductions from the TERP or DERIP programs. However, the State could use DERIP as a tool in future SIP revisions to obtain needed emission reductions.

As noted above, revisions to 30 TAC 114.622 changed the amount of time equipment needs to operate in the affected counties. This change will provide for an increase in the pool of vehicles and equipment eligible for this program and potentially generate more emission reductions through future state grants. Some of these reductions, however, will likely be outside of designated nonattainment areas. As Texas is not relying on emission reductions from future DERIP grants, it is not necessary for the reductions to occur exactly in an affected nonattainment area.

As stated previously, DERIP and TERP are not mandated by the Clean Air Act. The implementation of these programs is discretionary. The Texas legislature originally adopted the programs to apply in nonattainment areas and other affected areas deemed near-nonattainment areas. None of the reductions that will be achieved by these programs going forward are being relied upon in any plan for any affected area in Texas. The Texas legislature decided that it no longer should implement the program in Victoria County which is meeting all current

NAAQS. Not providing grants to reduce emissions from diesel equipment will not cause emissions to increase in Victoria county. Instead emissions in the county will not be impacted by this SIP revision. Therefore, approval of the revision to 30 TAC 114.629 will not contribute to nonattainment or interfere with maintenance in Victoria County. As more diesel equipment become eligible, the concentration of the DERIP program in nonattainment areas will likely result in additional emission reductions. As additional grants are issued to reduce emissions from diesel equipment, the air quality will benefit, which will assist in maintenance and attainment of the NAAQS. Therefore, the proposed approval of the SIP revision is consistent with the CAA section 110(1). Also, because the program is discretionary, it will not interfere with any applicable requirement for attainment and reasonable further progress, or any other applicable requirement of the CAA. Because the revised program will continue to achieve additional reductions not relied upon by any plan for attainment or maintenance, the revisions will not contribute to nonattainment or interfere with maintenance.

III. Proposed Action

We are proposing to approve the revisions to 30 TAC 114.622 and 114.629 adopted on June 10, 2020 and submitted on August 13, 2020.

IV. Incorporation by Reference

In this action, we are proposing to include in a final rule regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, we are proposing to incorporate by reference revisions to the Texas regulations as described in the Proposed Action section above. We have made, and will continue to make, these documents generally available electronically through www.regulations.gov (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as

meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: March 10, 2021.

David Gray,

Acting Regional Administrator, Region 6.

[FR Doc. 2021-05329 Filed 3-15-21; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA-HQ-OPPT-2021-0202; FRL-10021-08]

Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In accordance with the January 21, 2021, Executive Order entitled “Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis” and other Biden-Harris Administration Executive orders and other direction, the Environmental Protection Agency (EPA) is requesting additional public comments on five final rules recently issued under the Toxic Substances Control Act (TSCA). On January 6, 2021, EPA issued final rules to address its obligations under TSCA for five persistent, bioaccumulative, and toxic (PBT) chemicals that EPA determined met the criteria for expedited action under TSCA. These chemicals are 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP) (CASRN 732-26-3); decabromodiphenyl ether (decaBDE) (CASRN 1163-19-5); phenol, isopropylated phosphate (3:1) (PIP (3:1)) (CASRN 68937-41-7); pentachlorothiophenol (PCTP) (CASRN 133-49-3); and hexachlorobutadiene (HCBd) (CASRN 87-68-3). PBT chemicals are of particular concern in the Agency’s efforts to protect human health and the environment because they are toxic and remain in the environment for long periods of time and can build up or accumulate in the body. As a first step in its efforts to immediately review these rules to determine whether they are consistent with the Administration policy to limit exposure to dangerous chemicals (and to determine whether and how these rules should be revised), EPA invites public comment on the final rules, including whether there are further exposure reductions that could be achieved, including exposure reductions for potentially exposed or susceptible subpopulations and the environment; implementation issues

associated with these final rules; and whether to consider additional or alternative measures or approaches. In particular, EPA is seeking comment on specifics of recently raised issues regarding the compliance date for the prohibition on the processing and distribution of PIP (3:1) for use in articles, and PIP (3:1)-containing articles.

DATES: Comments must be received on or before May 17, 2021.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2021-0202, through the Federal eRulemaking Portal at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room were closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Cindy Wheeler, Existing Chemicals Risk Management Division (Mail Code 7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 566-0484; email address: TSCA-PBT-rules@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this apply to me?

This document is directed to the public in general and may be of interest to persons who currently or may manufacture (including import), process, distribute, use, and/or dispose of the five PBT chemicals: 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP) (CASRN 732-26-3); decabromodiphenyl ether

(decaBDE) (CASRN 1163-19-5); phenol, isopropylated phosphate (3:1) (PIP (3:1)) (CASRN 68937-41-7); pentachlorothiophenol (PCTP) (CASRN 133-49-3); and hexachlorobutadiene (HCBd) (CASRN 87-68-3). The action may also be of interest to persons who currently or may manufacture (including import), process, distribute, use, and/or dispose of products and articles containing these PBT chemicals. Non-governmental organizations in the environmental and public health sectors, state and local government agencies, and members of the public may also be interested in this action. Since other entities may also be interested, EPA has not attempted to describe all the specific entities that may be affected by this action.

B. What is EPA’s authority for taking this action?

EPA issued the final rules under TSCA section 6(h), 15 U.S.C. 2601 *et seq.*, for five persistent, bioaccumulative, and toxic (PBT) chemical substances that met the statutory criteria. More specifically, under TSCA section 6(h), EPA must take expedited action on those chemical substances identified in the 2014 Update to the TSCA Work Plan for Chemical Assessments (Ref. 1) that, among other factors, EPA has a reasonable basis to conclude are toxic and that with respect to persistence and bioaccumulation score high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals: Methods Document (Ref. 2). The chemical substances that meet these criteria are 2,4,6-TTBP, decaBDE, PIP (3:1), PCTP, and HCBd. Under TSCA, if EPA determines that exposure is likely to a chemical meeting these criteria, EPA must issue a rule that addresses the risks of injury to health or the environment that the Administrator determines are presented and reduces exposure to the chemical to the extent practicable. Based on the “Exposure and Use Assessment of Five Persistent, Bioaccumulative and Toxic Chemicals Assessment” (Ref. 3), EPA determined that exposure was likely to all five of the PBT chemicals. On January 6, 2021, EPA issued a final rule for each of the five chemicals under TSCA section 6(h), meeting the Agency’s obligation to promulgate the rules within 18 months of issuance of the proposed rules (Refs. 4–8). With the obligation to promulgate these rules, the Agency also has the authority to amend them if circumstances change, including in relation to the receipt of new information.

C. What action is EPA taking?

EPA is inviting public comment on the provisions of the final rules. The Agency is broadly re-examining TSCA section 6(h) requirements and other provisions of amended TSCA, including determining how the new Executive orders and other direction provided by the Biden-Harris Administration (Refs. 9–13) will be addressed, as well as new information received from stakeholders. As part of this process, EPA will review and consider revising the final PBT rules with an eye towards reducing exposure to the extent practicable, environmental justice, scientific integrity, and EPA's mission of protecting human health and the environment, taking into consideration information received while the rules were under development as well as any new information submitted since the rules were finalized and information received in response to this document. EPA is also aware of and plans to consider revisions in response to implementation issues that have been raised by a range of stakeholders. In particular, EPA is seeking comment on newly-raised issues associated with the March 8, 2021, compliance date in the PIP (3:1) rule for certain regulated articles.

D. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](https://www.epa.gov/regulations) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Summary of the Final PBT Rules

This unit provides a summary of the five TSCA section 6(h) final rules that published in the **Federal Register** of January 6, 2021. However, each rule should be consulted for additional

details on the requirements adopted and the rationale for those requirements.

A. 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h) (RIN 2070-AK59)

Uses of 2,4,6-TTBP may be grouped into four general categories: (1) Domestic manufacture and use as an intermediate/reactant in processing at chemical facilities; (2) use in formulations and mixtures for fuel treatment in refineries and fuel facilities; (3) use in formulations intended for the maintenance or repair of motor vehicles and machinery at small commercial operations and for retail sale, and (4) use in formulations and mixtures for liquid lubricant and grease additives/antioxidants additives. 2,4,6-TTBP is toxic to aquatic plants, aquatic invertebrates, and fish. Surveyed animal data indicate the potential for liver and developmental effects. The final rule for 2,4,6-TTBP (Ref. 4) prohibits the distribution in commerce of 2,4,6-TTBP and products containing 2,4,6-TTBP at concentrations above 0.3% by weight in any container with a volume of less than 35 gallons in order to minimize the use of 2,4,6-TTBP as a fuel additive or fuel injector cleaner by consumers and small commercial operations (e.g., automotive repair shops, marinas). The final rule also prohibits the processing and distribution in commerce of 2,4,6-TTBP, and products containing 2,4,6-TTBP, for use as an oil or lubricant additive in concentrations above 0.3% by weight regardless of container size. The final rule includes a number of broad exclusions or definitions intended to apply to each of the five PBT rules, including definitions of article and product and exclusions for research and development, disposal, and the resale of products and articles previously sold to an end user.

B. Decabromodiphenyl Ether (DecaBDE); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h) (RIN 2070-AK34)

DecaBDE (Ref. 5) is used as an additive flame retardant in plastic enclosures for televisions, computers, audio and video equipment, textiles and upholstered articles, wire and cables for communication and electronic equipment, and other applications. DecaBDE is also used as a flame retardant for multiple applications for aerospace and automotive vehicles, including replacement parts for aircraft and cars. DecaBDE is toxic to aquatic

invertebrates, fish, and terrestrial invertebrates. Data indicate the potential for developmental, neurological, and immunological effects, general developmental toxicity, liver effects, and carcinogenicity. The final rule for decaBDE (Ref. 5) prohibits the manufacture (including import) and processing of decaBDE, and products and articles containing decaBDE, as of March 8, 2021. Distribution in commerce of products and articles to which decaBDE has been added is prohibited as of January 6, 2022. Different compliance dates or exclusions include:

- Manufacture, processing, and distribution in commerce for use in curtains in the hospitality industry after July 6, 2022;
- Processing and distribution in commerce for use in wire and cable insulation in nuclear power generation facilities after January 6, 2023;
- Manufacture, processing, and distribution in commerce for use in parts for new aerospace vehicles after January 8, 2024;
- Manufacture, processing, and distribution in commerce for use in replacement parts for aerospace vehicles until the end of the vehicles' service lives;
- Manufacture, processing, and distribution in commerce for use in replacement parts for motor vehicles until the end of the vehicles' service lives or 2036, whichever is earlier;
- Distribution in commerce of plastic shipping pallets manufactured prior to the publication of the final rule that contain decaBDE until the end of the pallets service lives; and
- Processing and distribution in commerce for recycling of plastic that contained decaBDE before the plastic was recycled, and the articles and products made from such recycled plastic so long as no new decaBDE is added during the recycling or production process.

C. Phenol, Isopropylated Phosphate (3:1) (PIP 3:1); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h) (RIN 2070-AK58)

PIP (3:1) (Ref. 6) is used as a plasticizer, a flame retardant, an anti-wear additive, or an anti-compressibility additive in hydraulic fluid, lubricating oils, lubricants and greases, various industrial coatings, adhesives, sealants, and plastic articles. PIP (3:1) is toxic to aquatic plants, aquatic invertebrates, sediment invertebrates and fish. Data indicate the potential for reproductive and developmental effects, neurological effects and effects on systemic organs,

specifically adrenals, liver, ovary, heart, and lungs. The PIP (3:1) final rule (Ref. 6) prohibits processing and distribution in commerce of PIP (3:1), and products or articles containing the chemical substance, for all uses, except for the following different compliance dates or exclusions:

- Use in photographic printing articles after January 1, 2022;
- Use in aviation hydraulic fluid in hydraulic systems and use in specialty hydraulic fluids for military applications;
- Use in lubricants and greases;
- Use in new and replacement parts for the aerospace and automotive industries;
- Use as an intermediate in the manufacture of cyanoacrylate glue;
- Use in specialized engine air filters for locomotive and marine applications;
- Use in sealants and adhesives after January 6, 2025; and
- Recycling of plastic that contained PIP (3:1) before the plastic was recycled, and the articles and products made from such recycled plastic, so long as no new PIP (3:1) is added during the recycling or production process.

In addition, the final rule requires manufacturers, processors, and distributors of PIP (3:1) and products containing PIP (3:1) to notify their customers of these restrictions. Finally, the rule prohibits releases to water from the remaining manufacturing, processing, and distribution in commerce activities, and requires commercial users of PIP (3:1) and PIP (3:1)-containing products to follow existing regulations and best practices to prevent releases to water during use.

D. Pentachlorothiophenol (PCTP); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h) (RIN 2070-AK60)

PCTP was used in rubber manufacturing as a peptizer, or a chemical that makes rubber more amenable to processing. Although it is likely that PCTP is no longer used as a peptizer, it can be found as an impurity in the zinc salt of PCTP (zinc PCTP) (CASRN 117-97-5) after zinc PCTP manufacturing. PCTP is toxic to protozoa, fish, terrestrial plants, and birds. Data for analogous chemicals (pentachloronitrobenzene and hexachlorobenzene) indicate the potential for liver and reproductive effects. However, no animal or human hazard data has been identified. The final rule for PCTP (Ref. 7) prohibits all manufacturing (including import) and processing of PCTP, and products or articles containing PCTP, unless PCTP

concentrations are at or below 1% by weight. A prohibition on the distribution in commerce of PCTP or PCTP-containing products or articles, unless PCTP concentrations are at or below 1% by weight, will take effect on January 6, 2022.

E. Hexachlorobutadiene (HCBD); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h) (RIN 2070-AK61)

HCBD is a halogenated aliphatic hydrocarbon that is produced as an unintentional byproduct during the manufacture of chlorinated hydrocarbons, particularly perchloroethylene, trichloroethylene, and carbon tetrachloride, and is subsequently burned as a waste fuel. HCBD is toxic to aquatic invertebrates, fish, and birds, and has been identified as a possible human carcinogen. Data indicate the potential for renal, reproductive, and developmental effects. The final rule for HCBD (Ref. 8) prohibits the manufacture (including import), processing, and distribution in commerce of HCBD and HCBD-containing products or articles, except for the unintentional production of HCBD as a byproduct during the production of chlorinated solvents, and the processing and distribution in commerce of HCBD for burning as a waste fuel.

III. Request for Comment

During the comment period, the public may submit comments and information relevant to any aspect of the final PBT rules. The public is encouraged to provide comments and information relating to EPA's statutory obligations under TSCA section 6(h) and the extent to which there are further exposure reductions that could be achieved, including exposure reductions for potentially exposed or susceptible subpopulations and the environment. EPA is particularly interested in information relating to the impacts of the final rules on human health, including potentially exposed or susceptible subpopulations, and the environment. EPA is also requesting comment on implementation issues associated with these final rules. EPA specifically invites public comment on additional measures or approaches that EPA could take in addition to the provisions in the final rules.

In particular, EPA is seeking comment on newly-raised issues associated with the March 8, 2021 compliance date in the PIP (3:1) rule for certain regulated articles. Stakeholders recently informed EPA that the prohibition on processing

and distribution of PIP (3:1) could impact articles used in a wide variety of electronics, from cell phones, to robotics used to manufacture semiconductors, to equipment used to move COVID-19 vaccines and keep them at the appropriate temperature. Stakeholders note that the complexity of international supply chains makes locating the presence of, and finding alternatives to, PIP (3:1) in components challenging. They assert that an extension to the compliance deadline is necessary to avoid significant disruption to the supply chain for a wide variety of articles. It was clearly not EPA's intent during the development of the rule to have such a broad disruptive impact. Nonetheless, compliance deadlines for the PBT rules must be in place "as soon as practicable" and provide reasonable transition periods, pursuant to the requirements of TSCA section 6(d)(1). Thus, for EPA to amend the existing deadline, the Agency needs additional information regarding the impact of the deadline. EPA specifically asks commenters to specify the articles that need the alternative deadline; the basis for the alternative deadline, taking into consideration the reasons supporting alternative deadlines in the final rule already issued, such as the January 1, 2022, date for photographic printing articles and the January 6, 2025, date for adhesives and sealants, with supporting documentation; and the additional time needed for specific articles to clear channels of trade. EPA plans to address the compliance deadline in the PIP (3:1) rule as part of the broader re-examination of these rules and will take into account comments received during this comment period when deciding upon future action involving this matter. In the meantime, the Agency will exercise its enforcement discretion to not pursue enforcement actions for violations of the prohibitions on the processing and distribution of PIP (3:1) for use in articles, or articles containing PIP (3:1) for up to 180 days, while this review and agency action to address this matter are pending.

III. References

1. EPA. TSCA Work Plan for Chemical Assessments: 2014 Update. October 2014. <https://www.epa.gov/assessingandmanaging-chemicals-under-tsca/tscawork-plan-chemical-assessments-2014-update>. Accessed March 1, 2019.
2. EPA. TSCA Work Plan Chemicals: Methods Document. February 2012. https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf. Accessed March 1, 2019.

3. EPA. Exposure and Use Assessment of Five Persistent, Bioaccumulative, and Toxic Chemicals. December 2020.
4. EPA. 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Final Rule. **Federal Register** (86 FR 866, January 6, 2021) (FRL–10018–90).
5. EPA. Decabromodiphenyl Ether (DecaBDE); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Final Rule. **Federal Register** (86 FR 880, January 6, 2021) (FRL–10018–87).
6. EPA. Phenol, Isopropylated Phosphate (3:1) (PIP 3:1); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Final Rule. **Federal Register** (86 FR 894, January 6, 2021) (FRL–10018–88).
7. EPA. Pentachlorothiophenol (PCTP); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Final Rule. **Federal Register** (86 FR 911, January 6, 2021) (FRL–10018–89).
8. EPA. Hexachlorobutadiene (HCBd); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Final Rule. **Federal Register** (86 FR 922, January 6, 2021) (FRL–10018–91).
9. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. **Federal Register** (86 FR 7009, January 25, 2021).
10. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. **Federal Register** (86 FR 7037, of January 25, 2021).
11. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. **Federal Register** (86 FR 7619, February 1, 2021).
12. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. **Federal Register** (January 27, 2021).
13. Fact Sheet: List of Agency Actions for Review (January 21, 2021).

Authority: 15 U.S.C. 2601 *et seq.*

Dated: March 8, 2021.

Michal Freedhoff,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2021–05138 Filed 3–15–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 21–49; RM–11874; DA 21–158; FR ID 17557]

Television Broadcasting Services; Augusta, Georgia

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; correction.

SUMMARY: The Federal Communications Commission published a document in the **Federal Register** of March 8, 2021, concerning a petition for rulemaking filed by Gray Television Licensee, LLC (Gray) requesting the substitution of channel 27 for channel 12 at Augusta, Georgia in the DTV Table of Allotments. The document contained the incorrect address for counsel of petitioner.

FOR FURTHER INFORMATION CONTACT: Andrew Manley, *Andrew.Manley@fcc.gov*, Media Bureau, (202) 418–0596.

Correction

In the **Federal Register** of March 8, 2021, in FR Vol. 86, No. 43, on page 13278, in the second column, correct the **ADDRESSES** caption to read:

ADDRESSES: Federal Communications Commission, Office of the Secretary, 45 L Street NE, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for petitioner as follows: Joan Stewart, Esq., Wiley Rein LLP, 1776 K Street NW, Washington, DC 20006.

Dated: March 9, 2021.

Thomas Horan,

Chief of Staff, Media Bureau.

[FR Doc. 2021–05394 Filed 3–15–21; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[RTID 0648–XA797]

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Amendment 18 to the Coastal Pelagic Species Fishery Management Plan

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

ACTION: Announcement of availability of fishery management plan amendment; request for comments.

SUMMARY: NMFS announces that the Pacific Fishery Management Council has submitted Amendment 18 to the Coastal Pelagic Species Fishery Management Plan for review by the Secretary of Commerce. Amendment 18 would implement a rebuilding plan for the northern subpopulation of Pacific sardine, which NMFS declared overfished in June 2019. NMFS will consider public comments in deciding whether to approve, disapprove, or partially approve Amendment 18.

DATES: Comments on Amendment 18 must be received by May 17, 2021. Comments on the associated Environmental Assessment must be received by April 15, 2021.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–0008–2021, by the following electronic methods:

- The Pacific Fishery Management Council and NMFS prepared a draft excerpt of the Coastal Pelagic Species Fishery Management Plan as amended through Amendment 18, with notations showing how Amendment 18 would change the Fishery Management Plan, if approved. This draft can be viewed via the Federal eRulemaking Portal: <http://www.regulations.gov>, docket NOAA–NMFS–0008–2021 or by contacting the Pacific Fisheries Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384. In order to comment on this document and the draft Amendment 18 language, submit all electronic public comments via the Federal e-Rulemaking Portal. Go to www.regulations.gov and enter NOAA–NMFS–0008–2021 in the Search box. Click the “Comment” icon and complete the required fields, and enter or attach your comments.

- The Pacific Fishery Management Council and NMFS prepared a draft Environmental Assessment for this action pursuant to the National Environmental Policy Act. This draft can be viewed on NMFS’ website at <https://www.fisheries.noaa.gov/west-coast/laws-and-policies/west-coast-region-national-environmental-policy-act-documents>. In order to comment on the Environmental Assessment, submit all public comments to Lynn Massey at lynn.massey@noaa.gov, or Kerry Griffin at Kerry.griffin@noaa.gov.

Instructions: Comments must be submitted by the above methods to ensure that the comments are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the

public record and will generally be posted for public viewing on www.regulations.gov without change. All personal identifying information (e.g., name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT:

Lynn Massey, Sustainable Fisheries Division, NMFS, (562) 436-2462, lynn.massey@noaa.gov; or Kerry Griffin, Pacific Fishery Management Council, (503) 820-2409, kerry.griffin@noaa.gov.

SUPPLEMENTARY INFORMATION: The coastal pelagic species (CPS) fishery in the U.S. exclusive economic zone off the West Coast is managed under the CPS Fishery Management Plan (FMP). The Pacific Fishery Management Council (Council) developed the CPS FMP pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1801 *et seq.* The Secretary of Commerce approved the CPS FMP and implemented the provisions of the plan through regulations at 50 CFR part 660, subpart I. Species managed under the CPS FMP include Pacific sardine, Pacific mackerel, jack mackerel, northern anchovy, market squid, and krill.

The Magnuson-Stevens Act requires each regional fishery management council to submit any amendment to an FMP to NMFS for review and approval, disapproval, or partial approval. The Magnuson-Stevens Act also requires that NMFS, upon receiving an amendment to an FMP, publish notification in the **Federal Register** that the amendment is available for public review and comment. NMFS will consider the public comments received during the comment period described above in determining whether to approve, disapprove, or partially approve Amendment 18.

NMFS declared the northern subpopulation of Pacific sardine (hereafter, Pacific sardine) overfished in June 2019. This determination was based on the results of an April 2019 stock assessment, which indicated that the biomass of Pacific sardine had dropped below the overfished threshold of 50,000 metric tons (mt) defined in the CPS FMP. NMFS notified the Council about the overfished declaration on July 9, 2019. The Magnuson-Stevens Act requires that NMFS and the Council prepare a rebuilding plan within 2 years

of NMFS' overfished notification to the Council that specifies a rebuilding timeframe (*i.e.*, T_{target}) within 10 years, except where the biology of the stock or other environmental conditions dictate otherwise (*see* Magnuson-Stevens Act section 304(e)(4)(A)(2)).

In September 2020, the Council recommended a rebuilding plan strategy to NMFS that would maintain the existing management framework for the Pacific sardine fishery. Under the rebuilding plan, the harvest control rules and other FMP provisions currently in place for Pacific sardine would be maintained. This includes the harvest guideline control rule, which requires that the primary directed fishery for Pacific sardine be closed when the biomass is at or below 150,000 mt and restrictions on incidental landings of Pacific sardine in other CPS fisheries, including an automatic reduction in allowable incidental landings when the biomass is below 50,000 mt. The rebuilding plan would also maintain the Council's annual harvest specifications process for Pacific sardine, such that an overfishing limit and acceptable biological catch are calculated annually based on an estimate of that year's biomass from annual stock assessments and their respective control rules in the FMP (that have been approved by the Scientific and Statistical Committee to prevent overfishing). In addition to the harvest control rules prescribed by the CPS FMP, the rebuilding plan would allow the Council to maintain their ability to annually adjust the incidental harvest percentages or other accountability measures for the various sectors based on new information from the previous year or changes in fishery dynamics, if necessary. Although this framework would maintain the current management strategy, this management strategy already severely restricts fishing and will continue to do so until the stock is rebuilt.

Current fishing mortality is not considered to be the primary constraining factor or rebuilding Pacific sardine. The primary directed fishery for Pacific sardine has been closed since 2015 when the stock's biomass dropped below the 150,000 mt threshold in the CPS FMP for allowing a primary directed fishery. This closure of the primary directed fishery, which took place 4 years prior to the stock dropping, drastically reduced catch of Pacific sardine and has kept harvest at very low levels since that time. As such, the contribution of this rebuilding plan to stock recovery would be additional to measures already in place via the CPS

FMP and Council process that limit fishing mortality of Pacific sardine.

As described above, the Magnuson-Stevens Act specifies that the time period for rebuilding a fishery generally should not exceed 10 years unless the biology of the stock or environmental conditions dictate otherwise, as is the case for Pacific sardine. Pacific sardines are known for wide swings in population abundance, and studies show the species has long experienced boom-bust cycles even in the absence of fishing. Periods of low recruitment success driven by prevailing oceanographic conditions can lead to low population abundance over extended periods of time. Because environmental conditions represent the primary constraint on rebuilding Pacific sardine, the projected time for rebuilding, is 14 years (*i.e.*, T_{target}). This T_{target} was determined to be the shortest time possible to rebuild the stock, taking into account the biology of the species, current environmental conditions, and the needs of fishing communities. For more information about how this rebuilding target was determined, see the Environmental Assessment at <https://www.fisheries.noaa.gov/west-coast/laws-and-policies/west-coast-region-national-environmental-policy-act-documents>.

Amendment 18 would expand Section 4.5 of the CPS FMP to include the proposed rebuilding plan for Pacific sardine. There are no implementing regulations associated with Amendment 18, therefore NMFS will not promulgate proposed and final rules to implement this amendment.

Public comments on Amendment 18 must be received by May 17, 2021. Public comments on the associated EA for Amendment 18 must be received by May 17, 2021. All comments received by the end of the comment period on Amendment 18 will be considered in the Secretary's decision to approve, disapprove, or partially approve this amendment. To be considered in this decision, comments must be received by close of business on the last day of the comment period; that does not mean postmarked or otherwise transmitted by that date. NMFS will respond to any substantive comments received by the end of the comment period on Amendment 18 in a subsequent **Federal Register** document.

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

Dated: March 8, 2021.

Jennifer M. Wallace,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021-05101 Filed 3-15-21; 8:45 am]

BILLING CODE 3510-22-P

Notices

Federal Register

Vol. 86, No. 49

Tuesday, March 16, 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

[Docket Number: USDA–2021–0003]

Notice of Request for Public Comment on the Executive Order on Tackling the Climate Crisis at Home and Abroad

AGENCY: Office of the Chief Economist, U.S. Department of Agriculture.

ACTION: Request for public comment.

SUMMARY: On January 27, 2021, President Biden issued an Executive Order on Tackling the Climate Crisis at Home and Abroad. This Executive Order laid out a series of actions for Federal Agencies to take regarding climate change mitigation and resilience, including directing the Secretary of Agriculture to collect stakeholder input on a climate-smart agriculture and forestry strategy. As part of this process, the U.S. Department of Agriculture (USDA) is seeking input from the public to ensure that relevant information is considered. USDA is interested in your comments in response to the topics, categories and questions shown in the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: Interested persons are invited to submit comments on or before 11:59 p.m. Eastern Time April 29, 2021.

ADDRESSES: Comments may be submitted online via the Federal eRulemaking Portal. Go to <http://www.regulations.gov> and search for the Docket No. USDA–2021–0003. Follow the online instructions for submitting comments. All comments received will be posted without change and publicly available on www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: William Hohenstein, Director, USDA Office of Energy and Environmental Policy, Phone: 202–720–0450; Email: CCPOOCE@usda.gov.

SUPPLEMENTARY INFORMATION: Through the Executive Order on Tackling the Climate Crisis at Home and Abroad, the U.S. Department of Agriculture (USDA)

is being asked to seek public input regarding USDA's climate strategy. Part II Section 216(b) of this Executive Order directs the Secretary of Agriculture to, “collect input from Tribes, farmers, ranchers, forest owners, conservation groups, firefighters, and other stakeholders on how to best use Department of Agriculture programs, funding and financing capacities, and other authorities, and how to encourage the voluntary adoption of climate-smart agricultural and forestry practices that decrease wildfire risk fueled by climate change and result in additional, measurable, and verifiable carbon reductions and sequestration and that source sustainable bioproducts and fuels.” This public input will be considered as USDA prepares recommendations to expand climate-smart agriculture and forestry practices and systems. The feedback requested through this Executive Order is far-reaching; it encompasses the best use of USDA programs, funding and financing capabilities, authorities, and encouragement of voluntary conservation adoption.

USDA currently requests public comment on:

1. Climate-Smart Agriculture and Forestry Questions

A. How should USDA utilize programs, funding and financing capacities, and other authorities, to encourage the voluntary adoption of climate-smart agricultural and forestry practices on working farms, ranches, and forest lands?

1. How can USDA leverage *existing* policies and programs to encourage voluntary adoption of agricultural practices that sequester carbon, reduce greenhouse gas emissions, and ensure resiliency to climate change?

2. What *new* strategies should USDA explore to encourage voluntary adoption of climate-smart agriculture and forestry practices?

B. How can partners and stakeholders, including State, local and Tribal governments and the private sector, work with USDA in advancing climate-smart agricultural and forestry practices?

C. How can USDA help support emerging markets for carbon and greenhouse gases where agriculture and forestry can supply carbon benefits?

D. What data, tools, and research are needed for USDA to effectively carry out

climate-smart agriculture and forestry strategies?

E. How can USDA encourage the voluntary adoption of climate-smart agricultural and forestry practices in an efficient way, where the benefits accrue to producers?

2. Biofuels, Wood and Other Bioproducts, and Renewable Energy Questions

A. How should USDA utilize programs, funding and financing capacities, and other authorities to encourage greater use of biofuels for transportation, sustainable bioproducts (including wood products), and renewable energy?

B. How can incorporating climate-smart agriculture and forestry into biofuel and bioproducts feedstock production systems support rural economies and green jobs?

C. How can USDA support adoption and production of other renewable energy technologies in rural America, such as renewable natural gas from livestock, biomass power, solar, and wind?

3. Addressing Catastrophic Wildfire Questions

A. How should USDA utilize programs, funding and financing capacities, and other authorities to decrease wildfire risk fueled by climate change?

B. How can the various USDA agencies work more cohesively across programs to advance climate-smart forestry practices and reduce the risk of wildfire on all lands?

C. What additional data, tools and research are needed for USDA to effectively reduce wildfire risk and manage Federal lands for carbon?

D. What role should partners and stakeholders play, including State, local and Tribal governments, related to addressing wildfires?

4. Environmental Justice and Disadvantaged Communities Questions

A. How can USDA ensure that programs, funding and financing capacities, and other authorities used to advance climate-smart agriculture and forestry practices are available to all landowners, producers, and communities?

B. How can USDA provide technical assistance, outreach, and other assistance necessary to ensure that all

producers, landowners, and communities can participate in USDA programs, funding, and other authorities related to climate-smart agriculture and forestry practices?

C. How can USDA ensure that programs, funding and financing capabilities, and other authorities related to climate-smart agriculture and forestry practices are implemented equitably?

Please provide information including citations and/or contact details for the correspondent when submitting comments to *Regulations.gov*.

Seth Meyer,

Chief Economist, Office of the Chief Economist.

[FR Doc. 2021-05287 Filed 3-15-21; 8:45 am]

BILLING CODE 3410-GL-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2021-0008]

Notice of Request for Approval of an Information Collection; National Animal Health Monitoring System; On-Farm Monitoring of Antimicrobial Use and Resistance in U.S. Broiler Production Study

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: New information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request approval of a new information collection associated with the National Animal Health Monitoring System's On-Farm Monitoring of Antimicrobial Use and Resistance in U.S. Broiler Production Study.

DATES: We will consider all comments that we receive on or before May 17, 2021.

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

- *Federal eRulemaking Portal:* Go to www.regulations.gov. Enter APHIS-2021-0008 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2021-0008, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at *regulations.gov* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the NAHMS On-Farm Monitoring of Antimicrobial Use and Resistance in U.S. Broiler Production Study, contact Mr. Bill Kelley, Assistant Director, Program Coordination and Implementation, Center for Epidemiology and Animal Health, VS, 2150 Centre Avenue, Building B, Fort Collins, CO 80524; (970) 494-7270. For information on the information collection process, contact Mr. Joseph Moxey, APHIS Information Collection Coordinator, at (301) 851-2483; joseph.moxey@usda.gov.

SUPPLEMENTARY INFORMATION:

Title: National Animal Health Monitoring System; On-Farm Monitoring of Antimicrobial Use and Resistance in U.S. Broiler Production Study.

OMB Control Number: 0579-XXXX.
Type of Request: Approval of a new information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Secretary of the U.S. Department of Agriculture (USDA) is authorized to protect the health of the livestock, poultry, and aquaculture populations in the United States by preventing the introduction and interstate spread of serious diseases and pests of livestock, poultry, and aquaculture, and for eradicating such diseases and pests from the United States, when feasible. Within the USDA, this authority and mission is delegated to the Animal and Plant Health Inspection Service (APHIS).

In connection with this mission, APHIS operates the National Animal Health Monitoring System (NAHMS), which collects on a national basis, statistically valid and scientifically sound data on the prevalence and economic importance of livestock, poultry, and aquaculture disease risk factors. APHIS is the only agency responsible for collecting data on livestock, poultry, and aquaculture health. NAHMS' studies have evolved into a collaborative industry and Government initiative to help determine the most effective means of preventing and controlling diseases of livestock, poultry, and aquaculture. Participation

in any NAHMS study is voluntary, and all data are confidential.

APHIS plans to conduct the On-Farm Monitoring of Antimicrobial Use and Resistance in U.S. Broiler Production Study as part of an ongoing series of NAHMS studies on the U.S. livestock, poultry, and aquaculture populations. This study will support the following objectives: (1) Measure and track trends in antimicrobial use (AMU) and antimicrobial resistance (AMR) in broiler complexes within participating companies over time; (2) Evaluate the relationship between AMU patterns and AMR measured in select bacterial species collected; and (3) Quantify antimicrobial resistance genes in the litter of sampled broiler farms and examine the relationship between these quantities and antimicrobial use patterns.

This study is an information collection conducted by APHIS through a cooperative agreement with the University of Minnesota. The university completed previous work for APHIS under a different cooperative agreement in which APHIS received reports and completed analyses but not farm-level data. APHIS now seeks access to farm-level data that is presented in a manner in which the farms are not identified.

This study will monitor U.S. broiler operations for AMU, AMR, animal health and production practices, and the relationship between AMU, AMR, animal health, production practices, and changes over time. We will collect annual informed consent forms from producers, quarterly survey data, and litter samples from the same poultry complexes, and examine AMR in bacteria such as *Salmonella* and *Campylobacter*. This study meets objectives for both the U.S. National Action Plan for Combating Antibiotic Resistance (2015) and the USDA AMR National Action Plan (2013). Additionally, this information is an essential component in accomplishing one of APHIS' strategic goals, which is to safeguard American agriculture.

APHIS and the University of Minnesota will analyze and organize the information into one or more descriptive reports and scientific manuscripts, and for important or special topics, APHIS will develop and disseminate targeted information sheets to producers, stakeholders, academicians, veterinarians, and any other interested parties. This information benefits the poultry industry by supplying scientific estimates of AMU and stewardship by poultry producers and evaluation of the influence of these and other management practices on AMR.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate 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;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.*, permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 1.5 hours per response.

Respondents: Broiler producers.

Estimated annual number of respondents: 30.

Estimated annual number of responses per respondent: 20.

Estimated annual number of responses: 588.

Estimated total annual burden on respondents: 866 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 10th day of March 2021.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021-05360 Filed 3-15-21; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Form BC-170, U.S. Census Employment Application and Form BC-171, Additional Applicant Information

AGENCY: Census Bureau, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the reinstatement, without change, of Form BC-170, U.S. Census Employment Application and Form BC-171, Additional Applicant Information, prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before May 17, 2021.

ADDRESSES: Interested persons are invited to submit written comments by email to Michael DeFrank, Chief, Management Services Branch at Michael.A.DeFrank@census.gov.

Please reference Form BC-170, U.S. Census Employment Application and Form BC-171, Additional Applicant Information in the subject line of your comments. You may also submit comments, identified by Docket Number USBC-2021-0006, to the Federal e-Rulemaking Portal: <http://www.regulations.gov>. All comments received are part of the public record. No comments will be posted to <http://www.regulations.gov> for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or specific questions related to collection activities should be directed to Michael A. DeFrank, Chief, Management Services Branch. Mr. DeFrank can be reached by telephone on 301-763-2864 or by email at Michael.A.DeFrank@census.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

The U.S. Census Bureau is requesting to continue to use Form BC-170, U.S. Census Employment Application and Form BC-171, Additional Applicant Information. There are no changes requested to these forms at this time.

The Census Bureau uses these forms to collect applicant information. Selecting officials use Form BC-170 as part of the recruitment, assessment, and selection process for potential field employees. The form was used for the Decennial Census and will continue to be used for Current/Permanent Surveys, upcoming Special Censuses as well as Decennial Census tests. Applicants applying for Current/Permanent Survey positions will submit a paper version of these forms at no cost to the applicant. An online version of these forms will be used for Special Censuses and Decennial Census tests.

In 2018, Form BC-171, Additional Applicant Information replaced Equal Employment Opportunity Commission (EEOC) common use from 3046-0046, Demographic Information on Applicants for Federal Employment to collect voluntary applicant data and is not used in the selection process.

The Census Bureau intends for applicants to access, complete, and submit both the BC-170 and BC-171 to human resources staff via an online applicant system for census jobs. The Census Bureau will continue to use a paper version of the BC-170 and BC-171 forms for applicants to complete and submit to the Regional Office for the Field Representative, Field Supervisor, and temporary clerical positions until an online version is available for this group of applicants. Lastly, the online version, paper forms and the online PDF format forms will be available in Spanish for Puerto Rico.

II. Method of Collection

All interested applicants submit the forms as described above.

III. Data

OMB Control Number: 0607-0139.
Form Number(s): BC-170 and BC-171.

Type of Review: Regular submission, Request for an Extension, without

Change, of a Currently Approved Collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 12,000 persons (Note that in non-Decennial periods of data collection after 2020, the estimated number of respondents annually is approximately 12,000 persons).

Estimated Time per Response: 20 minutes (Note that this is based on calculations that determined 15 minutes for completing the BC-170 and 5 minutes for completing the BC-171. The combined total is 20 minutes for applicants completing both forms).

Estimated Total Annual Burden Hours: 4,000 annual hours on average.

Estimated Total Annual Cost to Public: \$0.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Chapter 1, Subchapter II, Section 23 a and c.; Title 5 U.S.C., Part II, Chapter 13; Title 5 U.S.C. part III, Chapter 33, Subchapter 1, Section 3301 and 3320.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. 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 may 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.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021-05419 Filed 3-15-21; 8:45 am]

BILLING CODE 3510-07-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-19-2021]

Foreign-Trade Zone (FTZ) 59—Lincoln, Nebraska; Notification of Proposed Production Activity; Zoetis Services, LLC; (Pharmaceutical Products); Lincoln, Nebraska

Zoetis Services, LLC (Zoetis) submitted a notification of proposed production activity to the FTZ Board for its facility in Lincoln, Nebraska. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on March 2, 2021.

The Zoetis facility is located within Subzone 59E. The facility is used for the production of pharmaceuticals for the animal pharmaceutical industry. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status material and specific finished product described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Zoetis from customs duty payments on the foreign-status components used in export production. On its domestic sales, for the foreign-status material noted below, Zoetis would be able to choose the duty rates during customs entry procedures that applies to Simparica® (Sarolaner) chewable tablets (duty-free). Zoetis would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The material sourced from abroad is sarolaner spray dried dispersion (duty rate 6.5%).

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 April 26, 2021.

A copy of the notification will be available for public inspection in the "Reading Room" section of the Board's website, which is accessible via www.trade.gov/ftz.

For further information, contact Christopher Wedderburn at Chris.Wedderburn@trade.gov.

Dated: March 10, 2021.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2021-05398 Filed 3-15-21; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-570-138]

Pentafluoroethane (R-125) from the People's Republic of China: Postponement of Preliminary Determination in the Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable March 16, 2021.

FOR FURTHER INFORMATION CONTACT: Joshua Tucker at (202) 482-2044 or Adam Simons at (202) 482-6172, AD/CVD Operations Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On February 1, 2021, the Department of Commerce (Commerce) initiated a countervailing duty (CVD) investigation of imports of pentafluoroethane (R-125) from the People's Republic of China (China).¹ Currently, the preliminary determination is due no later than April 7, 2021.

Postponement of Preliminary Determination

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a CVD investigation within 65 days after the date on which Commerce initiated the investigation. However, section 703(c)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation if: (A) The petitioner makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily

¹ See *Pentafluoroethane (R-125) From the People's Republic of China: Initiation of Countervailing Duty Investigation*, 86 FR 8589 (February 8, 2021).

complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.

On March 2, 2021, the petitioner² submitted a timely request that Commerce postpone the preliminary CVD determination.³ The petitioner stated that it requested postponement so that Commerce may sufficiently review all questionnaire responses and new factual information to permit a thorough investigation and the calculation of accurate subsidy rates.⁴

In accordance with 19 CFR 351.205(e), the petitioner has stated the reasons for requesting a postponement of the preliminary determination, and Commerce finds no compelling reason to deny the request. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determination to no later than 130 days after the date on which this investigation was initiated, *i.e.*, June 11, 2021. Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determination of this investigation will continue to be 75 days after the date of the preliminary determination.

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: March 10, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021-05400 Filed 3-15-21; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-062]

Cast Iron Soil Pipe Fittings From the People's Republic of China: Final Results of Antidumping Duty Administrative Review, 2018-2019; Correction

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

ACTION: Notice; correction.

SUMMARY: The Department of Commerce (Commerce) published a notice in the **Federal Register** of February 9, 2021, concerning the final results of the administrative review of cast iron soil pipe fittings (soil pipe fittings) from the People's Republic of China (China) for the period of review of February 20, 2018, through July 31, 2019. The notice contained an incorrect spelling of a company name.

FOR FURTHER INFORMATION CONTACT: Samantha Kinney, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-2285.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of February 9, 2021, in FR Doc. 2021-02597, on page 8763, in "The China-Wide Entity" section, correct the last company name to read "Yangcheng Country Huawang Universal."

This correction to the *Final Results* is published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended.

Dated: March 10, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021-05399 Filed 3-15-21; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 210308-0048; RTID 0648-XW032]

Endangered and Threatened Wildlife; 90-Day Finding on a Petition To List Southern Oregon and Northern California Coastal Spring-Run Chinook Salmon as Threatened or Endangered Under the Endangered Species Act

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

ACTION: 90-Day petition finding, request for information, and initiation of status review.

SUMMARY: We, NMFS, announce a 90-day finding on a petition to list Southern Oregon and Northern California Coastal (SONCC) spring-run Chinook salmon (*Oncorhynchus tshawytscha*) as a threatened or endangered Evolutionarily Significant Unit (ESU) under the Endangered Species Act (ESA) and to designate critical habitat concurrently with the listing. We find that the petition presents substantial scientific and commercial information indicating the petitioned action may be warranted. We will conduct a status review of SONCC spring-run Chinook salmon to determine whether the petitioned action is warranted. To ensure that the status review is comprehensive, we are soliciting scientific and commercial information pertaining to this species from any interested party.

DATES: Scientific and commercial information pertinent to the petitioned action must be received by May 17, 2021.

ADDRESSES: You may submit data and information relevant to our review of the status of Southern Oregon and Northern California Coastal spring-run Chinook salmon, identified by NOAA-NMFS-2020-0079, by either of the following methods:

- **Electronic Submission:** Submit all electronic public comments via the Federal eRulemaking Portal. Go to <https://www.regulations.gov> and enter NOAA-NMFS-2020-0079 in the Search box. Click on the "Comment" icon, complete the required fields, and enter or attach your comments.

- **Mail or hand-delivery:** Protected Resources Division, West Coast Region, NMFS, 1201 NE Lloyd Blvd., Suite #1100, Portland, OR 97232. Attn: Gary Rule.

² The petitioner is Honeywell International, Inc.

³ See Petitioner's Letter, "Countervailing Duty Investigation of Pentafluoroethane (R-125) from the People's Republic of China: Petitioner's Request to Postpone the Preliminary Determination," dated March 2, 2021.

⁴ *Id.*

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on <https://www.regulations.gov> without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

Electronic copies of the petition and other materials are available from the NMFS website at www.fisheries.noaa.gov/rules-and-regulations.

FOR FURTHER INFORMATION CONTACT: Gary Rule, NMFS West Coast Region, at gary.rule@noaa.gov, (503) 230–5424; or Heather Austin, NMFS Office of Protected Resources, at heather.austin@noaa.gov, (301) 427–8422.

SUPPLEMENTARY INFORMATION:

Background

On May 4, 2020, the Secretary of Commerce received a petition from Richard K. Nawa (hereafter, the Petitioner) to identify SONCC spring-run Chinook salmon as a separate ESU and list the ESU as threatened or endangered under the ESA. Previously, in 1999, we identified the SONCC Chinook salmon ESU as including both spring-run and fall-run Chinook salmon and determined that the ESU did not warrant listing as threatened or endangered under the ESA (64 FR 50394; September 16, 1999). The Petitioner is requesting that SONCC spring-run Chinook salmon be considered as a separate ESU and listed as threatened or endangered. The Petitioner asserts that new research into the genomic basis for premature migration in salmonids demonstrates that significant genetic differences underlie the spring- and fall-run life history types, and that the unique evolutionary lineage of spring-run Chinook salmon warrants their listing as a separate ESU. The Petitioner also requests the designation of critical habitat for SONCC spring-run Chinook salmon concurrent with ESA listing. The petition includes an overview of new research into the genomic basis for premature migration in salmonids, as well as general biological information about SONCC spring-run Chinook salmon including their distribution and range, life history characteristics, habitat

requirements, as well as basin-level population status and trends and factors contributing to the populations’ status. Copies of the petition are available as described above (see **ADDRESSES**, above).

ESA Statutory, Regulatory, and Policy Provisions, and Evaluation Framework

Section 4(b)(3)(A) of the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*), requires, to the maximum extent practicable, that within 90 days of receipt of a petition to list a species as threatened or endangered, the Secretary of Commerce make a finding on whether that petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted, and to promptly publish such finding in the **Federal Register** (16 U.S.C. 1533(b)(3)(A)). When it is found that substantial scientific or commercial information in a petition indicates the petitioned action may be warranted (a “positive 90-day finding”), we are required to promptly commence a review of the status of the species concerned during which we will conduct a comprehensive review of the best available scientific and commercial information. In such cases, we conclude the review with a finding as to whether, in fact, the petitioned action is warranted within 12 months of receipt of the petition. Because the finding at the 12-month stage is based on a more thorough review of the available information, as compared to the narrow scope of review at the 90-day stage, a positive 90-day finding does not prejudice the outcome of the status review.

Under the ESA, a listing determination may address a species, which is defined to also include subspecies and, for any vertebrate species, any distinct population segment (DPS) that interbreeds when mature (16 U.S.C. 1532(16)). In 1991, we issued the Policy on Applying the Definition of Species Under the Endangered Species Act to Pacific Salmon (ESU Policy; 56 FR 58612; November 20, 1991), which explains that Pacific salmon populations will be considered a DPS, and hence a “species” under the ESA, if it represents an “evolutionarily significant unit” of the biological species. The two criteria for delineating an ESU are: (1) It is substantially reproductively isolated from other conspecific populations, and (2) it represents an important component in the evolutionary legacy of the species. The ESU Policy was used to define the SONCC Chinook salmon ESU in 1999 (64 FR 50394; September 16, 1999), and we use it exclusively for defining distinct population segments of

Pacific salmon. A joint NMFS–U.S. Fish and Wildlife Service (USFWS) (jointly, “the Services”) policy clarifies the Services’ interpretation of the phrase “distinct population segment” for the purposes of listing, delisting, and reclassifying a species under the ESA (DPS Policy; 61 FR 4722; February 7, 1996). In announcing this policy, the Services indicated that the ESU Policy for Pacific salmon was consistent with the DPS Policy and that NMFS would continue to use the ESU Policy for Pacific salmon.

A species, subspecies, or DPS is “endangered” if it is in danger of extinction throughout all or a significant portion of its range, and “threatened” if it is likely to become endangered within the foreseeable future throughout all or a significant portion of its range (ESA sections 3(6) and 3(20), respectively, 16 U.S.C. 1532(6) and (20)). Pursuant to the ESA and our implementing regulations, we determine whether species are threatened or endangered based on any one or a combination of the following five section 4(a)(1) factors: The present or threatened destruction, modification, or curtailment of habitat or range; overutilization for commercial, recreational, scientific, or educational purposes; disease or predation; inadequacy of existing regulatory mechanisms to address identified threats; or any other natural or manmade factors affecting the species’ existence (16 U.S.C. 1533(a)(1), 50 CFR 424.11(c)).

ESA-implementing regulations issued jointly by NMFS and USFWS (50 CFR 424.14(h)(1)(i)) define “substantial scientific or commercial information” in the context of reviewing a petition to list, delist, or reclassify a species as “credible scientific or commercial information in support of the petition’s claims such that a reasonable person conducting an impartial scientific review would conclude that the action proposed in the petition may be warranted.” Conclusions drawn in the petition without the support of credible scientific or commercial information will not be considered “substantial information.” In reaching the initial (90-day) finding on the petition, we will consider the information described in sections 50 CFR 424.14(c), (d), and (g) (if applicable).

Our determination as to whether the petition provides substantial scientific or commercial information indicating that the petitioned action may be warranted will depend in part on the degree to which the petition includes the following types of information: (1) Information on current population status and trends and estimates of

current population sizes and distributions, both in captivity and the wild, if available; (2) identification of the factors under section 4(a)(1) of the ESA that may affect the species and where these factors are acting upon the species; (3) whether and to what extent any or all of the factors alone or in combination identified in section 4(a)(1) of the ESA may cause the species to be an endangered species or threatened species (*i.e.*, the species is currently in danger of extinction or is likely to become so within the foreseeable future), and, if so, how high in magnitude and how imminent the threats to the species and its habitat are; (4) information on adequacy of regulatory protections and effectiveness of conservation activities by states as well as other parties, that have been initiated or that are ongoing, that may protect the species or its habitat; and (5) a complete, balanced representation of the relevant facts, including information that may contradict claims in the petition. *See* 50 CFR 424.14(d).

If the petitioner provides supplemental information before the initial finding is made and states that it is part of the petition, the new information, along with the previously submitted information, is treated as a new petition that supersedes the original petition, and the statutory timeframes will begin when such supplemental information is received. *See* 50 CFR 424.14(g).

We may also consider information readily available at the time the determination is made. We are not required to consider any supporting materials cited by the petitioner if the petitioner does not provide electronic or hard copies, to the extent permitted by U.S. copyright law, or appropriate excerpts or quotations from those materials (*e.g.*, publications, maps, reports, letters from authorities). *See* 50 CFR 424.14(c)(6).

The “substantial scientific or commercial information” standard must be applied in light of any prior reviews or findings we have made on the listing status of the species that is the subject of the petition. Where we have already conducted a finding on, or review of, the listing status of that species (whether in response to a petition or on our own initiative), we will evaluate any petition received thereafter seeking to list, delist, or reclassify that species to determine whether a reasonable person conducting an impartial scientific review would conclude that the action proposed in the petition may be warranted despite the previous review or finding. Where the prior review resulted in a final agency action—such

as a final listing determination, 90-day not-substantial finding, or 12-month not-warranted finding—a petitioned action will generally not be considered to present substantial scientific and commercial information indicating that the action may be warranted unless the petition provides new information or analyses not previously considered.

At the 90-day finding stage, we do not conduct additional research, and we do not solicit information from parties outside the agency to help us in evaluating the petition. We will accept the petitioner’s sources and characterizations of the information presented if they appear to be based on accepted scientific principles, unless we have specific information in our files that indicates the petition’s information is incorrect, unreliable, obsolete, or otherwise irrelevant to the requested action. Information that is susceptible to more than one interpretation or that is contradicted by other available information will not be dismissed at the 90-day finding stage, so long as it is reliable and a reasonable person conducting an impartial scientific review would conclude it supports the petitioner’s assertions. In other words, conclusive information indicating that the species may meet the ESA’s requirements for listing is not required to make a positive 90-day finding. We will not conclude that a lack of specific information alone necessitates a negative 90-day finding if a reasonable person conducting an impartial scientific review would conclude that the unknown information itself suggests the species may be at risk of extinction presently or within the foreseeable future.

To make a 90-day finding on a petition to list a species, we evaluate whether the petition presents substantial scientific or commercial information indicating the subject species may be either threatened or endangered, as defined by the ESA. First, we evaluate whether the information presented in the petition, in light of the information readily available in our files, indicates that the petitioned entity constitutes a “species” eligible for listing under the ESA. Next, we evaluate whether the information indicates that the species faces an extinction risk such that listing, delisting, or reclassification may be warranted; this may be indicated in information expressly discussing the species’ status and trends, or in information describing impacts and threats to the species. We evaluate any information on specific demographic factors pertinent to evaluating extinction risk for the species (*e.g.*, population abundance and trends,

productivity, spatial structure, age structure, sex ratio, diversity, current and historical range, habitat integrity or fragmentation), and the potential contribution of identified demographic risks to extinction risk for the species. We then evaluate the potential links between these demographic risks and the causative impacts and threats identified in section 4(a)(1).

Information presented on impacts or threats should be specific to the species and should reasonably suggest that one or more of these factors may be operative threats that act or have acted on the species to the point that it may warrant protection under the ESA. Broad statements about generalized threats to the species, or identification of factors that could negatively impact a species, alone, do not constitute substantial information indicating that listing may be warranted. We look for information indicating that not only is the particular species exposed to a factor, but that the species may be responding in a negative fashion; then we assess the potential significance of that negative response.

Many petitions identify risk classifications made by nongovernmental organizations, such as the International Union on the Conservation of Nature (IUCN), the American Fisheries Society, or NatureServe, as evidence of extinction risk for a species. Risk classifications by such organizations or made under other Federal or state statutes may be informative, but such classification alone may not provide the rationale for a positive 90-day finding under the ESA. For example, as explained by NatureServe, their assessments of a species’ conservation status do “not constitute a recommendation by NatureServe for listing under the U.S. Endangered Species Act” because NatureServe assessments “have different criteria, evidence requirements, purposes and taxonomic coverage than government lists of endangered and threatened species, and therefore these two types of lists should not be expected to coincide” (<https://explorer.natureserve.org/AboutTheData/DataTypes/ConservationStatusCategories>). Additionally, species classifications under IUCN and the ESA are not equivalent; data standards, criteria used to evaluate species, and treatment of uncertainty are also not necessarily the same. Thus, when a petition cites such classifications, we will evaluate the source of information that the classification is based upon in light of the standards on extinction risk and impacts or threats discussed above.

Previous Federal Actions

On September 16, 1999, following completion of a status review of west coast Chinook salmon (*O. tshawytscha*) populations in Washington, Oregon, Idaho, and California, and an updated status review for four Chinook salmon ESUs, NMFS published a final rule to list two Chinook salmon ESUs as threatened under the Endangered Species Act (ESA) (64 FR 50394). In that final rule, NMFS identified the SONCC Chinook salmon ESU as composed of coastal populations of spring- and fall-run Chinook salmon from Euchre Creek, Oregon, through the Lower Klamath River, California (inclusive) (64 FR 50394). After assessing information concerning Chinook salmon abundance, distribution, population trends, and risks, and after considering efforts being made to protect Chinook salmon, NMFS determined in that final rule that the Southern Oregon and Northern California Coastal ESU of Chinook salmon did not warrant listing under the ESA.

Evaluation of Petition and Information Readily Available in NMFS' Files

The petition contains information and assertions in support of designating and listing the spring-run component of the SONCC Chinook salmon ESU as threatened or endangered under the ESA. As discussed above, based on biological, genetic, and ecological information compiled and reviewed as part of the previous status review of Chinook salmon (*O. tshawytscha*) populations in Washington, Oregon, Idaho, and California (Myers *et al.*, 1998) and the status review update for deferred ESUs of West Coast Chinook Salmon (NMFS, 1999), we included all spring-run and fall-run Chinook salmon populations from Euchre Creek, Oregon, through the Lower Klamath River, California, in the SONCC Chinook salmon ESU (64 FR 50394; September 16, 1999). While run-timing was recognized as having a heritable basis, review of genetic data at that time did not identify clear sub-groups associated with migration timing within the SONCC Chinook salmon ESU. Spring- and fall-run Chinook salmon were found to be separate ESUs in other areas (e.g., in the upper Columbia River, Snake River, and Sacramento River drainages). However, in coastal areas life-history and genetic differences between runs were found to be relatively modest, with spring- and fall-run fish exhibiting similar ocean distribution patterns and genetic characteristics (Myers *et al.*, 1998; NMFS, 1999).

The Petitioner asserts that spring-run Chinook salmon in the SONCC Chinook salmon ESU have been sufficiently isolated from fall-run Chinook salmon for evolutionarily important differences to have arisen and been maintained. The Petitioner presents new genetic evidence to suggest the SONCC spring-run Chinook salmon populations may qualify as a separate ESU from the fall-run populations. The Petitioner asserts that findings from recently published articles on the evolutionary basis of premature migration in Pacific salmon (Prince *et al.*, 2017; Davis *et al.*, 2017; Narum *et al.*, 2018; and Thompson *et al.*, 2019) indicate that spring-run Chinook salmon in the SONCC ESU should be considered a separate ESU. Prince *et al.* (2017) reported on a survey of genetic variation between mature- and premature-migrating populations of steelhead and Chinook salmon from California, Oregon, and Washington. Narum *et al.* (2018) replicated analysis of loci identified by Prince *et al.* (2017) as associated with premature and mature migratory phenotypes. Davis *et al.* (2017) genotyped Chinook salmon within the Siletz River using multiple genetic markers, including neutral markers and adaptive loci associated with migratory timing. Thompson *et al.* (2019) provide additional information about genetic differentiation between mature- and premature-migrating Chinook salmon in the Rogue River, Oregon, and in the Klamath River, California, particularly in response to anthropogenic changes. The Petitioner suggests that the results of these studies indicate that premature migration (e.g., spring-run Chinook salmon) arose from a single evolutionary event within the species and, if lost, is not likely to re-evolve in time frames relevant to conservation planning.

The Petitioner also asserts that the Chinook salmon spring-run life history represents an important component of the evolutionary legacy of the species. In support of this assertion, the Petitioner describes specific ecological and evolutionary benefits of the life history variation provided by spring-run stocks within the SONCC Chinook salmon ESU. The Petitioner describes how spring-run Chinook salmon tend to spawn higher up in the watershed than fall-run and how this adds to the spatial distribution of the species. The Petitioner notes that the presence of spring-run Chinook salmon in the headwaters could protect SONCC Chinook salmon from large mortality events due to disease outbreaks, interspecific competition for food and habitat, warm temperatures and low

flow regimes due to climate change, and temporal unfavorable conditions in the marine environment. The Petitioner asserts that diversity in run timing contributes to the resiliency and stability of salmon populations.

At the 90-day finding stage, we also consider information readily available in our files. We are currently processing another petition that cites the same scientific research in support of a request to identify and list a new coastal spring-run Chinook salmon ESU. On September 24, 2019, the Secretary of Commerce received a petition from the Native Fish Society, Center for Biological Diversity, and Umpqua Watersheds to identify Oregon Coast spring-run Chinook salmon as a separate ESU and list the ESU as threatened or endangered under the ESA. In the Oregon Coast spring-run Chinook salmon petition, the petitioners similarly asserted that findings from recently published articles on the evolutionary basis of premature migration in Pacific salmon (Prince *et al.*, 2017; Davis *et al.*, 2017; Narum *et al.*, 2018; and Thompson *et al.*, 2019) indicate that spring-run Chinook salmon in the Oregon Coast ESU should be considered a separate ESU. On April 13, 2020, we published notice of a positive 90-day finding on the petition to list Oregon Coast spring-run Chinook salmon (85 FR 20476) and announced our intent to conduct a status review.

We have reviewed the new genetic information and the information presented by the Petitioner about the evolutionary legacy of spring-run Chinook salmon in the SONCC ESU. Based on information provided by the Petitioner, as well as information readily available in our files, we find that a reasonable person would conclude that SONCC spring-run Chinook salmon may qualify as an ESU pursuant to our ESU Policy.

SONCC Spring-Run Chinook Salmon Status and Trends

The Petitioner asserts that spring-run Chinook salmon populations in the SONCC ESU have suffered significant declines in numbers from historical abundance. The Petitioner cited findings by Nicholas and Hankin (1989) that all spring-run Chinook salmon populations on the Oregon coast are smaller than fall-run populations and are depressed from historical population sizes. The Petitioner presents data from the Oregon Department of Fish and Wildlife (ODFW) that indicate a 25-year decline in abundance of spring-run Chinook salmon on the Rogue River (1981–2006) (ODFW 2019). During a 10-year period (1970–1979) that spans the

construction of the William Jess Dam (1977) on the Rogue River, an average of 28,052 adult spring-run Chinook salmon were counted annually. ODFW (2019) estimated that there were 10,240 adult spring-run Chinook salmon in 2017 and that the annual average for the years 2008–2017 was 9,663.

The Petitioner notes that following ODFW's adoption of the Rogue Spring Chinook Conservation Plan in 2007, the average annual abundance of natural-origin adult spring-run Chinook salmon increased from 7,596 to 9,663 in 2017. The Petitioner asserts that this increase of spring-run Chinook salmon in the Rogue River was likely a result of the removal of the Gold Hill, Savage Rapids, and Gold Ray dams, which allowed heterozygous and homozygous fall-run Chinook salmon to ascend upriver rapidly and spawn with homozygous spring-run Chinook. In the Final Rogue Spring Chinook Salmon Conservation Plan Comprehensive Assessment and Update, ODFW found that while the status of spring-run Chinook salmon improved over the past decade the ten year average is below the desired threshold of 15,000 naturally produced adult spring-run Chinook salmon returning to the Rogue River annually (ODFW, 2019). The Petitioner also calls attention to the Cole M. Rivers Hatchery and Genetic Management Plan that reports the smolt to adult return rate of Cole M. Rivers Hatchery spring-run Chinook salmon in the Rogue River has been below 1 percent since 2002 (ODFW, 2016). The Petitioner asserts that the smolt to adult return rate for natural fish is also likely low.

The Petitioner further asserts that the abundance of spring-run Chinook salmon in the Rogue River may actually be lower than reported. Hess *et al.* (2016), Prince *et al.* (2017) and Thompson *et al.* (2019) have studied the relationship between genetic material from a portion of the genome that includes the Greb1L gene (otherwise referred to as the Greb1L region of the genome) and run-timing in Chinook salmon and steelhead. The authors characterized the Greb1L region as two alleles (different forms) and three genotypes (different combinations of the alleles): Individuals with two early run-timing alleles (early-run homozygotes), individuals with two late run-timing alleles (late-run homozygotes), and individuals with one allele for the early and one for the late run-timing (heterozygotes). Thompson *et al.* (2019) asserted that there is a considerable amount of interbreeding between spring-run and fall-run Chinook salmon in the Rogue River as a result of dam construction. Thompson *et al.* (2019)

analyzed samples from 2004 and reported that many of the spring-run Chinook salmon counted at Gold Ray dam were in fact heterozygotes.

The Petitioner also calls attention to a declining trend in abundance of adult spring-run Chinook salmon in the Smith River. The Petitioner cites data from snorkel surveys of spring-run Chinook salmon in the South Fork, Middle Fork, and North Fork of the Smith River from 1982 to 2018 (Hanson, 2018). Hanson (2018) found that the number of adult spring-run Chinook salmon counted per mile (density) has been declining since survey counts peaked in 1996 at a density of 2.5 salmon per mile. Hanson (2018) reported that adult spring-run Chinook salmon densities have remained at less than 0.3 salmon per mile since 2007 (Hanson, 2018). The Petitioner asserts that this decline in spring-run Chinook salmon indicates that the population within the Smith River is threatened with extinction.

Based on information provided by the Petitioner, as well as information readily available in our files, we find that a reasonable person would conclude current demographic risks indicate that SONCC spring-run Chinook salmon populations may be at risk of extinction and thus warrant further investigation.

Analysis of ESA Section 4(a)(1) Factors

The Petitioner asserts that all five ESA section 4(a)(1) factors contribute to the need to list the SONCC spring-run Chinook salmon as a threatened or endangered ESU. Each of these factors is discussed in further detail below.

The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

The Petitioner asserts that SONCC spring-run Chinook salmon face numerous threats to suitable habitat, including impacts from dams, logging practices, road building, and mining operations. The Army Corps of Engineers completed construction of William Jess Dam/Lost Creek Reservoir on the upper Rogue River in 1977. The Petitioner cites the Rogue Spring Chinook Salmon Conservation Plan Comprehensive Assessment and Update (ODFW, 2019) in support of their assertion that artificially enhanced summer stream flows from Lost Creek Reservoir are adversely affecting spring-run Chinook salmon. ODFW (2019) found that enhanced summer stream flows allow fall-run Chinook salmon to spawn upstream in habitat that historically was utilized primarily by spring-run Chinook salmon.

The Petitioner asserts that artificially augmented high flows in August and September in the Rogue River may reduce egg to fry survival of spring-run Chinook salmon. If spring-run Chinook salmon spawn during high river flows in September, redds may be dewatered and embryos desiccated when releases from the Lost Creek Reservoir decrease during the reservoir fill season, which begins in January (ODFW, 2019). ODFW (2019) states that egg to fry survival has likely decreased as a result of redds being dewatered.

The Petitioner also asserts that other anthropogenic disturbances have degraded spring-run Chinook salmon spawning habitat in the Rogue and Smith Rivers. Specifically, the Petitioner asserts that increased fine sediments due to logging, road building, and mining have adversely affected spawning habitat which is supported by similar conclusions in NMFS' 1997 final rule listing the SONCC coho salmon ESU under the ESA (62 FR 24588; May 6, 1997), describing habitat that is co-extensive with the range of SONCC spring-run Chinook salmon.

NMFS' most recent SONCC coho salmon status review (NMFS, 2016) evaluated the status of habitat threats over an area that includes the range of SONCC spring-run Chinook salmon and concluded that degraded habitat conditions in this area continue to be of concern, particularly with regard to insufficient instream flow, unsuitable water temperatures, and insufficient rearing habitat due to a lack of floodplain and channel structure. While restoration and regulatory actions have been made to improve freshwater and estuary habitat conditions in the SONCC coho salmon ESU, habitat concerns remain throughout the range of the ESU particularly in regards to water quality, water quantity, and rearing habitat.

Based on information provided by the Petitioner, as well as information readily available in our files, we find that a reasonable person would conclude that habitat destruction and curtailment of their range may pose a threat to the continued existence of SONCC spring-run Chinook salmon.

Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

The Petitioner asserts that harvest of SONCC spring-run Chinook salmon for commercial and recreational fisheries in the ocean and freshwater may be a threat. The Petitioner notes that the fisheries off the coast of Oregon and California are not managed to minimize impacts on SONCC spring-run Chinook. The Petitioner notes that the Rogue

Spring Chinook Salmon Conservation Plan assumes the average harvest rate of naturally produced spring-run Chinook salmon is 15 percent (ODFW, 2007). The Petitioner does not specifically assert that the harvest rates of SONCC spring-run Chinook are too high.

The Petitioner additionally summarizes the freshwater angling regulations put in place in 2008 to protect spring-run Chinook salmon from direct harvest in the Rogue River. The Petitioner does not provide an explanation for why freshwater angling regulations may be inadequate. ODFW (2019) states that from January through May, anglers may only keep adipose fin-clipped hatchery spring-run Chinook Salmon on the Rogue River. Wild harvest opens at various sections of the Rogue River after the early-run fish have passed. ODFW also states that the fishery does not open to wild harvest upstream of Dodge Bridge, where early-run fish occupy deep pools during the spring and summer. ODFW (2019) found that following implementation of the freshwater angling regulations, there were immediate reductions in freshwater harvest and increased spawner escapement (2008–2011). As a result, adult returns of naturally produced spring-run Chinook salmon began to improve in 2012. The Petitioner notes that while the estimated harvest rates of natural spring-run Chinook salmon are low, spring-run Chinook salmon are not meeting the escapement goal and homozygous spring-run Chinook salmon are likely declining.

Based on information provided by the Petitioner, as well as information readily available in our files, we find that there is inadequate information for a reasonable person to determine if overutilization poses a threat to the continued existence of SONCC spring-run Chinook salmon.

Disease or Predation

The Petitioner asserts that disease poses a risk to naturally produced spring-run Chinook in the Rogue River. ODFW (2019) found that under certain conditions disease, primarily caused by the bacterium *Flexibacter columnaris*, can spread quickly in Rogue River Chinook salmon. Downstream of Gold Ray Dam, extensive mortalities of adults were documented in 1977, 1987, 1992, and 1994 due to disease (ODFW, 2007). Estimates of mortality rates during those years ranged between 28 percent and 70 percent of the spring-run Chinook salmon that entered the Rogue River (ODFW, 2007). The Petitioner cites the Rogue Spring Chinook Salmon Conservation Plan that states that

disease is known to be a primary factor that affects the abundance of spring-run Chinook salmon (ODFW, 2007). The Rogue Spring Chinook Salmon Conservation Plan also notes that spring-run Chinook salmon in the Rogue River are exposed annually to high water temperatures that increase the mortality rates of infected juvenile Chinook salmon (ODFW, 2007). The Petitioner notes that ODFW, the Oregon Water Resources Department, and the U.S. Army Corps of Engineers now release water from the Lost Creek Reservoir to minimize pre-spawning mortality of adult Chinook salmon due to disease (ODFW, 2019). The Rogue Spring Chinook Salmon Conservation Plan Comprehensive Assessment and Update (ODFW, 2019) states that during the 2013–2015 drought, careful reservoir management resulted in no significant loss of fish due to disease on the Rogue.

The Petitioner also asserts that hatchery produced coho salmon and steelhead prey upon natural origin spring-run Chinook salmon fry. Surveys conducted during 1979–81 indicated that both of these species prey upon the fry of spring-run Chinook salmon (ODFW, 2007). The Petitioner cites estimations made by Evenson *et al.* (1981) that hatchery origin steelhead consume between 134,000 to 218,000 spring-run Chinook salmon fry and that hatchery origin coho salmon are estimated to consume between 29,000 to 57,000 spring-run Chinook salmon fry. In the Rogue Spring Chinook Salmon Conservation Plan, ODFW reported that if these estimates are accurate, hatchery origin salmonids consume 3–7 percent of the natural origin spring-run Chinook salmon fry produced annually in the Rogue River (ODFW, 2007). ODFW (2007) noted that the rate of predation by juvenile steelhead and coho salmon from Cole M. Rivers Hatchery is highly dependent on the duration of time that hatchery fish reside in the river, and on the proportion of the release groups that fail to migrate downstream. ODFW (2007) also found that predation is likely not a primary factor contributing to the decline of spring-run Chinook salmon in the Rogue River.

Based on information provided by the Petitioner, as well as information readily available in our files, we find that there is inadequate information for a reasonable person to determine if disease or predation pose a threat to the continued existence of SONCC spring-run Chinook salmon.

Inadequacy of Existing Regulatory Mechanisms

The Petitioner asserts that existing federal and state regulatory mechanisms

are not sufficient to protect and recover SONCC spring-run Chinook salmon and their habitat. The Petitioner states that the Oregon Native Fish Conservation Policy, The Rogue Spring Chinook Salmon Conservation Plan, and the Coles M. Rivers Hatchery and Genetic Management Plan do not provide safeguards to stabilize or reverse increases in Chinook salmon heterozygous for run timing. The Petitioner asserts that insufficient measures have been taken to prevent the interbreeding between naturally produced spring-run Chinook salmon and hatchery produced spring-run Chinook salmon from the Cole M. Rivers Hatchery. The Petitioner further asserts that the Rogue Fall Chinook Conservation Plan (ODFW, 2007) does not adequately address the risks of interbreeding with spring-run fish as a result of artificially augmented summer flows (ODFW, 2013).

The Petitioner notes that spring-run Chinook salmon on the Rogue River are not listed as threatened or endangered under the Oregon state Endangered Species Act. The Petitioner asserts that while the Rogue Spring Chinook Species Management Unit/SONCC ESU is on the Oregon Sensitive Species List, the designation does not provide regulatory protection for SONCC Chinook salmon.

Consistent with the petition received to list an ESU of Oregon Coast spring-run Chinook salmon under the ESA, the Petitioner here asserts that the Oregon Forest Practices Act and Forest Practice Rules do not provide adequate habitat protections for spring-run Chinook salmon. For reasons previously described in the 90-day finding for that petition (85 FR 20476; April 13, 2020) the petitioner asserts that it is unlikely that the Oregon Forest Practices Act adequately protects the habitat of spring-run Chinook salmon in the Rogue River.

NMFS' most recent SONCC coho salmon status review (NMFS 2016) evaluated the inadequacy of existing regulatory mechanisms over an area in large part co-extensive with the range of SONCC spring-run Chinook salmon and concluded that the Oregon Forest Practices Act does not provide adequate protection for SONCC coho salmon. NMFS (2016) noted that particular areas of concern include: (1) Whether the widths of riparian management areas (RMAs) are sufficient to fully protect riparian functions and stream habitats; (2) whether operations allowed within RMAs will degrade stream habitats; (3) operations on high-risk landslide sites; and (4) watershed-scale effects. NMFS (2016) similarly expressed concerns

with the adequacy of California's forest practice rules to provide protection for SONCC coho salmon. Specifically, NMFS recommended the addition of the following standards to California's forest practice rules: (1) Provide Class II–S (standard) streams with the same protections afforded Class II–L (large) streams, (2) include provisions to ensure hydrologic disconnection between logging roads and streams, and (3) include provisions to avoid hauling logs on hydrologically connected streams during winter periods. Furthermore, NMFS concluded that the effects of past and present timber harvest activities in California continue to be an ongoing threat to the SONCC coho salmon ESU.

Based on information provided by the Petitioner, as well as information readily available in our files, we find that a reasonable person would conclude that the inadequacy of existing regulatory mechanisms may pose a threat to the continued existence of SONCC spring-run Chinook salmon.

Other Natural or Manmade Factors Affecting Its Continued Existence

Hatcheries

The Petitioner asserts that the Cole M. Rivers Hatchery threatens the future viability of spring-run Chinook salmon in the Rogue River. The Petitioner asserts that operation of the Cole M. Rivers Hatchery poses a risk to natural origin spring-run Chinook salmon due to multiple factors including competition, predation, disease, and interbreeding. The Petitioner asserts that the release of an average of 1.6 million spring-run Chinook salmon annually from the Cole M. Rivers Hatchery results in increased competition between naturally produced spring-run Chinook salmon and the more abundant artificially produced salmonids. As previously mentioned the Petitioner asserts that hatchery produced coho salmon and steelhead prey upon natural origin spring-run Chinook salmon fry. The Petitioner further notes that the hatchery is a known source of disease in Chinook salmon. Amandi *et al.* (1982) found that spring-run Chinook salmon in the Cole M. Rivers Hatchery were found to be infected with *F. columnaris* and that pathogen concentrations in the outflow from the hatchery were greater than concentrations from the other water bodies sampled. ODFW (2019) reported that it is unknown if the infected salmon were infected with *F. columnaris* before entering the hatchery or if the salmon contracted *F. columnaris* after entering the hatchery.

Climate Change and Ocean Conditions

The Petitioner also asserts that ongoing threats of poor ocean conditions and climate change are likely to threaten the continued existence of SONCC spring-run Chinook salmon. As described in NMFS' Oregon Coast Chinook salmon status reviews (NMFS, 2011; Stout *et al.*, 2012), variability in ocean conditions in the Pacific Northwest is a concern for the persistence of coastal Oregon Chinook salmon. The Petitioner also cites NMFS (2011) and Stout *et al.* (2012) in support of assertions that predicted effects of climate change are expected to negatively affect coastal Oregon salmonids through many different factors. The Petitioner cites the Oregon Coastal Management Plan (ODFW, 2014) in support of his assertion that regional changes in climate and weather patterns will negatively impact SONCC coastal aquatic ecosystems and salmonids. The Petitioner cites Reiman and Isaaks (2010) to support his assertion that variable weather and warming events will become more frequent in the Pacific Northwest and continue to threaten SONCC Chinook salmon.

Based on information provided by the Petitioner, as well as information readily available in our files, we find that a reasonable person would conclude that hatcheries and climate change may pose threats to the continued existence of SONCC spring-run Chinook salmon.

Petition Finding

After reviewing the information contained in the petition, as well as information readily available in our files, we conclude the petition presents substantial scientific information indicating that the petitioned action to delineate the SONCC spring-run Chinook salmon ESU and list it as threatened or endangered under the ESA may be warranted. Therefore, in accordance with section 4(b)(3)(A) of the ESA and NMFS' implementing regulations (50 CFR 424.14(h)(2)), we will commence a status review to determine whether the spring-run populations of SONCC Chinook salmon constitute an ESU, and, if so, whether that SONCC spring-run Chinook salmon ESU is in danger of extinction throughout all or a significant portion of its range, or likely to become so within the foreseeable future throughout all or a significant portion of its range. After the conclusion of the status review, we will make a finding as to whether listing the SONCC spring-run Chinook salmon ESU as endangered or threatened is

warranted as required by section 4(b)(3)(B) of the ESA.

Information Solicited

To ensure that our status review is informed by the best available scientific and commercial data, we are opening a 60-day public comment period to solicit information on spring-run Chinook salmon in the SONCC Chinook salmon ESU. We request information from the public, concerned governmental agencies, Native American tribes, the scientific community, agricultural and forestry groups, conservation groups, fishing groups, industry, or any other interested parties concerning the current and/or historical status of spring-run Chinook salmon in the SONCC Chinook salmon ESU. Specifically, we request information regarding: (1) Species abundance; (2) species productivity; (3) species distribution or population spatial structure; (4) patterns of phenotypic, genotypic, and life history diversity; (5) habitat conditions and associated limiting factors and threats; (6) ongoing or planned efforts to protect and restore the species and their habitats; (7) information on the adequacy of existing regulatory mechanisms, whether protections are being implemented, and whether they are proving effective in conserving the species; (8) data concerning the status and trends of identified limiting factors or threats; (9) information on targeted harvest (commercial and recreational) and bycatch of the species; (10) other new information, data, or corrections including, but not limited to, taxonomic or nomenclatural changes; and (11) information concerning the impacts of environmental variability and climate change on survival, recruitment, distribution, and/or extinction risk.

We request that all information be accompanied by: (1) Supporting documentation such as maps, bibliographic references, or reprints of pertinent publications; and (2) the submitter's name, address, and any association, institution, or business that the person represents.

References

A complete list of all references cited herein is available upon request (See **FOR FURTHER INFORMATION CONTACT**).

Authority: The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: March 10, 2021.

Samuel D. Rauch III,

*Deputy Assistant Administrator for
Regulatory Programs, National Marine
Fisheries Service.*

[FR Doc. 2021-05338 Filed 3-15-21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF EDUCATION

Applications for New Awards; American Indian Vocational Rehabilitation Training and Technical Assistance Center

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2021 for American Indian Vocational Rehabilitation Training and Technical Assistance Center (AIVRTTAC)—Assistance Listing Number 84.250Z—to provide training and technical assistance (TA) to governing bodies of Indian Tribes that have received an American Indian Vocational Rehabilitation Services (AIVRS) grant.

DATES:

Applications available: March 16, 2021.

Deadline for transmittal of applications: June 14, 2021.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.

FOR FURTHER INFORMATION CONTACT: Jerry Elliott, U.S. Department of Education, 400 Maryland Avenue SW, Room 5097, Potomac Center Plaza, Washington, DC 20202-2800. Telephone: (202) 245-7335. Email: jerry.elliott@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of this program is to provide training and TA to governing bodies of Indian Tribes, and consortia of those governing bodies, that have received an AIVRS grant

under section 121(a) of the Rehabilitation Act of 1973, as amended (Act). Under section 121(c)(2) of the Act, the Commissioner of the Rehabilitation Services Administration (RSA) makes grants to, or enters into contracts or other cooperative agreements with, entities that have experience in the operation of AIVRS programs to provide such training and TA on developing, conducting, administering, and evaluating these programs.

Priority: This priority is from the notice of final priority and definitions (NFP) for this program published elsewhere in this issue of the **Federal Register**.

Absolute Priority: For FY 2021, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

American Indian Vocational Rehabilitation Services—Training and Technical Assistance Program

This priority funds a five-year cooperative agreement to establish an American Indian Vocational Rehabilitation Training and Technical Assistance Center (AIVRTTAC) to provide four types of training and technical assistance (TA) for the personnel of the American Indian Vocational Rehabilitation Services (AIVRS) projects awarded under section 121(a) of the Rehabilitation Act of 1973, as amended (Act), to the governing bodies of Indian Tribes and consortia of those governing bodies. The four types of training and TA are: (1) Intensive training and TA; (2) targeted training and TA; (3) universal training and TA; and (4) capacity-building for AIVRS project personnel through training modules that build foundational skills for the delivery of vocational rehabilitation (VR) services to AIVRS project participants. The AIVRTTAC will develop and provide these types of training and TA for AIVRS projects in the following topic areas:

(a) Applicable laws and regulations governing the AIVRS program.

(b) Promising practices for providing VR services to American Indians with disabilities.

(c) The delivery of VR services to American Indians with disabilities, including the determination of eligibility, case management, case record documentation, assessment, development of the individualized plan for employment, and placement into competitive integrated employment.

(d) Knowledge of assistive technology (AT), including the definition of AT, how to evaluate the need for AT and

what types of AT are available, use of AT, and access to AT.

(e) Implementing professional development practices to ensure effective project coordination, administration, and management.

(f) Implementing appropriate financial and grant management practices to ensure compliance with OMB's Uniform Guidance (2 CFR part 200) and the Education Department General Administrative Regulations.

(g) Evaluating project performance, including data collection, data analysis, and reporting.

Specific subjects for training and TA in each of these topic areas will be identified on an annual basis and in coordination with RSA.

Project Activities

To be considered for funding under this priority, applicants must conduct the following activities, or a subset of the following activities as determined by the Department, in a culturally appropriate manner:

(a) Maintain and build upon the 12 training modules and the fiscal tool kit developed by the Tribal Vocational Rehabilitation Institute (the Institute) during Federal fiscal years (FFYs) 2015–2021, including maintaining the series of seven training modules that build foundational skills that, when satisfactorily completed, lead to a VR certificate to be awarded by the AIVRTTAC. To satisfy this activity requirement, the grantee—

(i) Must develop both academic and non-academic options for completing courses leading to the VR certificate, the requirements for obtaining a certificate including the specific requirements for academic credit for courses included in the certificate when applicable, and how the certificate may be used by the participants who earn it;

(ii) May offer the series of training modules in a traditional classroom setting, through distance learning, through week-long institutes, at regional trainings throughout the country as an extension of national conferences, and through other delivery methods, as appropriate, to meet the needs of the targeted audience;

(iii) May use grant funds to provide reasonable financial assistance for the cost of tuition, fees, and training materials and to offset costs associated with travel for participants who may be in remote areas of the country;

(iv) Must conduct an assessment before and after providing training for each participant in order to assess strengths and specific areas for improvement, educational attainment and application of skills, and any issues

or challenges to be addressed post-training to ensure improved delivery of VR services to American Indians with disabilities;

(v) Must provide follow-up TA to participants to address any issues or challenges that are identified post-training and to ensure that the training they received is applied effectively in their work setting, and such follow-up may be conducted as part of the provision of targeted training and TA or intensive training and TA as determined by the needs of the specific AIVRS project;

(vi) Must conduct an evaluation to obtain feedback on the training and follow-up TA and to determine whether this training and TA contributed to increased employment outcomes for American Indians with disabilities;

(vii) Are encouraged to develop a path by which courses offered for academic credit lead to a degree in Rehabilitation or a related field; and

(viii) May develop additional training modules as negotiated through the cooperative agreement.

(b) Maintain and build upon the topics and tools the current AIVRRTAC has developed to provide intensive training and TA. To satisfy this activity requirement, the grantee must—

(i) Develop and provide intensive training and TA to a minimum of three AIVRS projects in the first year. For future years, the minimum number of AIVRS projects to receive intensive training and TA will be negotiated through the cooperative agreement;

(ii) Develop and implement training and TA consistent with AIVRS project activities and tailored to the specific needs and challenges of the AIVRS project receiving the intensive training and TA;

(iii) Provide training and TA under an agreement with each AIVRS project receiving intensive training and TA that, at a minimum, details the purpose of the training and TA, intended outcomes, and requirements for the subsequent evaluation of the training and TA; and

(iv) Assess the results of the training and TA 90 days after its completion to ensure that the recipient is able to apply effectively the training and TA, identify any issues or challenges in its implementation, and provide additional training and TA, either virtually or on-site, as needed.

(c) Maintain and build upon the topics and tools the current AIVRTTAC has developed to provide a range of targeted training and TA in the topic areas described in this priority based on needs common to multiple AIVRS projects. The grantee must follow up with the recipients of targeted training

and TA it provides to determine the effectiveness of the training and TA;

(d) Maintain and build upon the topics and tools the current AIVRTTAC has developed to provide universal training and TA in the topic areas in this priority;

(e) Provide a minimum of two webinars or video conferences in each of the topic areas in this priority to describe and disseminate up-to-date information, guides, examples, and emerging and promising practices in each area;

(f) Develop new information technology (IT) platforms and systems, or modify existing platforms and systems, as follows:

(i) Develop or modify, and maintain, a state-of-the-art IT platform capable and reliable enough to support webinars, teleconferences, video conferences, and other virtual methods of dissemination of information and TA;

(ii) Develop or modify, and maintain, a state-of-the-art archiving and dissemination system that is open and available to all AIVRS projects and that provides a central location for all AIVRS training and TA products for later use, including course curricula, audiovisual materials, webinars, examples of promising practices related to the topic areas in this priority, the primary areas identified through the annual surveys completed by AIVRS projects, other topics identified by RSA, and other relevant TA products (the possibility of collaborating with the National Clearinghouse of Rehabilitation Training Materials will be considered with the grantee and included in the cooperative agreement, as appropriate);

(iii) Ensure that all products produced by the AIVRTTAC meet government and industry-recognized standards for accessibility; and

(iv) Ensure that all products, resources, and materials developed by the AIVRTTAC are widely disseminated across the AIVRS projects and reflect the AIVRS population and diversity among its communities to the maximum extent possible.

(g) Establish a community of practice (or communities of practice) that will serve as a vehicle for communication, an exchange of information among AIVRS projects, and a forum for sharing the results of training and TA projects that are in progress or have been completed;

(h) Conduct outreach to AIVRS projects so that they are aware of, and can participate in, training and TA activities; and

(i) Conduct an evaluation to determine the quality, relevance, and usefulness of the AIVRTTAC's training

and TA, including the impact of the AIVRTTAC's activities on the ability of AIVRS projects to effectively manage their projects and improve the delivery of VR services to American Indians with disabilities.

Project Requirements

To be funded under this priority, applicants must meet the project requirements in this priority. RSA encourages innovative approaches to meet these requirements, which are—

(a) Demonstrate in the narrative section of the application under “Significance of the Proposed Project” how the proposed project will—

(1) Use the applicant's knowledge and experience in the operation of AIVRS projects to provide training and TA for these projects;

(2) Address the AIVRS projects' capacity to effectively implement an AIVRS project. To meet this requirement, the applicant must—

(i) Demonstrate knowledge of emerging and promising practices in the topic areas in this priority;

(ii) Demonstrate knowledge of current RSA guidance and Federal initiatives designed to improve the functioning of grant projects in general and grant projects for American Indian Tribes in particular; and

(iii) Present information about the difficulties that AIVRS grantees have encountered in implementing effective AIVRS projects;

(b) Demonstrate in the narrative section of the application under “Quality of Project Design” how the proposed project will—

(1) Achieve its goals, objectives, and intended outcomes. To meet this requirement, the applicant must provide—

(i) Measurable intended project outcomes;

(ii) A plan for how the proposed project will achieve its intended outcomes;

(iii) A plan for communicating and coordinating with RSA and key personnel of AIVRS projects; and

(iv) A draft training module or outline for a targeted training and TA presentation or an outline for intensive training and TA activities for one of the topic areas in this priority to demonstrate how participants would be trained in that area. The module or outline is a required attachment in the application and must include, at a minimum, the following:

(A) The goals and objectives of this training module, targeted training and TA activity, or intensive training and TA activities;

(B) A specific list of what participants should know and be able to do as a

result of successfully completing the module, targeted training and TA activity, or intensive training and TA activities;

(C) Up-to-date resources, publications, applicable laws and regulations, and other materials that may be used to develop the module, targeted training and TA activity, or intensive training and TA activities;

(D) Exercises that will provide an opportunity for application of the subject matter;

(E) A description of how participant knowledge, skills, and abilities will be measured; and

(F) In the case of an intensive training and TA intervention, how the outcomes and impact of the intensive training and TA intervention will be measured;

(2) Use a logic model to develop project plans and activities that includes, at a minimum, the goals, activities, outputs, and outcomes of the proposed project;

(3) Be based on current research and make use of emerging and promising practices, and evidence-based practices, where available. To meet this requirement the applicant must describe—

(i) The current research on the emerging and promising practices in the topic areas in this priority; and

(ii) How the AIVRTTAC will incorporate current research and promising and evidence-based practices, including research about adult learning principles and implementation science, in the development and delivery of its products and services;

(4) Develop products and provide services that are of high quality and of sufficient intensity and duration to achieve the intended outcomes of the proposed project. To address this requirement the applicant must describe—

(i) Its proposed approach to universal training and TA;

(ii) Its proposed approach to targeted training and TA, which must identify—

(A) The intended recipients of the products and services under this approach, including the categories of personnel that would be receiving the training and TA;

(B) Its proposed methods for providing targeted training and TA; and

(C) Its proposed methodology for determining topics for the targeted training and TA;

(iii) Its proposed approach to intensive training and TA, which must identify—

(A) Its proposed approach to identifying recipients for intensive training and TA;

(B) Its proposed methodology for providing intensive training and TA to recipients; and

(C) Its proposed approach to assessing the training and TA needs of recipients, including their ability to respond effectively to the training and TA; and

(iv) Its proposed approach to maintaining and building upon capacity-building modules, which must identify—

(A) Its proposed approach to maintaining the 12 training modules and the fiscal tool kit developed by the Institute in FFYs 2015–2021, including maintaining the series of seven training modules that build foundational skills that, when satisfactorily completed, lead to a VR certificate to be awarded by the grantee; and

(B) Its proposed approach to identifying, developing, and delivering new capacity-building modules; and

(5) Develop products and implement services to maximize the proposed project's efficiency. To address this requirement, the applicant must describe—

(i) How the proposed project will use technology to achieve the intended project outcomes;

(ii) With whom the proposed project will collaborate and the intended outcomes of this collaboration; and

(iii) In particular, how the proposed project will coordinate and collaborate with other RSA-funded technical assistance centers to exchange and adapt relevant products and materials to avoid duplication and make effective use of grant funds to better manage the AIVRTTAC project and its available resources to improve service delivery to AIVRS projects;

(c) Demonstrate in the narrative section of the application under “Adequacy of Project Resources” how—

(1) The applicant and any key partners possess adequate resources to carry out the proposed activities; and

(2) The proposed costs are reasonable in relation to the anticipated results and benefits;

(d) Demonstrate in the narrative section of the application under “Quality of Project Personnel” how—

(1) The proposed project will encourage applications for employment from persons who are members of groups that have historically been underrepresented based on race, color, national origin, gender, age, or disability, as appropriate; and

(2) The proposed key project personnel, consultants, and subcontractors have the qualifications and experience to provide training and TA to AIVRS projects in each of the topic areas in this priority and to

achieve the project's intended outcomes, including how the proposed project personnel have a high degree of knowledge and understanding of cultural factors that will be sufficient to ensure the delivery of training and TA in a culturally appropriate manner;

(e) Demonstrate in the narrative section of the application under “Quality of the Management Plan” how the proposed management plan will ensure that the project's intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(1) Clearly defined roles and responsibilities for at least two full-time key project personnel designated to the AIVRTTAC through the entire project period and for consultants and subcontractors, as applicable;

(2) Timelines and milestones for accomplishing the project tasks;

(3) Using a personnel loading chart, detailed project activities through the entire project period, key personnel and any consultants or subcontractors that will be allocated to each activity, and the designated level of effort for each of those activities;

(4) How the personnel allocations in the personnel loading chart are appropriate and adequate to achieve the project's intended outcomes, including an assurance that all personnel will communicate with stakeholders and RSA in a timely way;

(5) How the proposed management plan will ensure that the training and TA products developed through this cooperative agreement are complete, accurate, and of high quality; and

(6) How the proposed project will benefit from a diversity of perspectives, including AIVRS projects and consumers, State VR agencies, TA providers, and policy makers, in its development and operation; and

(f) Demonstrate in the narrative section of the application under “Quality of the Evaluation Plan” how the applicant proposes to collect and analyze data on specific and measurable goals, objectives, and intended outcomes of the project, including the effectiveness of the training and TA provided. To address this requirement, the applicant must describe—

(i) Its proposed evaluation methodologies, including instruments, data collection methods, and analyses;

(ii) Its proposed standards or targets for determining effectiveness;

(iii) How it will use the evaluation results to examine the effectiveness of its implementation and its progress toward achieving the intended outcomes; and

(iv) How the methods of evaluation will produce quantitative and qualitative data that demonstrate whether the project and individual training and TA activities achieved their intended outcomes.

Definitions: These definitions are from the NFP.

Intensive training and technical assistance means training and TA provided to the governing bodies of Indian Tribes that have received an AIVRS grant and to the current personnel of the AIVRS projects primarily on-site over an extended period. Intensive training and TA is based on an ongoing relationship between the training and TA center staff and the governing bodies of Indian Tribes that have received an AIVRS grant and the current personnel of the AIVRS projects under the terms of a signed intensive training and TA agreement.

Targeted training and technical assistance means training and TA based on needs common, to one or more governing bodies of Indian Tribes that have received an AIVRS grant and to the current personnel of the AIVRS projects on a time-limited basis and with limited commitment of training and TA center resources. Targeted training and TA are delivered through virtual or in-person methods tailored to the identified needs of the participating governing bodies of Indian Tribes that have received an AIVRS grant and to the current personnel of the AIVRS projects.

Universal training and technical assistance means training and TA broadly available to governing bodies of Indian Tribes that have received an AIVRS grant and to the current personnel of the AIVRS projects and other interested parties through their own initiative, resulting in minimal interaction with training and TA center staff. Universal training and TA includes generalized presentations, products, and related activities available through a website or through brief contacts with the training and TA center staff.

Program Authority: 29 U.S.C. 741.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 81, 82, 84, and 86. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as

regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The NFP.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grant.

Estimated Available Funds:

\$1,013,000.

Estimated Average Size of Awards:

\$1,013,000.

Estimated Number of Awards: 1.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

Continuing the Fourth and Fifth Years of the Program: In deciding whether to continue funding fourth and fifth years, the Department will consider, as part of the review, the cooperative agreement, the application narrative, and the annual performance reports; the degree to which AIVRRTAC demonstrates substantial progress in providing intensive training and TA to AIVRS projects, targeted training and TA to AIVRS projects, universal training and TA to AIVRS projects, and capacity-building for AIVRS project personnel through training modules that build foundational skills for the delivery of VR services to AIVRS project participants; and the extent to which the training and TA provided has had an impact on the ability of AIVRS projects to implement appropriate practices in the seven topic areas outlined in the priority.

III. Eligibility Information

1. *Eligible Applicants:* State, local, or Tribal governments, nonprofit organizations, or institutions of higher education that have experience in the operation of AIVRS programs.

Note: If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing: (1) Proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar

document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

2. a. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* This program uses an unrestricted indirect cost rate. Applicants for this program are State, local, or Tribal governments, nonprofit organizations, or institutions of higher education that have experience in the operation of AIVRS programs and have negotiated indirect cost rate agreements with a cognizant agency if indirect costs will be charged to the grant. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see www2.ed.gov/about/offices/list/ocft/intro.html.

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

IV. Application and Submission Information

1. Application Submission

Instructions: Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf, which contain requirements and information on how to submit an application.

2. *Intergovernmental Review:* This competition is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

3. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210, have a maximum score of 100 points, and are as follows:

(a) *Need for Project and Significance* (10 Points):

The Secretary considers the need for and significance of the proposed project. In determining the need for and significance of the proposed project, the Secretary considers the following factors:

(1) The magnitude of the need for the services to be provided or the activities to be carried out by the proposed project.

(2) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses.

(3) The potential contribution of the proposed project to increased knowledge or understanding of rehabilitation problems, issues, or effective strategies.

(4) The extent to which the proposed project is likely to build local capacity to provide, improve, or expand services that address the needs of the target population.

(b) *Quality of the Project Design* (20 Points):

The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(1) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(2) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs.

(3) The extent to which the proposed project will establish linkages with other appropriate agencies and organizations providing services to the target population.

(c) *Quality of Project Services* (20 Points):

The Secretary considers the quality of the services to be provided by the proposed project. In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

In addition, the Secretary considers the following factors:

(1) The extent to which the services to be provided by the proposed project

are appropriate to the needs of the intended recipients or beneficiaries of those services.

(2) The likely impact of the services to be provided by the proposed project on the intended recipients of those services.

(3) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services.

(d) *Quality of Project Personnel* (15 Points):

In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

In addition, the Secretary considers the qualifications, including relevant training and experience, of key project personnel.

(e) *Adequacy of Resources* (10 Points):

The Secretary considers the adequacy of resources for the proposed project. In determining the adequacy of resources for the proposed project, the Secretary considers the following factors:

(1) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization.

(2) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

(3) The extent to which the costs are reasonable in relation to the number of persons to be served and to the anticipated results and benefits.

(f) *Quality of the Management Plan* (15 Points):

The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(2) The adequacy of procedures for ensuring feedback and continuous improvement in the operation of the proposed project.

(3) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and

adequate to meet the objectives of the proposed project.

(g) *Quality of the Project Evaluation* (10 Points):

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors:

(1) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(2) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

(3) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period

may exceed the simplified acquisition threshold (currently \$250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds \$10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed \$10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115—232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email

containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to www.ed.gov/fund/grant/apply/appforms/appforms.html.

4. *Performance Measures:* The Government Performance and Results Act of 1993 (GPRA) directs Federal departments and agencies to improve the effectiveness of their programs by engaging in strategic planning, setting outcome-related goals for programs, and measuring program results against those goals.

For the purposes of GPRA and Department reporting under 34 CFR 75.110, we have established the following performance measures for this program:

(a) Of all AIVRS project staff, the number and percentage of AIVRS project staff that complete at least on personnel preparation class offered by the AIVRTTAC.

(b) Of all AIVRS projects, the number and percentage of AIVRS projects that have at least one staff member that has completed at least one personnel

preparation class offered by the AIVRTTAC.

(c) Of all AIVRS project staff, the number and percentage of AIVRS project staff that receive a certificate based on classes offered by the AIVRTTAC.

(d) Of AIVRS projects that received intensive training and technical assistance, the number and percentage of AIVRS projects that completed all activities in the intensive TA agreement.

(e) Of AIVRS projects that received intensive training and technical assistance, the number and percentage of AIVRS projects that show an increase in consumers achieving an employment outcome compared to the prior year.

(f) Of AIVRS projects that received intensive training and technical assistance, the number and percentage of AIVRS projects that show an increase in consumers receiving services under an IPE compared to the prior year.

Applicable short-term and long-term indicators and targets will be specified in the AIVRTTAC cooperative agreement.

Annual project progress toward meeting project goals must be posted on the project website.

5. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at www.govinfo.gov. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

David Cantrell,

Deputy Director, Office of Special Education Programs. Delegated the authority to perform the functions and duties of the Assistant Secretary for the Office of Special Education and Rehabilitative Services.

[FR Doc. 2021-05429 Filed 3-11-21; 4:15 pm]

BILLING CODE 4000-01-P

ELECTION ASSISTANCE COMMISSION

Notice of Agency Organization, Procedure, and Practice; New Agency Seal

AGENCY: U.S. Election Assistance Commission.

ACTION: Notice.

SUMMARY: The EAC is implementing a new official agency seal for use on all agency internal and external correspondence, communications, media, materials, and methods of identification.

DATES: The new agency seal is effective on March 15, 2021.

FOR FURTHER INFORMATION CONTACT: Kristen Muthig, Telephone: (202) 897-9285, Email: kmuthig@eac.gov.

SUPPLEMENTARY INFORMATION: In 2021, the U.S. Election Assistance Commission (EAC) underwent the process to rebrand and develop a new seal for the agency to better reflect the mission and work of the EAC. Since the agency was established by the Help America Vote Act of 2002 (HAVA), the EAC used a variation of the Great Seal of the United States for its logo.

As the new seal was developed, the following considerations were made and elements incorporated:

- The seal reflects the EAC's testing and certification of voting machines by showing a circuit board.
- The circuit board diodes incorporate the word "VOTE" in Braille reflecting the importance of accessibility for voters with disabilities and EAC's role in ensuring all Americans can vote privately and independently.
- The flag reflects democracy, the EAC as a federal agency, and voters' rights.
- The three stars in the flag represent the three main functions of the EAC: Clearinghouse, Testing and Certification, Research.
- The ballot box reflects the various options of voting and the EAC's mission to assist with election administration best practices.

Permission is required for the replication or use of this seal. The seal is effective on March 15, 2021. The EAC believes that delaying the effective date is unnecessary as this is a notice regarding agency organization, procedure, and practice and there are no changes to public access to the agency or agency services provided to the public. Additionally, the public will benefit immediately from recognition of the new official logo of the EAC on official documents and materials.

Amanda Joiner,

Associate Counsel, U.S. Election Assistance Commission.

[FR Doc. 2021-05417 Filed 3-15-21; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15054-000]

Kinet, Inc.; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On November 6, 2020, Kinet, Inc., filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of a conventional hydropower project located in Jessamine, Garrard, and Madison Counties, Kentucky. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed Kentucky River Lock and Dam No. 8 Hydroelectric Project would consist of the following: (1) An existing 309-foot-long, 31-foot-high, timber crib dam with concrete overlay connected to a 384-foot-long, and 52-foot-wide abandoned navigation lock, which are owned by the Kentucky River Authority; (2) a reservoir with a surface area of 499 acres and a storage capacity of 8,700 acre-feet; (3) six, proposed, 32-foot-long, 9-foot-diameter penstocks connected to six generating units with a combined capacity of 3.7 megawatts, within the existing lock; (4) a proposed powerhouse/control room adjacent to the lock; (5) a 30-foot-long by 75-foot-wide tailrace; and (6) a 675-foot-long, 12.47 kilo-Volt transmission line. The proposed project would have an estimated annual generation of 21,002 megawatt-hours.

Applicant Contact: Jessica Penrod, Natel Energy, Inc., 2401 Monarch Street, Alameda, CA 9401; phone: (415) 845-1933.

FERC Contact: Joshua Dub; phone: (202) 502-8138.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at <https://ferconline.ferc.gov/FEROnline.aspx>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <https://ferconline.ferc.gov/QuickComment.aspx>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FEROnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). 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.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of the Commission's website at

<https://elibrary.ferc.gov/eLibrary/search>. Enter the docket number (P-15054) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: March 10, 2021.

Kimberly D. Bose,
Secretary.

[FR Doc. 2021-05382 Filed 3-15-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15059-000]

Kinet, Inc.; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On December 3, 2020, Kinet, Inc., filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of a conventional hydropower project located in Anderson, Woodford, and Mercer Counties, Kentucky. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed Kentucky River Lock and Dam No. 5 Hydroelectric Project would consist of the following: (1) An existing 594-foot-long, 36-foot-high, timber crib dam with concrete overlay connected to a 390-foot-long, and 38-foot-wide abandoned navigation lock, which are owned by the Kentucky River Authority; (2) a reservoir with a surface area of 448 acres and a storage capacity of 7,500 acre-feet; (3) five, proposed, 32-foot-long, 9-foot-diameter penstocks connected to five generating units with a combined capacity of 2.4 megawatts, within the existing lock; (4) a proposed powerhouse/control room adjacent to the lock; (5) a 30-foot-long by 63-foot-wide tailrace; and (6) a 175-foot-long, 12.47 kilo-Volt transmission line. The proposed project would have an estimated annual generation of 16,243 megawatt-hours.

Applicant Contact: Dan Panko, Kinet, Inc., 2401 Monarch Street, Alameda, CA 9401; phone: (802) 578-7973.

FERC Contact: Joshua Dub; phone: (202) 502-8138.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at <https://ferconline.ferc.gov/FEROnline.aspx>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <https://ferconline.ferc.gov/QuickComment.aspx>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FEROnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). 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.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of the Commission's website at <https://elibrary.ferc.gov/eLibrary/search>. Enter the docket number (P-15059) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: March 10, 2021.

Kimberly D. Bose,
Secretary.

[FR Doc. 2021-05383 Filed 3-15-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14863-001]

BM Energy Park, LLC; Notice of Surrender of Preliminary Permit

Take notice that BM Energy Park LLC, permittee for the proposed Banner

Mountain Pumped Storage Hydro Project, has requested that its preliminary permit be terminated. The permit was issued on May 8, 2018 and would have expired on April 30, 2021.¹ The project would have been located in Converse County, Wyoming.

The preliminary permit for Project No. 14863 will remain in effect until the close of business, April 9, 2021. But, if the Commission is closed on this day, then the permit remains in effect until the close of business on the next day in which the Commission is open.² New applications for this site may not be submitted until after the permit surrender is effective.

Dated: March 10, 2021.

Kimberly D. Bose,
Secretary.

[FR Doc. 2021-05381 Filed 3-15-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. 94-409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

TIME AND DATE: March 18, 2021, 10:00 a.m.

PLACE: Open to the public via audio Webcast only. Join FERC online to listen live at <http://ferc.capitolconnection.org/>.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

* *Note*—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Kimberly D. Bose, Secretary, Telephone (202) 502-8400.

For a recorded message listing items struck from or added to the meeting, call (202) 502-8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed on line at the Commission's website at <http://ferc.capitolconnection.org/> using the eLibrary link.

¹ 163 FERC ¶ 62,080 (2018).

² 18 CFR 385.2007(a)(2) (2020).

1076TH—MEETING

[Open meeting; March 18, 2021; 10:00 a.m.]

Item No.	Docket No.	Company
ADMINISTRATIVE		
A-1	AD21-1-000	Agency Administrative Matters.
A-2	AD21-2-000	Customer Matters, Reliability, Security and Market Operations.
A-3	AD06-3-000	Market Update.
ELECTRIC		
E-1	RM18-9-002	Participation of Distributed Energy Resource Aggregations in Markets Operated by Regional Transmission Organizations and Independent System Operators.
E-2	RM21-14-000	Participation of Aggregators of Retail Demand Response Customers in Markets Operated by Regional Transmission Organizations and Independent System Operators.
E-3	QF17-454-006	Broadview Solar, LLC.
E-4	EL19-47-000	<i>Independent Market Monitor for PJM v. PJM Interconnection, L.L.C.</i>
	EL19-63-000	<i>Office of the People's Counsel for the District of Columbia, Delaware Division of the Public Advocate, Citizens Utility Board, Indiana Office of Utility Consumer Counselor, Maryland Office of People's Counsel, Pennsylvania Office of Consumer Advocate, West Virginia Consumer Advocate Division, and PJM Industrial Customer Coalition v. PJM Interconnection, L.L.C.</i>
E-5	EL21-35-000	Hollow Road Solar LLC.
E-6	EL21-14-000	NextEra Energy, Inc., Evergy, Inc., American Electric Power Company, Exelon Corporation, Xcel Energy Services Inc.
E-7	RM16-17-000	Data Collection for Analytics and Surveillance and Market-Based Rate Purposes.
E-8	Omitted	
E-9	ER21-679-000	Midcontinent Independent System Operator, Inc.
E-10	ER20-1210-001	Hazleton Generation LLC.
E-11	ER20-1237-000	Ameren Illinois Company.
E-12	ER19-1276-001	Ameren Illinois Company.
E-13	ER20-1892-000	Midcontinent Independent System Operator, Inc.
E-14	ER17-801-010	Constellation Power Source Generation, LLC.
E-15	ER18-2497-005	Lawrenceburg Power, LLC.
E-16	EC21-10-000	NextEra Energy Transmission, LLC, GridLiance West LLC, GridLiance High Plains LLC, and GridLiance Hearthland LLC.
E-17	RD21-2-000	North American Electric Reliability Corporation.
E-18	EL21-13-000	<i>Californians for Green Nuclear Power, Inc. v. The North American Electric Reliability Corporation, the Western Electricity Coordinating Council, the California Independent System Operator, the California Public Utilities Commission, the California State Water Resources Control Board, and the California State Lands Commission.</i>
E-19	EL20-69-000	<i>Californians for Renewable Energy and Michael E. Boyd v. California Independent System Operator Corporation, California Public Utilities Commission, Pacific Gas and Electric Company, San Diego Gas and Electric Company and Southern California Edison Company.</i>
E-20	EL21-33-000, QF86-381-001	Citrus World, Inc.
E-21	ER19-2547-001	Pheasant Run Wind, LLC.
E-22	ER18-2404-000	Southwest Power Pool, Inc.
E-23	ER19-477-000	Southwest Power Pool, Inc.
E-24	ER21-502-001	New York Independent System Operator, Inc.
Gas		
G-1	Omitted	
G-2	RP21-153-000	Texas Eastern Transmission, LP.
HYDRO		
H-1	P-405-106 P-405-121	Exelon Generation Company, LLC.
H-2	P-12726-002	Warm Springs Hydro LLC
Certificates		
C-1	RM20-18-000	Waiver of the Water Quality Certification Requirements of Section 401(a)(1) of the Clean Water Act.
C-2	CP20-466-000	New Fortress Energy LLC.
C-3	CP20-487-000	Northern Natural Gas Company.
C-4	CP17-40-000, CP17-40-001	Spire STL Pipeline LLC.
C-5	CP17-458-000, CP19-17-000	Midship Pipeline Company, LLC.
C-6	IN19-4-000	Rover Pipeline, LLC and Energy Transfer Partners, L.P.

Issued: March 11, 2021.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

The public is invited to listen to the meeting live at <http://ferc.capitolconnection.org/>. Anyone with internet access who desires to hear this event can do so by navigating to www.ferc.gov's Calendar of Events and locating this event in the Calendar. The event will contain a link to its audio webcast. The Capitol Connection provides technical support for this free audio webcast. It will also offer access to this event via phone bridge for a fee. If you have any questions, visit <http://ferc.capitolconnection.org/> or contact Shirley Al-Jarani at 703-993-3104.

[FR Doc. 2021-05492 Filed 3-12-21; 11:15 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG21-104-000.

Applicants: Crystal Lake Wind Energy III, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Crystal Lake Wind Energy III, LLC.

Filed Date: 3/8/21.

Accession Number: 20210308-5276.

Comments Due: 5 p.m. ET 3/29/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER19-465-000; ER19-465-001; ER19-465-003; ER19-465-004.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Midcontinent Independent System Operator, Inc. submits Request to Defer Effective Date of Compliance with Order No. 841.

Filed Date: 3/4/21.

Accession Number: 20210304-5215.

Comments Due: 5 p.m. ET 3/19/21.

Docket Numbers: ER19-2858-001.

Applicants: East Coast Power Linden Holding, L.L.C.

Description: Report Filing: Refund Report to be effective N/A.

Filed Date: 3/10/21.

Accession Number: 20210310-5077.

Comments Due: 5 p.m. ET 3/31/21.

Docket Numbers: ER21-1320-000.

Applicants: Crystal Lake Wind Energy III, LLC.

Description: Baseline eTariff Filing: Crystal Lake Wind Energy III, LLC Application for MBR Authority to be effective 5/10/2021.

Filed Date: 3/10/21.

Accession Number: 20210310-5210.

Comments Due: 5 p.m. ET 3/31/21.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by 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: March 10, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021-05386 Filed 3-15-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 5728-021]

Sandy Hollow Hydroelectric Company, Inc.; Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* 5728-021.

c. *Date filed:* March 1, 2021.

d. *Applicant:* Sandy Hollow Hydroelectric Company, Inc. (Sandy Hollow Hydro).

e. *Name of Project:* Sandy Hollow Hydroelectric Project.

f. *Location:* On the Indian River, in the Town of Philadelphia in Jefferson County, New York. The project does not occupy any federal land.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)-825(r).

h. *Applicant Contact:* Ms. Kelly Sackheim, 32151 Sandy Hollow Road, Philadelphia, NY 13673; (916) 877-5947; sandyhollow@kchydro.com.

i. *FERC Contact:* Chris Millard at (202) 502-8256, or christopher.millard@ferc.gov.

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. See 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* April 30, 2021.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at <https://ferconline.ferc.gov/FEROnline.aspx>. For assistance, please contact FERC Online Support at FEROnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). 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. All filings must clearly identify the project name and docket number on the first page: Sandy Hollow Hydroelectric Project (P-5728-021).

m. The application is not ready for environmental analysis at this time.

n. *Project Description:* The existing Sandy Hollow Hydroelectric Project consists of (1) a 20-acre reservoir at a normal pool elevation of 419.1 feet National Geodetic Vertical Datum of 1929; (2) a main 106-foot-long concrete gravity dam with a maximum height of 25 feet that includes a 55-foot-long spillway, and three 3- to 4-foot-high concrete diversion spillway dams that are 21 feet, 46 feet and 64 feet long, respectively; (3) a 23-foot-long by 23-foot-wide brick and concrete powerhouse containing a 150-kilowatt (kW), a 265-kW, and a 400-kW turbine-generator unit; (4) two 12- to 15-foot-long, 6-foot-diameter steel penstocks, with one penstock that bifurcates before joining the two turbine units; (5) two trash racks; (6) a 400-foot-long tailrace channel; (7) a 480-volt, 300-foot-long transmission line connecting to a 480-volt to 23-kilovolt step-up transformer at a nearby substation; and (8) appurtenant facilities. The average annual generation was 933 megawatt-hours between 2012 and 2017.

The project is operated in a run-of-river mode and discharges a minimum flow of 35 cubic feet per second (cfs) or inflow to the reservoir, whichever is less, into the project's bypassed reach for the protection and enhancement of aquatic resources.

As part of the license application, Sandy Hollow Hydro filed a settlement agreement entered into between itself, the U.S. Fish and Wildlife Service, and the New York State Department of Environmental Conservation. As part of the settlement agreement, Sandy Hollow Hydro proposes to: (1) Continue to operate the project in a run-of-river mode; (2) provide a year-round minimum flow in the bypassed reach of 35 cfs, or inflow, whichever is less; (3) continue the existing stream flow and water level monitoring; (4) maintain the existing trash rack on turbine unit 3 with 1-inch clear spacing and, within 5 years of any license issued for the project, install trash racks with either 1-inch clear spacing or the equivalent (e.g., an overlay-type system) on turbine units 1 and 2; (5) within 3 years of the effective date of any license issued for the project, install and maintain a year-round downstream fish passage structure at one of the three diversion spillway dams; (6) maintain the existing portage trail; and (7) implement the Invasive Species Management Plan filed with the final license application.

o. In addition to publishing the full text of this notice in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this notice, as well as other documents in

the proceeding (e.g., license application) 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 (P-5728). 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, (866) 208-3676 or (202) 502-8659 (TTY).

You may also register online at <https://ferconline.ferc.gov/FEROnline.aspx> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. *Procedural schedule:* The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Issue Deficiency Letter (if necessary).	April 2021
Request Additional Information.	April 2021
Issue Acceptance Letter	July 2021
Issue Scoping Document 1 for comments.	August 2021
Request Additional Information (if necessary).	October 2021
Issue Scoping Document 2 ..	November 2021
Issue Notice of Ready for Environmental Analysis.	November 2021

q. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: March 10, 2021.

Kimberly D. Bose,
Secretary.

[FR Doc. 2021-05389 Filed 3-15-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Effectiveness of Exempt Wholesale Generator Status

Wolf Ridge Wind Energy, LLC.	EG21-43-000
Blue Summit I Wind, LLC ...	EG21-44-000
Dickerson Power, LLC	EG21-45-000
Morgantown Power, LLC	EG21-46-000
Morgantown Station, LLC	EG21-47-000
Water Strider Solar, LLC	EG21-48-000
325MK 8ME LLC	EG21-49-000

Chalk Point Power, LLC	EG21-50-000
Flat Ridge 2 Wind Energy LLC.	EG21-51-000
Harry Allen Solar Energy LLC.	EG21-52-000
Centerfield Cooper Solar, LLC.	EG21-53-000
PGR Lessee O, LLC	EG21-54-000
Dry Lake Solar Holdings LLC.	EG21-55-000
HO Clarke II, LLC	EG21-57-000
Indiana Crossroads Wind Farm LLC.	EG21-58-000
Wallingford Renewable Energy LLC.	EG21-59-000
Topaz II, LLC	EG21-60-000
Braes Bayou Generating, LLC.	EG21-61-000
KCE TX 23, LLC	EG21-62-000
Midway-Sunset Cogeneration Company.	EG21-63-000

Take notice that during the month of February 2021, the status of the above-captioned entities as Exempt Wholesale Generators became effective by operation of the Commission's regulations. 18 CFR 366.7(a) (2020).

Dated: March 10, 2021.

Kimberly D. Bose,
Secretary.

[FR Doc. 2021-05388 Filed 3-15-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15060-000]

Kinet, Inc.; Notice of Preliminary Permit Application Accepted For Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On December 3, 2020, Kinet, Inc., filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of a conventional hydropower project located in Jessamine, Woodford, and Mercer Counties, Kentucky. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed Kentucky River Lock and Dam No. 6 Hydroelectric Project would consist of the following: (1) An existing 465-foot-long, 34-foot-high, timber crib dam with concrete overlay connected to a 280-foot-long, and 45-foot-wide abandoned navigation lock, which are owned by the Kentucky River

Authority; (2) a reservoir with a surface area of 666 acres and a storage capacity of 12,000 acre-feet; (3) five, proposed, 32-foot-long, 9-foot-diameter penstocks connected to five generating units with a combined capacity of 2.1 megawatts, within the existing lock; (4) a proposed powerhouse/control room adjacent to the lock; (5) a 30-foot-long by 63-foot-wide tailrace; and (6) a 270-foot-long, 12.47 kilo-Volt transmission line. The proposed project would have an estimated annual generation of 13,998 megawatt-hours.

Applicant Contact: Dan Panko, Kinet, Inc., 2401 Monarch Street, Alameda, CA 9401; phone: (802) 578-7973.

FERC Contact: Joshua Dub; phone: (202) 502-8138.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at <https://ferconline.ferc.gov/FERCOOnline.aspx>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <https://ferconline.ferc.gov/QuickComment.aspx>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOOnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). 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.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of the Commission's website at <https://elibrary.ferc.gov/eLibrary/search>. Enter the docket number (P-15060) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: March 10, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021-05384 Filed 3-15-21; 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 exempt wholesale generator filings:

Docket Numbers: EG21-105-000.

Applicants: Elara Energy Project, LLC.

Description: Elara Energy Project, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 3/4/21.

Accession Number: 20210304-5214.

Comments Due: 5 p.m. ET 3/25/21.

Docket Numbers: EG21-106-000.

Applicants: Taygete Energy Project II, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Taygete Energy Project II, LLC.

Filed Date: 3/10/21.

Accession Number: 20210310-5068.

Comments Due: 5 p.m. ET 3/31/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10-2034-007; ER15-190-016; ER18-490-000.

Applicants: Duke Energy Renewable Services, LLC, Duke Energy Indiana, LLC.

Description: Supplement to December 18, 2020 Triennial Market Power Analysis for Central Region of Duke Companies.

Filed Date: 3/4/21.

Accession Number: 20210304-5210.

Comments Due: 5 p.m. ET 3/25/21.

Docket Numbers: ER18-126-001; ER16-2019-005.

Applicants: AL Solar A, LLC, Five Points Solar Park LLC.

Description: Notice of Non-Material Change in Status of AL Solar A, LLC, et al.

Filed Date: 3/9/21.

Accession Number: 20210309-5195.

Comments Due: 5 p.m. ET 3/30/21.

Docket Numbers: ER21-1176-000.

Applicants: Delta's Edge Solar, LLC.

Description: Delta's Edge Solar, LLC submits Supplemental Information Regarding the Application for Market Based Rate Authority.

Filed Date: 2/25/21.

Accession Number: 20210225-5221.

Comments Due: 5 p.m. ET 3/18/21.

Docket Numbers: ER21-1249-001.

Applicants: Vineyard Reliability LLC.

Description: Tariff Amendment:

Vineyard Rel MBRA_App_Supp to be effective 3/5/2021.

Filed Date: 3/10/21.

Accession Number: 20210310-5000.

Comments Due: 5 p.m. ET 3/24/21.

Docket Numbers: ER21-1310-000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of ISA, SA No. 4730; Queue No. AC1-039 to be effective 4/26/2021.

Filed Date: 3/9/21.

Accession Number: 20210309-5166.

Comments Due: 5 p.m. ET 3/30/21.

Docket Numbers: ER21-1312-000.

Applicants: New York State Electric & Gas Corporation, New York Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 205: NYISO-NYSEG Joint LGIA 2487 among NYISO, NYSEG, Baron Winds to be effective 2/24/2021.

Filed Date: 3/10/21.

Accession Number: 20210310-5051.

Comments Due: 5 p.m. ET 3/31/21.

Docket Numbers: ER21-1314-000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: § 205(d) Rate Filing: Amendment to Service Agreement No. 849 to be effective 2/11/2021.

Filed Date: 3/10/21.

Accession Number: 20210310-5091.

Comments Due: 5 p.m. ET 3/31/21.

Docket Numbers: ER21-1315-000.

Applicants: Midcontinent Independent System Operator Inc., American Transmission Company LLC.

Description: § 205(d) Rate Filing: 2021-03-10_SA 2775 ATC-Marshfield 1st Rev CFA to be effective 5/10/2021.

Filed Date: 3/10/21.

Accession Number: 20210310-5106.

Comments Due: 5 p.m. ET 3/31/21.

Docket Numbers: ER21-1316-000.

Applicants: Louisville Gas and Electric Company.

Description: § 205(d) Rate Filing: EKPC Bullitt County CIAC Agreement to be effective 3/10/2021.

Filed Date: 3/10/21.

Accession Number: 20210310-5138.

Comments Due: 5 p.m. ET 3/31/21.

Docket Numbers: ER21-1317-000.

Applicants: Kentucky Utilities Company.

Description: § 205(d) Rate Filing: KU Concurrence EKPC Bullitt County CIAC Agreement to be effective 3/10/2021.

Filed Date: 3/10/21.

Accession Number: 20210310-5139.

Comments Due: 5 p.m. ET 3/31/21.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH21–8–000.

Applicants: Greenidge Generation Holdings Inc., Atlas Capital Resources (A9-Parallel) LP.

Description: Greenidge Generation Holdings Inc. et al., submits FERC–65–A Exemption Notification.

Filed Date: 3/9/21.

Accession Number: 20210309–5194.

Comments Due: 5 p.m. ET 3/30/21.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by 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: March 10, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–05385 Filed 3–15–21; 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:

Docket Numbers: RP21–607–000.

Applicants: Natural Gas Pipeline Company of America.

Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing—BP Energy Company to be effective 4/1/2021.

Filed Date: 3/5/21.

Accession Number: 20210305–5003.

Comments Due: 5 p.m. ET 3/17/21.

Docket Numbers: RP21–608–000.
Applicants: Natural Gas Pipeline Company of America.

Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing—

Morgan Stanley Capital to be effective 4/1/2021.

Filed Date: 3/5/21.

Accession Number: 20210305–5004.

Comments Due: 5 p.m. ET 3/17/21.

Docket Numbers: RP21–609–000.

Applicants: Natural Gas Pipeline Company of America.

Description: § 4(d) Rate Filing: Negotiated Rate Agreements Filing—Wells Fargo Commodities to be effective 4/1/2021.

Filed Date: 3/5/21.

Accession Number: 20210305–5005.

Comments Due: 5 p.m. ET 3/17/21.

Docket Numbers: RP21–610–000.

Applicants: Adelphia Gateway, LLC.

Description: Penalty Revenue Crediting Report of Adelphia Gateway, LLC under RP21–610.

Filed Date: 3/8/21.

Accession Number: 20210308–5206.

Comments Due: 5 p.m. ET 3/22/21.

Docket Numbers: RP21–611–000.

Applicants: Enable Gas Transmission, LLC.

Description: Petition for Limited Waiver of Tariff Provision of Enable Gas Transmission, LLC under RP21–611.

Filed Date: 3/8/21.

Accession Number: 20210308–5233.

Comments Due: 5 p.m. ET 3/15/21.

Docket Numbers: RP13–459–000.

Applicants: Trailblazer Pipeline Company LLC.

Description: Report Filing: TPC 2021–03–09 2020 Penalty Revenues Refund Report.

Filed Date: 3/9/21.

Accession Number: 20210309–5098.

Comments Due: 5 p.m. ET 3/22/21.

Docket Numbers: RP21–555–001.

Applicants: Destin Pipeline Company, L.L.C.

Description: Tariff Amendment: Destin Pipeline Amended Negotiated Rate Filing to be effective 4/1/2021.

Filed Date: 3/9/21.

Accession Number: 20210309–5146.

Comments Due: 5 p.m. ET 3/22/21.

Docket Numbers: RP21–612–000.

Applicants: Vector Pipeline L.P.
Description: Vector Pipeline L.P. submits Annual Fuel Use Report for 2020 under RP21–612.

Filed Date: 3/9/21.

Accession Number: 20210309–5044.

Comments Due: 5 p.m. ET 3/22/21.

Docket Numbers: RP21–613–000.

Applicants: Midcontinent Express Pipeline LLC.

Description: Compliance filing Annual Report of Operational Purchases and Sales 2021.

Filed Date: 3/9/21.

Accession Number: 20210309–5045.

Comments Due: 5 p.m. ET 3/22/21.

Docket Numbers: RP21–614–000.

Applicants: Devon Energy Production Company, L.P., Denbury Onshore, LLC.

Description: Petition For Limited Waiver, et al. of Devon Energy Production Company, L.P., et al. under RP21–614.

Filed Date: 3/9/21.

Accession Number: 20210309–5105.

Comments Due: 5 p.m. ET 3/16/21.

Docket Numbers: RP21–615–000.

Applicants: Enable Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rate Filing—March 9, 2021 GEP to be effective 3/9/2021.

Filed Date: 3/9/21.

Accession Number: 20210309–5139.

Comments Due: 5 p.m. ET 3/22/21.

Docket Numbers: RP21–616–000.

Applicants: Panhandle Eastern Pipe Line Company, LP.

Description: Request for Limited Waiver Determination of Panhandle Eastern Pipe Line Company, LP under RP21–616.

Filed Date: 3/9/21.

Accession Number: 20210309–5175.

Comments Due: 5 p.m. ET 3/16/21.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by 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: March 10, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–05387 Filed 3–15–21; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID: 17566]

Privacy Act of 1974; Matching Program

AGENCY: Federal Communications Commission.

ACTION: Notice of a new matching program.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (“Privacy Act”), this document announces the modification of a computer matching program the Federal Communications Commission (“FCC” or “Commission” or “Agency”) and the Universal Service Administrative Company (USAC) will conduct with the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) (“Agency”). The purpose of this matching program is to verify the eligibility of applicants to and subscribers of Lifeline (existing purpose) and the new Emergency Broadband Benefit Program, both of which are administered by USAC under the direction of the FCC. More information about these programs is provided in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Written comments are due on or before April 15, 2021. This computer matching program will commence on April 15, 2021, and will conclude 18 months after the effective date.

ADDRESSES: Send comments to Margaret Drake, FCC, 45 L Street NE, Washington, DC 20554, or to Privacy@fcc.gov.

FOR FURTHER INFORMATION CONTACT: Margaret Drake at 202–418–1707 or Privacy@fcc.gov.

SUPPLEMENTARY INFORMATION: The Lifeline program provides support for discounted broadband and voice services to low-income consumers. Lifeline is administered by the Universal Service Administrative Company (USAC) under FCC direction. Consumers qualify for Lifeline through proof of income or participation in a qualifying program, such as Medicaid, the Supplemental Nutritional Assistance Program (SNAP), Federal Public Housing Assistance, Supplemental Security Income (SSI), Veterans and Survivors Pension Benefit, or various Tribal-specific Federal assistance programs.

The Emergency Broadband Benefit Program (EBBP) was established by Congress in the Consolidated Appropriations Act of 2021, Public Law 116–260, 134 Stat. 1182. EBBP is a program that will help low-income Americans obtain discounted broadband service and one-time co-pay for a connected device (laptop, desktop computer or tablet). This program was created specifically to assist American families’ access to broadband, which has proven to be essential for work, school, and healthcare during the public health emergency that exists as a result

of COVID–19. A household may qualify for the EBBP benefit under various criteria, including an individual qualifying for the FCC’s Lifeline program.

In a Report and Order adopted on March 31, 2016 (81 FR 33026 (May 24, 2016)), the Commission ordered USAC to create a National Lifeline Eligibility Verifier (“National Verifier”), including the National Lifeline Eligibility Database (LED), that would match data about Lifeline applicants and subscribers with other data sources to verify the eligibility of an applicant or subscriber. The Commission found that the National Verifier would reduce compliance costs for Lifeline service providers, improve service for Lifeline subscribers, and reduce waste, fraud, and abuse in the program.

The Consolidated Appropriations Act of 2021 directs the FCC to leverage the National Verifier to verify applicants’ eligibility for EBBP. The purpose of this matching program is to verify the eligibility of EBBP applicants and subscribers by determining whether they receive Medicaid or Supplemental Nutrition Assistance Program (SNAP) benefits administered by the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. Under FCC rules, consumers receiving these benefits qualify for Lifeline discounts and also for EBBP benefits.

Participating Non-Federal Agencies

U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services.

Authority for Conducting the Matching Program

The authority for the FCC’s EBBP is Consolidated Appropriations Act of 2021, Public Law 116–260, 134 Stat. 1182; 47 CFR part 54, subpart P. The authority for the FCC’s Lifeline program is 47 U.S.C. 254; 47 CFR part 54, subpart E; Lifeline and Link Up Reform and Modernization, *et al.*, Third Report and Order, Further Report and Order, and Order on Reconsideration, 31 FCC Rcd 3962, 4006–21, paras. 126–66 (2016) (81 FR 33026 (May 24, 2016) (*2016 Lifeline Modernization Order*)).

Purposes(s)

In the 2016 Lifeline Modernization Order, the FCC required USAC to develop and operate the National Verifier to improve efficiency and reduce waste, fraud, and abuse in the Lifeline program. The stated purpose of the National Verifier is “to increase the integrity and improve the performance of the Lifeline program for the benefit of

a variety of Lifeline participants, including Lifeline providers, subscribers, states, community-based organizations, USAC, and the Commission.” 31 FCC Rcd 3962, 4006, para. 126. To help determine whether Lifeline applicants and subscribers are eligible for Lifeline benefits, the Order contemplates that the USAC-operated LED will communicate with information systems and databases operated by other Federal and State agencies. *Id.* at 4011–2, paras. 135–7. The Consolidated Appropriations Act of 2021 directs the FCC to leverage the National Verifier to verify applicants’ eligibility for EBBP.

The purpose of this modified matching agreement is to verify the eligibility of applicants and subscribers to Lifeline (existing purpose), as well as to the new EBBP and to other Federal programs that use qualification for Lifeline as an eligibility criterion. This new agreement would replace the existing agreement with CMS, which permits matching only for the Lifeline program by checking an applicant’s/ subscriber’s participation in Medicaid. Under FCC rules, consumers receiving these benefits qualify for Lifeline discounts and also for EBBP benefits.

Categories of Individuals

The categories of individuals whose information is involved in the matching program include, but are not limited to, those individuals who have applied for Lifeline and/or EBBP benefits; are currently receiving Lifeline and/or EBBP benefits; are individuals who enable another individual in their household to qualify for Lifeline and/or EBBP benefits; are minors whose status qualifies a parent or guardian for Lifeline and/or EBBP benefits; or are individuals who have received Lifeline and/or EBBP benefits.

Categories of Records

The categories of records involved in the matching program include, but are not limited to, the last four digits of the applicant’s Social Security Number, date of birth, state of residence, first name, and last name. The National Verifier will transfer these data elements to the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services which will respond either “yes” or “no” that the individual is enrolled in a qualifying assistance program: U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Medicaid.

System(s) of Records

The records shared as part of this matching program reside in the Lifeline system of records, FCC/WCB–1,

Lifeline, which was published in the **Federal Register** at 86 FR 11526 (Feb. 25, 2021).

The records shared as part of this matching program reside in the EBBP system of records, FCC/WCB-3, Emergency Broadband Benefit Program, which was published in the **Federal Register** at 86 FR 11523 (Feb. 25, 2021).

Federal Communications Commission.

Marlene Dortch,
Secretary.

[FR Doc. 2021-05424 Filed 3-15-21; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[FRS 17568]

Privacy Act of 1974; System of Records

AGENCY: Federal Communications Commission.

ACTION: Notice of a modified system of records.

SUMMARY: The Federal Communications Commission (FCC, Commission, or Agency) has modified an existing system of records, FCC/WTB-7, Licensing and Related Support Services (formerly FCC/WTB-7, Remedy Action Request System (RARS)), subject to the Privacy Act of 1974, as amended. This action is necessary to meet the requirements of the Privacy Act to publish in the **Federal Register** notice of the existence and character of records maintained by the Agency. The FCC uses this information to record and process requests for assistance from individuals or groups in connection with FCC systems, research tools, electronic databases, licenses, authorizations, and registrations.

DATES: This action will become effective on March 16, 2021. Written comments on the system's routine uses are due by April 15, 2021. The routine uses in this action will become effective on April 15, 2021, unless written comments are received that require a contrary determination.

ADDRESSES: Send comments to Privacy Team, Office of General Counsel, Federal Communications Commission (FCC), 45 L Street NE, Washington, DC 20554 or Privacy@fcc.gov.

FOR FURTHER INFORMATION CONTACT: Margaret Drake, Privacy Team, Office of General Counsel, Federal Communications Commission, 45 L Street NE, Washington, DC 20554, 202-418-1707, or Privacy@fcc.gov (and to obtain a copy of the Narrative Statement

and the Supplementary Document, which includes details of the modifications to this system of records).

SUPPLEMENTARY INFORMATION: The Wireless Telecommunications Bureau (WTB) uses the information in FCC/WTB-7 to record and process requests for assistance from individuals or groups in connection with FCC systems, research tools, electronic databases, licenses, authorizations, and registrations.

This notice serves to modify FCC/WTB-7 to reflect various necessary changes and updates, which include clarification of the purpose of the system, format changes required by OMB Circular A-108 since its previous publication, the revision of five Routine Uses, and the addition of two new Routine Uses. The substantive changes and modification to the previously published version of FCC/WTB-7 (formerly FCC/WTB-7, Remedy Action Request System (RARS)) system of records include:

1. Changing the name of the system of records to FCC/WTB-7, Licensing and Related Support Services.
2. Updating the Security Classification to follow OMB and FCC guidance.
3. Clarifying the Purpose for the system.
4. Updating and/or revising language in six Routine Uses: (1) Third Parties, (2) Adjudication and Litigation, (3) Law Enforcement and Investigation, (4) Congressional Inquiries, (5) Government-wide Program Management and Oversight, and (6) Breach Notification, the changes to this routine required by OMB Memorandum M-17-12.

6. Adding two new Routine Uses: (7) Assistance to Federal Agencies and Entities, to allow the FCC to provide assistance to other Federal agencies in their data breach situations, as required by OMB Memorandum M-17-12; and (8) For Non-Federal Personnel, to allow contractors performing or working on a contract for the Federal Government access to information in this system.

7. Adding two new sections: Reporting to a Consumer Reporting Agency, to address valid and overdue debts owed by individuals to the FCC under the Debt Collection Act, as recommended by OMB; and a History section referencing the previous publication of this SORN in the **Federal Register**, as required by OMB Circular A-108.

The system of records is also updated to reflect various administrative changes related to the policy and practices for storage and retrieval of the information;

administrative, technical, and physical safeguards; and updated notification, records access, and procedures to contest records.

SYSTEM NAME AND NUMBER:

FCC/WTB-7, LICENSING AND RELATED SUPPORT SERVICES.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Wireless Telecommunications Bureau (WTB), Federal Communications Commission (FCC), Washington, DC 20554.

SYSTEMS MANAGER(S) AND ADDRESS:

Wireless Telecommunications Bureau (WTB), Federal Communications Commission (FCC), Washington, DC 20554.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

47 U.S.C. 151, 154, 208, 258, 301, 303, 309(e), and 312.

PURPOSE(S) OF THE SYSTEM:

The FCC staff uses the records in this system to process requests for assistance from individuals or groups in connection with FCC systems, research tools, electronic databases, licenses, authorizations, and registrations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The categories of individuals in the system include individuals who request assistance in connection with FCC systems, research tools, electronic databases, licenses, authorizations, and registrations.

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records in the system include:

1. Requests for assistance by the requester's first name, last name, telephone number and extension, international telephone number and extension, email address(es), computer operating system, web browser, FCC Registration Number (FRN), and personal security question and answer.
2. Records verifying identity information by the individual's first name, last name, contact telephone number, FRN, and personal security question and answer.

RECORD SOURCE CATEGORIES:

Information in this system is provided by users who request assistance in connection with FCC systems, research tools, electronic databases, licenses, authorizations, and registrations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed to authorized entities, as is determined to be relevant and necessary, outside the FCC as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows.

1. Third Parties—To third parties, including Federal, state, local, or tribal agencies, or entities that may be subject to the Communications Act of 1934, as amended, to resolve requests for assistance.

2. Adjudication and Litigation—To disclose to the Department of Justice (DOJ), or to other administrative or adjudicative bodies before which the FCC is authorized to appear, when: (a) The FCC or any component thereof; or (b) any employee of the FCC in his or her official capacity; or (c) any employee of the FCC in his or her individual capacity where the DOJ or the FCC have agreed to represent the employee; or (d) the United States is a party to litigation or has an interest in such litigation, and the use of such records by the DOJ or the FCC is deemed by the FCC to be relevant and necessary to the litigation.

3. Law Enforcement and Investigation—To disclose pertinent information to the appropriate Federal, State, local, or tribal agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, when the FCC becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation.

4. Congressional Inquiries—To 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.

5. Government-wide Program Management and Oversight—To provide information to the National Archives and Records Administration (NARA) for the use in its records management inspections; to the Department of Justice (DOJ) to obtain that department's advice regarding disclosure obligations under the Freedom of Information Act; or to the Office of Management and Budget (OMB) to obtain that office's advice regarding obligations under the Privacy Act.

6. Breach Notification—To appropriate agencies, entities, and persons when: (a) The Commission suspects or has confirmed that there has

been a breach of PII maintained in the system of records; (b) the Commission 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 system, 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.

7. Assistance to Federal Agencies and Entities—To another Federal agency or Federal entity, when the Commission determines that information from this system 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, program, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

8. Non-Federal Personnel—To disclose information to third parties, including contractors, performing or working on a contract in connection with resolving requests for assistance and/or IT services for the Federal Government, who may require access to this system of records.

REPORTING TO A CONSUMER REPORTING AGENCY:

In addition to the routine uses cited above, the Commission may share information from this system of records with a consumer reporting agency regarding an individual who has not paid a valid and overdue debt owed to the Commission, following the procedures set out in the Debt Collection Act, 31 U.S.C. 3711(e).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Information in the information system consists of electronic data, files, and records, which are housed in the FCC's computer network databases. Any paper documents that WTB receives are scanned into the electronic database upon receipt, and then the paper documents are destroyed.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

The electronic data, files, and records may be retrieved by searching electronically using a variety of parameters including the requester's name, entity name, telephone number, licensee, applicant or unlicensed

individual, call sign, file number, problem type, FRN, email address, and/or subject matter.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The information in the system is maintained according to General Records Schedules 5.8 and 6.5. The electronic records, files, and data are destroyed physically (electronic storage media) or by electronic erasure. Paper documents are destroyed by shredding after they are scanned into the information system's electronic databases.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The records in the FCC's computer network are protected by the FCC privacy safeguards, a comprehensive and dynamic set of IT safety and security protocols and features that are designed to meet all Federal IT privacy standards, including those required by the Federal Information Security Modernization Act of 2014 (FISMA), the Office of Management and Budget (OMB), and the National Institute of Standards and Technology (NIST).

RECORDS ACCESS PROCEDURES:

Individuals wishing to request access to and/or amendment of records about themselves should follow the Notification Procedure below.

CONTESTING RECORD PROCEDURES:

Individuals wishing to request an amendment of records about themselves should follow the Notification Procedure below.

NOTIFICATION PROCEDURE:

Individuals wishing to determine whether this system of records contains information about themselves may do so by writing to the Privacy Team, Office of General Counsel, Federal Communications Commission, Washington, DC 20554, Privacy@fcc.gov.

Individuals requesting access must also comply with the FCC's Privacy Act regulations regarding verification of identity to gain access to the records (47 CFR part 0, subpart E).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

The FCC last gave full notice of this system of records, FCC/WTB-7, Licensing and Related Support Services (formerly: FCC/WTB-7, Remedy Action Request System (RARS)), by publication in the **Federal Register** on May 28, 2010 (75 FR 30025).

Federal Communications Commission.

Marlene H. Dortch,
Secretary.

[FR Doc. 2021-05425 Filed 3-15-21; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID: 17565]

Privacy Act of 1974; Matching Program

AGENCY: Federal Communications Commission.

ACTION: Notice of a new matching program.

SUMMARY: In accordance with the Privacy Act of 1974, as amended ("Privacy Act"), this document announces the modification of a computer matching program the Federal Communications Commission ("FCC" or "Commission" or "Agency") and the Universal Service Administrative Company (USAC) will conduct with the Indiana Family and Social Services Administration Division of Family Resources (FSSA/DFR) ("Agency"). The purpose of this matching program is to verify the eligibility of applicants to and subscribers of Lifeline (existing purpose) and the new Emergency Broadband Benefit Program, both of which are administered by USAC under the direction of the FCC. More information about these programs is provided in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Written comments are due on or before April 15, 2021. This computer matching program will commence on April 15, 2021, and will conclude 18 months after the effective date.

ADDRESSES: Send comments to Margaret Drake, FCC, 45 L Street NE, Washington, DC 20554, or to Privacy@fcc.gov.

FOR FURTHER INFORMATION CONTACT: Margaret Drake at 202-418-1707 or Privacy@fcc.gov.

SUPPLEMENTARY INFORMATION: The Lifeline program provides support for discounted broadband and voice services to low-income consumers. Lifeline is administered by the Universal Service Administrative Company (USAC) under FCC direction. Consumers qualify for Lifeline through proof of income or participation in a qualifying program, such as Medicaid, the Supplemental Nutritional Assistance Program (SNAP), Federal Public Housing Assistance, Supplemental Security Income (SSI), Veterans and Survivors Pension Benefit, or various Tribal-specific Federal assistance programs.

The Emergency Broadband Benefit Program (EBBP) was established by Congress in the Consolidated Appropriations Act of 2021, Public Law 116-260, 134 Stat. 1182. EBBP is a program that will help low-income Americans obtain discounted broadband service and one-time co-pay for a connected device (laptop, desktop computer or tablet). This program was created specifically to assist American families' access to broadband, which has proven to be essential for work, school, and healthcare during the public health emergency that exists as a result of COVID-19. A household may qualify for the EBBP benefit under various criteria, including an individual qualifying for the FCC's Lifeline program.

In a Report and Order adopted on March 31, 2016 (81 FR 33026 (May 24, 2016)), the Commission ordered USAC to create a National Lifeline Eligibility Verifier ("National Verifier"), including the National Lifeline Eligibility Database (LED), that would match data about Lifeline applicants and subscribers with other data sources to verify the eligibility of an applicant or subscriber. The Commission found that the National Verifier would reduce compliance costs for Lifeline service providers, improve service for Lifeline subscribers, and reduce waste, fraud, and abuse in the program.

The Consolidated Appropriations Act of 2021 directs the FCC to leverage the National Verifier to verify applicants' eligibility for EBBP. The purpose of this matching program is to verify the eligibility of EBBP applicants and subscribers by determining whether they receive Medicaid or Supplemental Nutrition Assistance Program (SNAP) benefits administered by the Indiana Family and Social Services Administration Division of Family Resources. Under FCC rules, consumers receiving these benefits qualify for Lifeline discounts and also for EBBP benefits.

Participating Non-Federal Agencies

Indiana Family and Social Services Administration Division of Family Resources.

Authority for Conducting the Matching Program

The authority for the FCC's EBBP is Consolidated Appropriations Act of 2021, Public Law 116-260, 134 Stat. 1182; 47 CFR part 54, subpart P. The authority for the FCC's Lifeline program is 47 U.S.C. 254; 47 CFR part 54, subpart E; Lifeline and Link Up Reform and Modernization, *et al.*, Third Report and Order, Further Report and Order, and

Order on Reconsideration, 31 FCC Rcd 3962, 4006-21, paras. 126-66 (2016) 81 FR 33026 (May 24, 2016) (*2016 Lifeline Modernization Order*).

Purpose(s)

In the 2016 Lifeline Modernization Order, the FCC required USAC to develop and operate the National Verifier to improve efficiency and reduce waste, fraud, and abuse in the Lifeline program. The stated purpose of the National Verifier is "to increase the integrity and improve the performance of the Lifeline program for the benefit of a variety of Lifeline participants, including Lifeline providers, subscribers, states, community-based organizations, USAC, and the Commission." 31 FCC Rcd 3962, 4006, para. 126. To help determine whether Lifeline applicants and subscribers are eligible for Lifeline benefits, the Order contemplates that the USAC-operated LED will communicate with information systems and databases operated by other Federal and State agencies. Id. at 4011-2, paras. 135-7. The Consolidated Appropriations Act of 2021 directs the FCC to leverage the National Verifier to verify applicants' eligibility for EBBP.

The purpose of this modified matching agreement is to verify the eligibility of applicants and subscribers to Lifeline (existing purpose), as well as to the new EBBP and to other Federal programs that use qualification for Lifeline as an eligibility criterion. This new agreement would replace the existing agreement with Indiana, which permits matching only for the Lifeline program by checking an applicant's/ subscriber's participation in SNAP and Medicaid. Under FCC rules, consumers receiving these benefits qualify for Lifeline discounts and also for EBBP benefits.

Categories of Individuals

The categories of individuals whose information is involved in the matching program include, but are not limited to, those individuals who have applied for Lifeline and/or EBBP benefits; are currently receiving Lifeline and/or EBBP benefits; are individuals who enable another individual in their household to qualify for Lifeline and/or EBBP benefits; are minors whose status qualifies a parent or guardian for Lifeline and/or EBBP benefits; or are individuals who have received Lifeline and/or EBBP benefits.

Categories of Records

The categories of records involved in the matching program include, but are not limited to, the last four digits of the applicant's Social Security Number,

date of birth, first name, and last name. The National Verifier will transfer these data elements to the Indiana Family and Social Services Administration Division of Family Resources which will respond either “yes” or “no” that the individual is enrolled in a qualifying assistance program: Indiana Family and Social Services Administration Division of Family Resources, SNAP or Medicaid.

System(s) of Records

The records shared as part of this matching program reside in the Lifeline system of records, FCC/WCB-1, Lifeline, which was published in the **Federal Register** at 86 FR 11526 (Feb. 25, 2021).

The records shared as part of this matching program reside in the EBBP system of records, FCC/WCB-3, Emergency Broadband Benefit Program, which was published in the **Federal Register** at 86 FR 11523 (Feb. 25, 2021).

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2021-05423 Filed 3-15-21; 8:45 am]

BILLING CODE 6712-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Annual Statistical Report on Children in Foster Homes and Children in Families Receiving Payment in Excess of the Poverty Income Level From a State Program Funded Under Part A of Title IV of the Social Security Act (OMB #0970-0004)

AGENCY: Office of Family Assistance, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Family Assistance (OFA), Administration for Children and Families, is requesting a 3-year extension of the form ACF-4125: Annual Report on Children in Foster Homes and Children in Families Receiving Payment in Excess of the Poverty Income Level from a State Program Funded Under Part A of Title IV of the Social Security Act (OMB #0970-0004, expiration 3/21/2021). There are no changes requested to the form.

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 Elementary and Secondary Education Act of 1965 (ESEA), section 1124 of Title I, as amended by Public Law 114-95, requires the Secretary of Health and Human Services to determine the number of children aged 5 to 17, inclusive, that (1) are being supported in foster homes with public funds; or (2) are from families receiving assistance payments in excess of the current poverty income level for a family of four. The information gathered is to be passed on to the Secretary of Education for purposes of allocating grants authorized under this law. The statute requires that the formula to allocate these grants and distribute funds be based, in part, on October caseload data on the number of children in foster care or in families receiving payments from state programs funded under Title IV-A of the Social Security Act [Temporary Assistance for Needy Families]. The purpose of this annual survey is to provide annually updated data so that funds may be allocated in accordance with the ESEA.

Respondents: State agencies (including the District of Columbia and Puerto Rico) administering child welfare and public assistance programs.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Total annual burden hours
Annual Report on Children in Foster Homes and Children Receiving Payments	52	1	264.35	13,746.20

Estimated Total Annual Burden Hours: 13,746.20.

Authority: Pub. L. 107-110 Sec. 1124(c)(4) and Pub. L. 104-193 Sec. 110(j).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021-05413 Filed 3-15-21; 8:45 am]

BILLING CODE 4184-36-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Community-Based Family Resource and Support Grants (Name Changed to Child Abuse Prevention Program—OIS Notified 6/2007) (OMB No.: 0970-0155)

AGENCY: Children’s Bureau, Administration on Children, Youth and Families, HHS.

ACTION: Request for Public Comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the Program Instruction (PI) for the Community-Based Family Resource and Support Grants or the Community-Based Child Abuse Prevention (CBCAP) program (OMB No.: 0970-0155, expiration 3/31/2021), which outlines information collection requirements pursuant to receiving a grant award. There are no changes requested to the information collection process.

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 PI, prepared in response to the enactment of the CBCAP program, as set forth in Title II of the Child Abuse Prevention and Treatment Reauthorization Act of 2010 (Public Law 111–320) or CAPTA, provides direction to the states and territories to accomplish the purposes of (1) supporting community-based efforts to develop, operate, expand, and where appropriate to network, initiatives aimed at the prevention of child abuse and neglect, and to support networks of coordinated resources and activities to better strengthen and support families to

reduce the likelihood of child abuse and neglect; and (2) fostering an understanding, appreciation, and knowledge of diverse populations in order to be effective in preventing and treating child abuse and neglect. This PI contains information collection requirements that are found in CAPTA and pursuant to receiving a grant award. The information submitted will be used by the agency to ensure compliance with the statute, complete the calculation of the grant award entitlement, and provide training and technical assistance to the grantee.

Respondents: State governments, quasi-public entities, and non-profit private agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Total annual burden hours
Application	52	1	40	2,080
Annual Report	52	1	24	1,248

Estimated Total Annual Burden Hours: 3,328.

Authority: The CAPTA Reauthorization Act of 2010; Title II of the CAPTA, Pub. L. 115–271 (42 U.S.C. 5116 *et seq.*).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–05411 Filed 3–15–21; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Social Services Block Grant (SSBG) Post-Expenditure Report, Pre-Expenditure Report, and Intended Use Plan (OMB #0970–0234)

AGENCY: Office of Community Services, Administration for Children and Families, HHS.

ACTION: Request for Public Comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a revision to the Social Services Block Grant (SSBG) Post-Expenditure Report, Pre-Expenditure Report, and Intended Use Plan (OMB #0970–0234, previously titled, “Social Services Block Grant (SSBG) Post-Expenditure Report”). ACF is proposing

to expand the information collection to include the collection of states’ Intended Use Plans and retitle the information collection to clarify the role of the Pre-Expenditure Report.

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: On an annual basis, states and territories are required to submit the following reports: (1) An Intended Use Plan that provides data and narrative descriptions related to the state’s SSBG program. The Intended Use Plan includes details about the delivery of SSBG services, and the state agency administering the SBG Program. ACF is proposing to expand the currently approved information collection to include collection of states’ Intended

Use Plans. Grantees are required to submit their Pre-Expenditure Report no less than 30 days prior to the start of the period covered by the report. (2) A Pre-Expenditure Report that demonstrates the state’s anticipated allocation of SSBG funding among the 29 pre-defined SSBG service categories. Historically, states have submitted this report using the Post-Expenditure Report Form, and the associated burden is included in the currently approved information collection. Grantees are required to submit their Intended Use Plan no less than 30 days prior to the start of the period covered by the report. (3) A Post-Expenditure Report that details the state’s actual use of SSBG funding among each of the 29 service categories. Grantees are required to submit their Post-Expenditure Report within 6 months of the end of the period covered by the report.

Respondents: Agencies that administer the SSBG at the state or territory level, including the 50 states; District of Columbia; Puerto Rico; and the territories of American Samoa, Guam, the Virgin Islands, and the Commonwealth of Northern Mariana Islands.

Annual Burden Estimates: This request is specific to the Intended Use Plan. Currently approved materials and associated burden can be found at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202011-0970-006.

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Total/annual burden hours
Intended Use Plan	56	1	40	2,240.

Estimated Total Annual Burden Hours: 2,240.

Authority: 42 U.S.C. 1397 through 1397e.

Mary B. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2021-05408 Filed 3-15-21; 8:45 am]

BILLING CODE 4184-24-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0547]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on “Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types.”

DATES: Submit either electronic or written comments on the collection of information by May 17, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 17, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 17, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service

acceptance receipt is on or before that date.

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-2012-N-0547 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal

Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and

assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types

OMB Control Number 0910–0744—Extension

I. Background

From 1998 to 2008, the FDA’s National Retail Food Team conducted a study to measure trends in the occurrence of foodborne illness risk factors, preparation practices, and employee behaviors most commonly reported to the Centers for Disease Control and Prevention as contributing factors to foodborne illness outbreaks at the retail level. Specifically, data was collected by FDA Specialists in retail and foodservice establishments at 5-year intervals (1998, 2003, and 2008) in order to observe and document trends in the occurrence of the following foodborne illness risk factors:

- Food from Unsafe Sources,
- Poor Personal Hygiene,
- Inadequate Cooking,
- Improper Holding/Time and Temperature, and
- Contaminated Equipment/Cross-Contamination.

FDA developed reports summarizing the findings for each of the three data collection periods, released in 2000, 2004, and 2009 (Refs. 1 to 3). Data from all three data collection periods were analyzed to detect trends in improvement or regression over time and to determine whether progress had been made toward the goal of reducing the occurrence of foodborne illness risk factors in selected retail and foodservice facility types (Ref. 4).

Using this 10-year survey as a foundation, in 2013–2014, FDA initiated a new study in full-service and fast-food restaurants. This study will span 10 years with data collections completed in 2013–2014 and 2017–2018, and an additional collection planned for 2021–2022. Three data collections are necessary to trend the data. Data collected in 2013–2014 is published, and data from 2017–2018 is currently being evaluated for trends and significance.

TABLE 1—DESCRIPTION OF THE FACILITY TYPES INCLUDED IN THE SURVEY

Facility type	Description
Full-Service Restaurants	A restaurant where customers place their orders at their tables, are served their meals at the tables, receive the services of the wait staff, and pay at the end of the meals.
Fast-Food Restaurants	A restaurant that is not a full-service restaurant. This includes restaurants commonly referred to as quick-service restaurants and fast, casual restaurants.

The results of this 10-year study period will be used to:

- Develop retail food safety initiatives, policies, and targeted intervention strategies focused on controlling foodborne illness risk factors;
- Provide technical assistance to State, local, tribal, and territorial regulatory professionals;
- Identify FDA retail work plan priorities; and
- Inform FDA resource allocation to enhance retail food safety nationwide.

The statutory basis for FDA conducting this study is derived from the Public Health Service Act (PHS Act) (42 U.S.C. 243, section 311(a)). Responsibility for carrying out the provisions of the PHS Act relative to food protection was transferred to the Commissioner of Food and Drugs in 1968 (21 CFR 5.10(a)(2) and (4)). Additionally, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*)

and the Economy Act (31 U.S.C. 1535) require FDA to provide assistance to other Federal, State, and local government bodies.

The objectives of this study are to:

- Identify the least and most often occurring foodborne illness risk factors and food safety behaviors/practices in restaurants within the United States;
- Determine the extent to which Food Safety Management Systems and the presence of a Certified Food Protection Manager impact the occurrence of foodborne illness risk factors and food safety behaviors/practices; and
- Determine whether the occurrence of foodborne illness risk factors food safety behaviors/practices in delis differs based on an establishment’s risk categorization and status as a single-unit or multiple-unit operation (*e.g.*, restaurants that are part of an operation with two or more units).

The methodology to be used for this information collection is described as

follows. To obtain a sufficient number of observations to conduct statistically significant analysis, FDA will conduct approximately 400 data collections in each facility type. This sample size has been calculated to provide for sufficient observations to be 95 percent confident that the compliance percentage is within 5 percent of the true compliance percentage.

A geographical information system database containing a listing of businesses throughout the United States provides the establishment inventory for the data collections. FDA samples establishments from the inventory based on the descriptions in table 1. FDA does not intend to sample operations that handle only prepackaged food items or conduct low-risk food preparation activities. The “FDA Food Code” contains a grouping of establishments by risk, based on the type of food preparation that is normally conducted within the operation (Ref. 5). The intent

is to sample establishments that fall under risk categories 2 through 4.

FDA has approximately 25 Retail Food Specialists (Specialists) who serve as the data collectors for the 10-year study. The Specialists are geographically dispersed throughout the United States and possess technical expertise in retail food safety and a solid understanding of the operations within each of the facility types to be surveyed. The Specialists are also standardized by FDA's Center for Food Safety and Applied Nutrition personnel in the application and interpretation of the FDA Food Code (Ref. 5).

Sampling zones have been established that are equal to the 175-mile radius around a Specialist's home location. The sample is selected randomly from among all eligible establishments located within these sampling zones. The Specialists are generally located in major metropolitan areas (*i.e.*, population centers) across the contiguous United States. Population centers usually contain a large concentration of the establishments FDA intends to sample. Sampling from the 175-mile radius sampling zones around the Specialists' home locations provides three advantages to the study:

1. It provides a cross-section of urban and rural areas from which to sample the eligible establishments.
2. It represents a mix of small, medium, and large regulatory entities having jurisdiction over the eligible establishments.
3. It reduces overnight travel and, therefore, reduces travel costs incurred by the Agency to collect data.

The sample for each data collection period is evenly distributed among Specialists. Given that participation in the study by industry is voluntary and the status of any given randomly selected establishment is subject to change, substitute establishments have been selected for each Specialist for cases where the restaurant facility is misclassified, closed, or otherwise unavailable, unable, or unwilling to participate.

Prior to conducting the data collection, Specialists contact the State or local jurisdiction that has regulatory responsibility for conducting retail food inspections for the selected establishment. The Specialist verifies with the jurisdiction that the facility has been properly classified for the purposes of the study and is still in operation. The Specialist ascertains whether the selected facility is under legal notice from the State or local regulatory authority. If the selected facility is under legal notice, the Specialist will not conduct a data

collection, and a substitute establishment will be used. An invitation is extended to the State or local regulatory authority to accompany the Specialist on the data collection visit.

A standard form is used by the Specialists during each data collection. The form is divided into three sections: Section 1—"Establishment Information"; Section 2—"Regulatory Authority Information"; and Section 3—"Foodborne Illness Risk Factor and Food Safety Management System Assessment." The information in Section 1 "Establishment Information" of the form is obtained during an interview with the establishment owner or person in charge by the Specialist and includes a standard set of questions.

The information in Section 2 "Regulatory Authority Information" is obtained during an interview with the program director of the State or local jurisdiction that has regulatory responsibility for conducting inspections for the selected establishment.

Section 3 includes three parts: Part A for tabulating the Specialists' observations of the food employees' behaviors and practices in limiting contamination, proliferation, and survival of food safety hazards; Part B for assessing the food safety management system being implemented by the facility; and Part C for assessing the frequency and extent of food employee handwashing. The information in Part A is collected from the Specialists' direct observations of food employee behaviors and practices. Infrequent, nonstandard questions may be asked by the Specialists if clarification is needed on the food safety procedure or practice being observed. The information in Part B is collected by making direct observations and asking follow-up questions of facility management to obtain information on the extent to which the food establishment has developed and implemented food safety management systems. The information in Part C is collected by making direct observations of food employee handwashing. No questions are asked in the completion of Section 3, Part C of the form.

FDA collects the following information associated with the establishment's identity: Establishment name, street address, city, State, ZIP Code, county, industry segment, and facility type. The establishment-identifying information is collected to ensure the data collections are not duplicative. Other information related to the nature of the operation, such as seating capacity and number of

employees per shift, is also collected. Data will be consolidated and reported in a manner that does not reveal the identity of any establishment included in the study.

FDA has collaborated with the Food Protection and Defense Institute to develop a web-based platform in FoodSHIELD to collect, store, and analyze data for the Retail Risk Factor Study. This platform is accessible to State, local, territorial, and tribal regulatory jurisdictions to collect data relevant to their own risk factor studies. For the 2015–2016 data collection, FDA piloted the use of hand-held technology for capturing the data onsite during the data collection visits. The tablets that were made available for the data collections were part of a broader Agency initiative focused on internal uses of hand-held technology. The tablets provided for the data collection presented several technical and logistical challenges and increased the time burden associated with the data collection as compared to the manual entry of data collections. For these reasons, FDA will not be further evaluating hand-held technology in subsequent data collections during the 10-year study period.

When a data collector is assigned a specific establishment, he or she conducts the data collection and enters the information into the web-based data platform. The interface will support the manual entering of data, as well as the ability to directly enter information in the database via a web browser.

The burden for the 2021–2022 data collection is as follows. For each data collection, the respondents will include: (1) The person in charge of the selected facility (whether it be a fast-food or full-service restaurant); and (2) the program director (or designated individual) of the respective regulatory authority. In order to provide the sufficient number of observations needed to conduct a statistically significant analysis of the data, FDA has determined that 400 data collections will be required in each of the two restaurant facility types. Therefore, the total number of responses will be 1,600 (400 data collections \times 2 facility types \times 2 respondents per data collection).

The burden associated with the completion of Sections 1 and 3 of the form is specific to the persons in charge of the selected facilities. The burden includes the time it will take the person in charge to accompany the data collector during the site visit and answer the data collector's questions. The burden related to the completion of Section 2 of the form is specific to the program directors (or designated

individuals) of the respective regulatory authorities. The burden includes the time it will take to answer the data collectors' questions and is the same regardless of the facility type.

To calculate the estimate of the hours per response, FDA will use the average data collection duration for the same facility types during the 2015–2016 data collection. FDA estimates that it will take the persons in charge of full-service restaurants and fast-food restaurants 104 minutes (1.73 hours) and 82 minutes (1.36 hours), respectively, to accompany the data collectors while they complete Sections 1 and 3 of the form. In comparison, for the 2017–2018 data

collection, the burden estimate was 106 minutes (1.76 hours) in full-service restaurants and 73 minutes (1.21 hours) in fast-food restaurants. FDA estimates that it will take the program director (or designated individual) of the respective regulatory authority 30 minutes (0.5 hours) to answer the questions related to Section 2 of the form. This burden estimate is unchanged from the last data collection. Hence, the total burden estimate for a data collection in a full-service restaurant, including both the program director's and the person in charge's responses, is 134 minutes (104 + 30) (2.23 hours). The total burden

estimate for a data collection in a fast-food restaurant, including both the program director's and the person in charge's responses, is 112 minutes (82 + 30) (1.86 hours).

Based on the number of entry refusals from the 2017–2018 data collection, we estimate a refusal rate of 2 percent for the data collections within restaurant facility types. The estimate of the time per non-respondent is 5 minutes (0.08 hours) for the person in charge to listen to the purpose of the visit and provide a verbal refusal of entry.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Number of non-respondents	Number of responses per non-respondent	Total annual non-responses	Average burden per response	Total hours
2021–2022 Data Collection (Fast Food Restaurants)—Completion of Sections 1 and 3.	400	1	400	1.36	544
2021–2022 Data Collection (Full-Service Restaurants)—Completion of Sections 1 and 3.	400	1	400	1.73	692
2021–2022 Data Collection—Completion of Section 2—All Facility Types.	800	1	800	0.5 (30 minutes)	400
2021–2022 Data Collection—Entry Refusals—All Facility Types.	16	1	16	0.08 (5 minutes)	1.28
Total Hours	1,637.28

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

II. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, "Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors (2000)." Available at <https://wayback.archive-it.org/7993/20170406023019/https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM123546.pdf>
2. FDA, "FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)." Available at <https://wayback.archive-it.org/7993/20170406023011/https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM423850.pdf>
3. FDA, "FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store

Facility Types (2009)." Available at <https://wayback.archive-it.org/7993/20170406023004/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm224321.htm>

4. FDA National Retail Food Team, "FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998–2008)." (2010). Available at <https://wayback.archive-it.org/7993/20170406022950/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm223293.htm>
5. FDA, "FDA Food Code." Available at <https://www.fda.gov/FoodCode>.

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–05325 Filed 3–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1857]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Animal Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements associated with current good manufacturing practice,

hazard analysis, and risk-based preventive controls for human and animal food.

DATES: Submit either electronic or written comments on the collection of information by May 17, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 17, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 17, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-2018-N-1857 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Animal Food." Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

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: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Current Good Manufacturing Practice and Hazard Analysis, and Risk-Based Preventive Controls for Human Food—21 CFR Part 117; Current Good Manufacturing Practice and Hazard Analysis, and Risk-Based Preventive Controls for Animal Food—21 CFR Part 507

OMB Control Number 0910-0751—Revision

This information collection supports FDA regulations setting forth criteria and definitions applicable to human food and to animal food, as established under the FDA Food Safety and Modernization Act (FSMA) (Pub. L.

111–353). Congress enacted FSMA in response to dramatic changes in the global food system and in our understanding of foodborne illness and its consequences, including the realization that preventable foodborne illness is both a significant public health problem and a threat to the economic well-being of the food system. The purpose of the regulations is to prevent the introduction of adulterated and/or misbranded products into the marketplace and ensure the safety of both human foods and animal foods in accordance with sections 402 and 403 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342 and 343). Generally, domestic and foreign food facilities that are required to register in accordance with section 415 of the FD&C Act (21 U.S.C. 350d) must comply with these requirements, unless an exemption applies. It is important to note, however, that applicability of the current good manufacturing practice requirements is not dependent upon whether a facility is required to register. Regulations governing human food are set forth in part 117 (21 CFR part 117),

while regulations governing animal food are found in part 507 (21 CFR part 507). Respondents to the information collection are those who manufacture, prepare, pack, or hold food intended for humans or animals.

The regulations include recordkeeping necessary to demonstrate compliance with the requirements; however, respondents that meet the definition of a “qualified facility,” under 21 CFR 117.3 and 507.3, are subject to reporting. To be subject to the modified requirements set forth in part 117, subpart D and part 507, subpart D for human food and animal food, respectively, respondents must attest to their status. To assist respondents in this regard, we have developed Forms FDA 3942a (Quality Facility Attestation: Human Food) and 3942b (Quality Facility Attestation: Animal Food), available for downloading from our website at: <https://www.fda.gov/food/registration-food-facilities-and-other-submissions/qualified-facility-attestation>.

Section 418(l)(2)(B)(ii) of the FD&C Act (21 U.S.C. 350g(l)(2)(B)(ii)) directs

us to issue guidance on documentation required to determine status as a qualified facility. Accordingly, we issued a guidance for industry entitled “Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals,” also available for downloading from our website at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-determination-status-qualified-facility>. The guidance discusses the content, format, frequency, and timing of submissions. For efficiency of Agency operations, we are now accounting for burden we attribute to reporting associated with Forms FDA 3942a and 3942b, currently approved under OMB control number 0910–0854, with this information collection.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section; reporting	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
117.201(c); qualified facility as reported on Form FDA 3942a.	37,134	² 0.5	18,567	0.5 (30 minutes)	9,284
507.7(c); qualified facility as reported on Form FDA 3942b.	1,120	0.5	560	0.5 (30 minutes)	280
Total	9,564

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Reporting occurs biennially.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN: HUMAN FOODS ¹

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
117.126(c) and 117.170(d); food safety plan and reanalysis.	46,685	1	46,685	110	5,135,350
117.136; assurance records	16,285	1	16,285	0.25 (15 minutes)	4,071
117.145(c); monitoring records	8,143	730	5,944,390	0.05 (3 minutes)	297,220
117.150(d); corrective actions and corrections records.	16,285	2	32,570	1	32,570
117.155(b); verification records	8,143	244	1,986,892	0.05 (3 minutes)	99,345
117.160; validation records	3,677	6	22,062	0.25 (15 minutes)	5,515
117.475(c)(7)–(9); supplier records	16,285	10	162,850	4	651,400
117.180(d); training records for preventive controls qualified individual.	46,685	1	46,685	0.25 (15 minutes)	11,671
Total	6,237,142

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN: ANIMAL FOODS ¹

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours ²
Subpart A—General Provisions					
507.4(d); documentation of animal food safety and hygiene training.	7,469	0.75	5,579	0.05 (3 minutes)	279
Subpart C—Hazard Analysis and Risk-Based Preventive Controls					
507.31 through 507.55; food safety plan—including hazard analysis, preventive controls, and procedures for monitoring, corrective actions, verification, recall plan, validation, reanalysis, modifications, and implementation records.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Subpart E—Supply Chain Program					
507.105 through 507.175; written supply-chain program—including records documenting program.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Subpart F—Requirements Applying to Records That Must Be Established and Maintained					
507.200 through 507.215; general requirements, additional requirements applying to food safety plan, requirements for record retention, use of existing records, and special requirements applicable to written assurance.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Total	11,635,372	1,163,258

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.² Total hours have been rounded.TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN: HUMAN FOODS ¹

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
117.201(e); disclosure of food manufacturing facility address.	37,134	1	37,134	0.25 (15 minutes)	9,284

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.TABLE 5—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
507.27(b); labeling for the animal food product contains the specific information and instructions needed so the food can be safely used for the intended animal species.	330	10	3,300	0.25 (15 minutes)	825
507.7(e)(1); change labels on products with labels.	1,120	4	4,480	1	4,480
507.7(e)(2); change address on labeling (sales documents) for qualified facilities.	974	1	974	1	974
507.25(a)(2); animal food, including raw materials, other ingredients, and rework, is accurately identified.	373	312	116,376	0.01 (36 seconds)	1,163.76
507.28(b); holding and distribution of human food byproducts for use as animal food.	40,798	2	81,596	0.25 (15 minutes)	20,399
Total	27,841.76

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made slight

adjustments to reflect a decrease in third-party disclosure burden associated with animal foods. In this submission

we provide a cumulative estimate for related disclosure activities that we had previously accounted for separately.

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-05332 Filed 3-15-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-5666]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Empirical Study of Promotional Implications of Proprietary Prescription Drug Names

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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by April 15, 2021.

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 title of this information collection is “Empirical Study of Promotional Implications of Proprietary Prescription Drug Names.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@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.

Empirical Study of Promotional Implications of Proprietary Prescription Drug Names

OMB Control Number 0910-NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

The Office of Prescription Drug Promotion’s (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. OPDP’s research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission. Our research focuses in particular on three main topic areas: (1) Advertising features, including content and format; (2) target populations; and (3) research quality. Through the evaluation of advertising features we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits; focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience; and our focus on research quality aims at maximizing the quality of our research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first two topic areas, advertising features and target populations.

Because we recognize that the strength of data and the confidence in the robust nature of the findings is improved by utilizing the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage, which can be found at: <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/>

[cder/ucm090276.htm](https://www.fda.gov/oc/ucm090276.htm). The website includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office. The website maintains information on studies we have conducted, dating back to a survey on direct-to-consumer advertisements conducted in 1999.

During the prescription drug approval process, sponsors propose proprietary names for their products. These names undergo a proprietary name review that involves the Office of Drug Safety, the relevant medical office, and OPDP. OPDP reviews names to assess for alignment with the FD&C Act, which, among other things, provides that labeling can misbrand a product if false or misleading representations are made (see 21 U.S.C. 321(n), 352(a)). A proprietary name, which appears in labeling, could result in such misbranding if it is false or misleading. OPDP focuses its review on identifying names that overstate the efficacy or safety of the drug, suggest drug indications that are not accurate, suggest superiority without substantiation, or are of a fanciful nature that misleadingly implies unique effectiveness or composition. This research will focus on the effect on consumers’ and/or healthcare providers’ perceptions of a drug product of names that overstate the efficacy of the drug product. An overstatement of efficacy can occur, for example, in terms of level of efficacy, in which the degree of relief is overstated, or in terms of the type of effect, in which case there is a mismatch with the indication of the drug. The drug products that are studied will be fictitious, and whether the names overstate the drug products’ efficacy will be determined with regard to the products’ fictitious degree of efficacy.

The proposed study is designed to provide systematic, empirical evidence to answer two research questions:

- **Primary research question:** How, if at all, do names that suggest the medical condition for which a drug is indicated affect consumers’ and/or healthcare providers’ perceptions of prescription drugs?
- **Secondary research question:** How, if at all, do names that suggest an overstatement of the degree of efficacy of the drug affect consumers’ and/or healthcare providers’ perceptions of prescription drugs?

The ideas generated in the Prescription Drug User Fee Amendments pilot project proprietary name review concept paper of 2008¹ provided a starting point for the study.

¹ <https://www.regulations.gov/docket?D=FDA-2008-N-0281>.

Based on ideas from that document, a review of the linguistics and social sciences literature, and an environmental scan of existing proprietary names, FDA developed and pretested an extreme, explicitly suggestive name (*e.g.*, CuresFlux) and a neutral name (*e.g.*, Zerpexin) for two medical conditions, high cholesterol and gastroesophageal reflux disease (GERD) (pretesting approved under OMB control number 0910–0695). In the proposed main study, approximately 500 consumers from the general population and 500 healthcare providers (including physicians, nurse practitioners, and physician assistants) will see these pretested extreme and neutral names plus five target names per indication (names that may suggest the medical condition and vary in terms of promise of effect) and answer questions about the names, before and after they have been told what each drug's indication is. Target names will vary such that some efficacy implications are more apparent than others, and some will more clearly imply the medical condition for which a drug is indicated than others. Dependent variables will include identification of the medical condition for which a drug is indicated, efficacy, and perceptions.

To our knowledge, this study is the first to provide a systemic investigation of a variety of proprietary prescription drug names.

In the **Federal Register** of January 21, 2020 (85 FR 3392), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received seven submissions that were PRA-related. One submission was outside the scope of the research and is not addressed further. Within the remaining six submissions, FDA received multiple comments that the Agency has addressed below. For brevity, some public comments are paraphrased and therefore may not include the exact language used by the commenter. We assure commenters that the entirety of their comments was considered even if not fully captured by our paraphrasing in this document. The following acronyms are used here: HCP = healthcare provider; FDA and Agency = Food and Drug Administration; OPDP = FDA's Office of Prescription Drug Promotion.

(Comment 1) Two comments recommended that the study should exclude consumers who work in the healthcare, marketing, or branding industries; primary care providers that spend less than 50 percent of their time on patient care; and the Department of Health and Human Services employees.

(Response 1) We agree and currently have those exclusions included in the screener.

(Comment 2) Two comments recommended the screener should include additional inclusion/exclusion criteria, such as number of years in practice and in what size facility they work (HCPs), and whether consumers have any of five diagnoses and how many HCPs they see (consumers).

(Response 2) We plan to include most of the screening criteria and demographic data mentioned, including years in practice (HCPs); amount of time treating patients (HCPs); size of facility (HCPs); age (consumers); and diagnosis with one of the two illnesses which the hypothetical drugs in this study are indicated to treat—GERD and high cholesterol (consumers). Some of the other suggested questions for the screener are beyond the scope of this study. For this study, we have chosen to focus on primary care providers, as drugs for these two specific medical conditions are prescribed by primary care providers and should thus be salient for them. Additionally, we will ask relevant background questions of all participants, both HCPs and consumers, to determine age, sex, and race, as well as familiarity with the target conditions.

(Comment 3) One comment recommended that the complexity of the target names should be equivalent across indications.

(Response 3) We have attempted to make these as similar as possible, including having them reviewed by a linguist and checking the number of syllables across conditions.

(Comment 4) Three comments recommend better clarity around what the definitions of “typical” and “standard” and “extreme” and “neutral” mean when describing the fictitious drug name and how these categories were identified and validated.

(Response 4) The list of names was developed by our multimedia and creative services team who are well-versed in the practice of proprietary name development. The list was reviewed by the study team and also by a consultant with a Ph.D. in linguistics, who helped to screen for any overlap between categories.

In July 2019, we conducted a pretest of 120 healthcare providers and 121 consumers to establish the categories for these names. We combined results of four measures to determine the most extreme and most neutral amongst a list of names. These measures included ability to identify the medical condition for which the drug is indicated; perceived benefit and perceived balance of benefit and risk; and, finally, a

ranking of most obvious benefit. Names with the lowest joint rank across the four measures were considered most extreme and those with highest were considered most neutral. The results were consistent between HCPs and consumers.

(Comment 5) One comment recommended excluding “extreme, explicitly suggestive” proprietary names that FDA would never permit or names that suggest the drug indication. The comment suggested instead that FDA use data that could assist the Agency in determining impressions produced by permissible proprietary names and names that would marginally fail FDA's misbranding review.

(Response 5) The purpose of including “extreme” names in this study is not to have data on names that do not mimic real-world conditions, but to have something against which to compare the target names, which are similar to the kind of names that would be submitted to FDA for approval. Our findings may suggest that “extreme” and target names are very different and that target names are similar to more neutral names in their effects on perceptions.

(Comment 6) One comment inquired if FDA will be providing sound files with the intended pronunciation of each of the test names.

(Response 6) In consideration of this comment, and after hearing from our cognitive interview participants, we will introduce sound files at the beginning of the survey.

(Comment 7) One comment expressed concerns about how the selection of target names will represent the current landscape—that is, it questioned how FDA will generalize these study results across therapeutic areas not tested if only representing one or two therapeutic areas.

(Response 7) We recognize that our study is making use of only two therapeutic areas. As one research study, it cannot examine all possible therapeutic areas. Although our two divergent medical conditions will not provide us with unlimited information, they will provide limited generalizability and provide important information that may help inform the proprietary name review process.

(Comment 8) Two comments were concerned that the questionnaire would take longer than the estimated 20 minutes.

(Response 8) See our response to Comment 4 concerning the pretest that we conducted in July 2019. In the pretest, we successfully tested a total of 16 names across two indications in this time frame. During cognitive testing, we

examined burden and decided to eliminate Q[uestion]7, which will speed response. We will also conduct a soft launch of the survey with approximately 10 percent of the sample and can look at actual length at that time. This gives us the ability to pause fielding of the survey and make further cuts if the soft launch data suggest it is necessary.

(Comment 9) Five comments recommended that we add “none of the above,” “no impression,” “no opinion” or “do not know” response options to some questions.

(Response 9) The rationale usually given for including “don’t know”/“no opinion”/“none” options is to allow participants who cannot form a relevant judgment (*e.g.*, due to insufficient information) a way to indicate as much. However, an unintended consequence of including these options is that they can facilitate satisficing, where participants who have enough information to form a relevant judgment nonetheless choose “don’t know”/“no opinion”/“none” because it takes less effort. As a result, “don’t know”/“no opinion”/“none” options do not tend to improve measurement and tend to increase item nonresponse (*i.e.*, missing data) (Ref. 1). For these reasons, we will not add these options.

(Comment 10) Seven comments suggested adding more open-ended responses to explain why respondents answered questions in certain ways.

(Response 10) As noted by two comments the survey may be longer than an average of 20 minutes, which will cause us to remove questions after cognitive testing. Unfortunately, it is impractical to include many open-ended questions in this particular research because of time constraints. Qualitative research on this topic may be a good idea for a future study.

(Comment 11) One comment recommended checks to ensure that respondents are not being careless in their responses (*e.g.*, just guessing, providing random answers, straight-lining).

(Response 11) We intend to check for inattentive respondents by testing for straight-lining and examining the distribution of time to complete the study for outliers. Participants who complete the study plus or minus three standard deviations from the sample mean will be excluded from the main analysis. We agree with the recommendation to include speed traps/attention checks in the questionnaire and will add one to the study.

(Comment 12) Three comments requested access to the screener or study target names.

(Response 12) We have described the purpose of the study, the design, the population of interest, and have provided the questionnaire to numerous individuals upon request. Our full stimuli are under development during the PRA process. We do not make draft stimuli public during this time because of concerns that this may contaminate our participant pool and compromise the research. We strive to publish the results of our research in peer-reviewed journals and all stimuli will be available at that time.

(Comment 13) One comment recommended a specific approach for addressing the issue of broadening the indication that included an unaided “fit to category” question and an open-ended “does the brand name tell you anything about the product?” OR “what does this name mean to you?”—type question for each name.

(Response 13) The approach described in this comment is one method to approach the issue of broadening the indication and may be useful for future research. However, in the current study we aim to collect information about multiple names, which precludes open-ended questions for each name in a single participant session. Moreover, our initial examination is focused on overstatement of efficacy. Broadening of the indication is another topic that researchers could pursue.

(Comment 14) One comment mentioned that we had no particular items on the issue of unique composition and suggested adding an open-ended question regarding general associations to determine whether a particular ingredient or dosage formulation is implied by a proprietary name.

(Response 14) Our current research is focused on the issue of overstatement of efficacy in proposed proprietary drug names. Future research could examine issues related to composition and dosage formulation, but that is beyond the scope of the current research.

(Comment 15) One comment suggested FDA should conduct two survey pretests: One to assess whether the survey answers the research questions, and one that allows respondents to complete the survey under the supervision of a moderator, who is able to converse with respondents and gather feedback on how participants interpret the questions. Further, the comment suggests FDA should consider conducting qualitative followup interviews with survey respondents to gain deeper insight into how the sample proprietary names affected their

impressions of safety, efficacy and indication.

(Response 15) We have accomplished the goals recommended in this comment by conducting cognitive interviewing. During these cognitive interviews, participants were encouraged to think aloud as they reviewed and answered the survey with prompts from a trained moderator. These interviews enabled us to capture deeper, more qualitative responses from a small nonrepresentative sample of individuals in order to improve the questionnaire.

(Comment 16) One comment suggested FDA consider the inverse approach of our design by setting up the research to examine how, if at all, names that do suggest the drug’s indication increase the chance for proper usage, reduce the potential for medication errors, do not mislead HCPs or patients regarding non-approved use of the drug, and increase the chance that if a patient does ask an HCP about a certain medication then that medication would be one approved to treat a condition with which the patient has been diagnosed.

(Response 16) The purpose of the current study is to provide evidence about whether certain types of names influence consumers’ perceptions, as well as benefit and risk perceptions so that FDA reviewers may better assess names during premarket review. Other effects of names are beyond the scope of the current study but may be considered in future research.

(Comment 17) One comment suggested the ability of HCPs who prescribe drug products to determine whether a proprietary name overstates the efficacy of that product *without* the ability to review the respective package insert labeling fails to meet the intent of 21 U.S.C. 321(n). The comment further stated that OPDP and the sponsor of the product are in the best position to determine the relationship between the proprietary name and the material facts in the labeling of the product, which sometimes is not available at the investigational new drug (IND) application stage when proprietary names are developed and tested with consumers and HCPs.

(Response 17) The purpose of the current study is to determine whether a proprietary name itself could play a role in influencing consumer and HCP perceptions of drug risks or benefits by suggesting the medical condition for which the drug is indicated or by suggesting an overstatement of the efficacy of the drug. Including the package insert would confound any potential results of this study, as it would not be possible to tease apart

whether perceptions were influenced by the name itself or the accompanying materials. We note that this is a large-scale study examining multiple names and that our purpose in conducting it differs from that of a pharmaceutical company engaged in developing and testing the proprietary name of one of its products.

(Comment 18) One comment suggested that the proposed primary research question, which is designed to determine how, if at all, a proprietary name that suggests the medical condition for which it is indicated affects perceptions of the drug, does not determine whether a name overstates the efficacy of the product.

(Response 18) We agree that whether a name suggests the medical condition for which a drug is indicated is a separate question from whether the name overstates the drug's efficacy. However, we aim, in part, to investigate how individuals perceive the efficacy of products when the names do suggest the medical condition they are indicated to treat. The purpose of this study is to compare names that: (1) With varying degrees of specificity, may suggest the medical condition for which a drug is indicated, with or without varied promises of effect (target names); (2) we know through pretesting overstate the efficacy (extreme names); and (3) we know to be neutral through pretesting. Perceptions of consumers and HCPs are important to consider when reviewing proprietary names and thus, important to test empirically.

(Comment 19) One comment suggested that research is not necessary because names should be evaluated by those who have medical and regulatory experience.

(Response 19) We agree that people who are knowledgeable about the relevant fields should make decisions about proprietary names based on the best information in their fields. Determining how names are processed and understood by consumers and HCPs is important information to be considered in the review of these names. Therefore, this research is being conducted to increase the body of evidence upon which experts can rely when assessing proposed proprietary names for misbranding concerns.

(Comment 20) Three comments mentioned the study sample size. One comment stated that the reason for selecting approximately 1000 respondents was not provided, and it suggested that the size of such a study on a proposed drug product would not be reasonable or cost effective for the pharmaceutical industry. One comment recommended that an appropriate

sample size be used, and another comment remarked that the sample size seemed appropriate.

(Response 20) The sample size was selected based on power analysis. We have set statistical power for the main study to test five proposed names against both the neutral control name and the extreme control name, using a 7×7 Latin squares design. With a Bonferroni correction for up to 10 pairwise comparisons, the study is powered to detect conventionally small effects ($f \geq 0.06$, $d_z \geq 0.21$, or 0.14 difference in proportions) assuming a family-wise alpha level of 0.005 and 90 percent power for all tests.

This is a large-scale study examining multiple names, whose purpose differs from that of one pharmaceutical company assessing their chosen names.

(Comment 21) One comment concurred that an automated online survey would be the most efficient means to conduct the research.

(Response 21) Thank you for this comment.

(Comment 22) One comment asked that we clarify what specific statistical tests will be performed to determine whether a particular target name has an improper (biasing) impact on perceptions of drug efficacy and/or safety—and (possibly) on other perceptions.

(Response 22) To compare names based on the categorical name recognition and perceived indication questions, we will apply nonparametric tests of dependent proportions. First, we plan to conduct Cochran's Q test separately for each list of names, testing whether the proportions of at least two names per list are significantly different from one another. We will follow up significant Cochran's Q tests with McNemar's pairwise tests, comparing each target name against the neutral and extreme names in each list.

To test for evidence of mean differences by drug name on interval-level outcomes (e.g., perceived efficacy magnitude, perceived severity of risks, and perceived balance of risks and benefits), we will use repeated-measures analyses of variance or mixed model analysis. We will run separate models for each list of names and study cohort. We will follow-up significant omnibus tests by conducting pairwise comparisons between each of the target names versus the neutral and extreme names.

See information about the study's statistical power assumptions above.

(Comment 23) One comment asked for clarity regarding what decision rule or norm/standard will be used to conclude

that there is or is not improper suggestiveness.

(Response 23) There is an important distinction between investigating the effect of a prescription drug name on perceptions and establishing that the name is improperly suggestive. This study is focused on the effect on perceptions of: (1) Names that suggest the medical condition for which a drug is indicated with varying degrees of explicitness and (2) names that suggest an overstatement of the efficacy of the drug with varying degrees of explicitness. Determining whether what a prescription drug name suggests or the name's degree of suggestiveness is "improper," or could contribute to misbranding the drug or to other violation(s) of the FD&C Act and Agency regulations, falls beyond the scope of the current project.

(Comment 24) One comment suggested clarifying the purpose and intended use of the data and further suggests that regardless of the purpose of the proposed information collection, in addressing use of the survey data, FDA should account for the First Amendment protection provided to proprietary names.

(Response 24) As stated in the 60-day notice, the purpose of this study is to expand the body of knowledge by answering questions about whether names alone impact consumer and provider perceptions of a drug. This information will help inform the proprietary name review process. FDA's review of proprietary names is conducted to help ensure that proposed proprietary names do not contribute to misbranding a drug or to other violation(s) of the FD&C Act and Agency regulations, particularly when that proprietary name appears in labeling (see, e.g., 21 U.S.C. 321(n) and 352(a)). We conduct our review of proprietary names in accordance with applicable legal authorities, including the First Amendment.

(Comment 25) One comment suggested Q1 should have a timer element (i.e., 15–20 seconds) for each set of seven names that will help to standardize the time spent by viewers on both sets and mitigate viewers who would quickly scan Set 1, only to spend more time on Set 2 after realizing they will be asked to recognize the names.

(Response 25) In addition to counterbalancing the sets of names, we will institute a time limit for each viewing.

(Comment 26) Another comment suggested that for Q1, we use names that were found unacceptable due to promotional reasons for foils.

(Response 26) The purpose of Q1 is to determine how well participants recall the names they viewed. The foils are used to help determine whether participants are merely checking off the complete list of names or marking ones they truly saw on the previous screen. Thus, we do not believe using actual names as foils would add value.

(Comment 27) One comment mentioned that Q3–Q7 introduce an aided portion of the survey (by grouping names into two specific medical conditions and identifying those names with each medical condition to the respondents) and suggested that, without seeing the product profile, “it will be difficult to get responsible data on efficacy perceptions of the respondents.” Another comment suggested that Q3 should ask a more specific question, perhaps on unique effectiveness or overstatement of efficacy.

(Response 27) Our research questions focus on whether the names alone result in perceptions of risk or efficacy, thus, Q3–Q7 are directly relevant to the research questions. Regarding Q3, we do not want to lead participants into answers or confuse them by asking them about regulatory terms with which they are unfamiliar. We will delete Q7.

(Comment 28) Regarding Q2, one comment suggested caution in terms of handling responses in which respondents presented with a particular target name (e.g., “AltAFlux”) fail to identify the indication that the name is hypothesized to be suggestive of (e.g., “Acid Reflux”), checking another indication instead (e.g., “Asthma”). In such cases, it would be inappropriate to interpret any observed effects on drug perceptions to the name being overly suggestive of a particular indication. A conservative course of action would therefore be to remove from subsequent analyses all instances in which a target name is not attributed to its hypothesized indication.

(Response 28) The target names are representative of the types of names that are frequently submitted to FDA for review. They may include information about the medical condition for which the drug is indicated, or both the medical condition and efficacy. We do not presuppose that a name’s effect on perceptions of drug effectiveness are dependent on recognition of the medical

condition for which the drug is indicated, though we will consider this mediation effect as we refine the analysis plan for this project.

(Comment 29) One comment suggested that Q4 does not seem relevant since serious side effects of the drug would normally be evaluated in the context of the clinical studies or post-marketing studies and would be presented in the package insert labeling.

(Response 29) The question is whether the name alone influences perception of risk and benefit; thus, Q4 is directly relevant to answering those questions.

(Comment 30) Three comments suggested deleting Q5. For example, one comment discussed that perceived balance of risks and benefits is usually communicated in advertising by utilizing the approved labeling in presenting fair balance and, thus, a proprietary name would not normally present risks and benefits. The comment stated that names that do present benefits within the name without context to its risk would not be considered misleading since the approved labeling would represent balance of risks and benefits.

(Response 30) Our research questions focus on whether the proprietary name alone affects consumer and HCP perceptions of risk or efficacy of the drug. Q5 helps to answer those research questions by asking participants to opine on whether the proprietary name alone indicates to them that the benefits of a product outweigh the risks. Our research will not answer the question whether a given name is misleading or whether labeling or advertising incorporating the name would violate the FD&C Act and its implementing regulations.

(Comment 31) One comment suggested that measuring attitudes toward each name (Q6) does not seem to add anything toward measuring the efficacy claims of a name and another comment recommends changing semantic differential endpoints for this item.

(Response 31) Measuring attitudes adds to our knowledge of how individuals interpret particular drug names. The semantic differential endpoints used in the original attitude question, as well as the proposed replacements, are among those

recommended by prominent attitude theorists (Ref. 2). We have used these items in several studies without any issues, including studies measuring consumer and physician attitudes toward prescription drugs. Nevertheless, we will replace the negative-positive item with an item using worthless-valuable as endpoints.

(Comment 32) Five comments suggested reducing or eliminating Q7, which questions participants about their attitudes toward the drug names.

(Response 32) As noted in Response 17, in the interest of reducing time burden for participants, we will delete this question.

(Comment 33) Two comments questioned the utility of or recommended deleting Q8.

(Response 33) We agree and will delete this item.

(Comment 34) Two comments suggested that Q9 and two comments suggested that Q10 and Q11 are not applicable to the objectives of this survey.

(Response 34) Similarity, typicality, and familiarity could reasonably influence perceptions of drug names independently of the experimental manipulation. These measures are being included in this study as potential covariates.

(Comment 35) One comment suggested that Q11 is confusing, as respondents are asked to rate if they “have heard of each of the following drug names before,” after being previously told in the questionnaire introduction that the drugs “have been recently developed” and before being informed in the debriefing that the names are fictitious. Moreover, some respondents could interpret the present question as meaning “Were the following names mentioned in this survey?” which is presumably not the intent of the question.

(Response 35) We agree that this item as written was confusing, and this was confirmed by cognitive testing. Thus, we will alter the question to clarify that we are interested in whether respondents had heard the drug name prior to the study. This question will be used as a covariate in the study design.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
Consumer Screener	1,233	1	1,233	.08 (5 minutes)	98.64

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
HCP Screener	1,233	1	1,233	.08 (5 minutes)	98.64
Consumer Study	493	1	493	.33 (20 minutes)	162.69
HCP Study	493	1	493	.33 (20 minutes)	162.69
Total					522.66

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

References

The following references are on display with the Dockets Management Staff, HFA-305, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852, 240-402-7500 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at <https://www.regulations.gov> as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Krosnick, J.A. and S. Presser, "Question and Questionnaire Design." In P.V. Marsden and J.D. Wright (Eds.). *Handbook of Survey Research* (2nd Ed.). Emerald: Bingley, UK, 2010.
2. Fishbein, M. and I. Ajzen, *Predicting and Changing Behavior: The Reasoned Action Approach*. New York, NY: Psychology Press, 2010.

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-05330 Filed 3-15-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-E-0340]

Determination of Regulatory Review Period for Purposes of Patent Extension; HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period

for HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by May 17, 2021. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 13, 2021. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 17, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 17, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-2020-E-0340 for "Determination of Regulatory Review Period for Purposes of Patent Extension; HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM." Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and

an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM. HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM is indicated for use as a non-cemented implant to replace a painful arthritic ankle joint due to primary osteoarthritis, post-traumatic osteoarthritis, or arthritis secondary to inflammatory disease (e.g., rheumatoid arthritis, hemochromatosis, etc.). The device system is for prescription use. Subsequent to this approval, the USPTO received a patent term restoration application for HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM (U.S. Patent No. 6,409,767) from European Foot Platform, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 14, 2020, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM is 4,676 days. Of this time, 3,661 days occurred during the testing phase of the regulatory review period, while 1,015 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date on which the device is first used with human subjects as part of a clinical investigation to be filed with FDA to secure premarket approval*

of the device: August 17, 2006. FDA has verified the applicant's claim that the date on which the device is first used with human subjects as part of a clinical investigation to be filed with FDA to secure premarket approval of the device was August 17, 2006.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* August 24, 2016. FDA has verified the applicant's claim that the premarket approval application (PMA) for HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM (PMA 160036) was initially submitted August 24, 2016.

3. *The date the application was approved:* June 4, 2019. FDA has verified the applicant's claim that PMA 160036 was approved on June 4, 2019.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,825 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-05371 Filed 3-15-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0212]

Bristol-Myers Squibb Company, et al.; Withdrawal of Approval of 19 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 19 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of April 15, 2021.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-

796-3137, *Kimberly.Lehrfeld@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 009218	Coumadin (warfarin sodium) Tablets, 1 milligram (mg), 2 mg, 2.5 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7.5 mg, and 10 mg. Coumadin (warfarin sodium) Injection, 5 mg/vial, 50 mg/vial, and 75 mg/vial.	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543.
NDA 011664	Decadron (dexamethasone) Tablets, 0.25 mg, 0.5 mg, 0.75 mg, 1.5 mg, 4 mg, and 6 mg.	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., 1 Merck Dr., Whitehouse Station, NJ 08889.
NDA 017481	Vermox (mebendazole) Chewable Tablets, 100 mg	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 018538	Lozol (indapamide) Tablets, 1.25 mg, and 2.5 mg	Sanofi-aventis U.S. LLC, 55 Corporate Dr., Bridgewater, NJ 08807.
NDA 018986	Pralidoxime Chloride Injection (auto-injector), 600 mg/2 milliliters (mL) (300 mg/mL).	Meridian Medical Technologies, Inc., 1945 Craig Rd., St. Louis, MO 63146.
NDA 019999	Morphine Sulfate Injection (auto-injector), 10 mg/0.7 mL	Do.
NDA 020363	Famvir (famciclovir) Tablets, 125 mg, 250 mg, and 500 mg ...	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936-1080.
NDA 020711	Zyban (bupropion hydrochloride (HCl)) Extended-Release Tablets, 100 mg, and 150 mg.	GlaxoSmithKline LLC, 5 Crescent Dr., Philadelphia, PA 19112.
NDA 020809	Diclofenac Sodium Ophthalmic Solution, 0.1%	Alcon Research, LLC, 6201 South Freeway, Fort Worth, TX 76134.
NDA 021713	Abilify (aripiprazole) Oral Solution, 1 mg/mL	Otsuka Pharmaceutical Co., Ltd. c/o Otsuka Pharmaceutical Development & Commercialization, Inc., 2440 Research Blvd., Rockville, MD 20850.
NDA 021729	Abilify (aripiprazole) Discmelt Orally Disintegrating Tablets, 10 mg, 15 mg, 20 mg, and 30 mg.	Do.
NDA 021866	Abilify (aripiprazole) Injection, 9.75 mg/1.3 mL (7.5 mg/mL) ...	Do.
NDA 022024	Actoplus Met XR (metformin HCl and pioglitazone) Extended-Release Tablets, 1 gram (g)/Equivalent to (EQ) 15 mg base and 1 g/EQ 30 mg base.	Takeda Pharmaceutical U.S.A. Inc., 95 Hayden Ave., Lexington, MA 02421.
NDA 050605	Ceftin (cefuroxime axetil) Tablets, EQ 125 mg base, EQ 250 mg base, and EQ 500 mg base.	GlaxoSmithKline Intellectual Property (no. 2) Ltd. England, c/o GlaxoSmithKline, 1250 South Collegeville Rd., Collegeville, PA 19426.
NDA 050672	Ceftin (cefuroxime axetil) Oral Suspension, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL.	Do.
NDA 207988	Zurampic (lesinurad) Tablets, 200mg	Ironwood Pharmaceuticals, Inc., 100 Summer St., Suite 2300, Boston MA 02110.
NDA 208383	Bevyxxa (betrixaban) Capsules, 40 mg and 80 mg	Portola Pharmaceuticals, Inc., 270 East Grand Ave., South San Francisco, CA 94080.
NDA 210709	Tektura (aliskiren hemifumarate) Capsules (Pellets), EQ 37.5 mg base.	Nodem Pharma DAC, 4820 Emperor Blvd., Durham, NC 27703.
NDA 210874	Qternmet XR (dapagliflozin, metformin HCl and saxagliptin) Extended-Release Tablets, 2.5 mg/1 g/EQ 2.5 mg base, 5 mg/1 g/EQ 2.5 mg base, 5 mg/1 g/EQ 5 mg base, and 10 mg/1 g/EQ 5 mg base.	AstraZeneca AB, c/o AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, DE 19803.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of April 15, 2021. Approval of each entire

application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products

without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table

that are in inventory on April 15, 2021 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-05368 Filed 3-15-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2002-N-0314]

Agency Information Collection Activities; Proposed Collection; Comment Request; Request for Samples and Protocols

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to the regulations that state that protocols for samples of biological products must be submitted to the Agency.

DATES: Submit either electronic or written comments on the collection of information by May 17, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 17, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 17, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-2002-N-0314 for "Request for Samples and Protocols." Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice

of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Request for Samples and Protocols

OMB Control Number 0910-0206—Extension

This information collection supports Agency regulations. Under section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to ensure the safety, purity, and potency of biological products and to ensure that the biologics licenses for such products are only issued when a product meets the prescribed standards. Under § 610.2 (21 CFR 610.2), the Center for Biologics Evaluation and Research (CBER) or the Center for Drug Evaluation and Research may at any time require manufacturers of licensed biological products to submit to FDA samples of any lot, along with the protocols showing the results of applicable tests, prior to distributing the lot of the product. In addition to § 610.2, there are other regulations that require the submission of samples and protocols for specific licensed biological products: §§ 660.6, 660.36, and 660.46 (21 CFR 660.6, 660.36, and 660.46).

Section 660.6(a) provides requirements for the frequency of submission of samples from each lot of Antibody to Hepatitis B Surface Antigen product, and § 660.6(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.6 products subject to official release by CBER, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history

of manufacture of the product, including all results of each test for which test results are requested by CBER. After official release is no longer required, one sample along with a protocol is required to be submitted at 90-day intervals. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to CBER if continued evaluation is deemed necessary.

Section 660.36(a) requires, after each routine establishment inspection by FDA, the submission of samples from a lot of final Reagent Red Blood Cell product along with a protocol containing specific information. Section 660.36(a)(2) requires that a protocol contain information, including, but not limited to, manufacturing records, certain test records, and identity test results. Section 660.36(b) requires a copy of the antigenic constitution matrix specifying the antigens present or absent to be submitted to the CBER Director at the time of initial distribution of each lot.

Section 660.46(a) contains requirements as to the frequency of submission of samples from each lot of Hepatitis B Surface Antigen product, and § 660.46(b) contains the requirements as to the submission of a protocol containing specific information along with each required sample. For § 660.46 products subject to official release by CBER, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history or manufacture of the product, including all results of each test for which test results are requested by CBER. After notification of official release is received, one sample along with a protocol is required to be submitted at 90-day intervals. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to CBER if continued evaluation is deemed necessary.

Samples and protocols are required by FDA to help ensure the safety, purity, or potency of the product because of the potential lot-to-lot variability of a product produced from living organisms. In cases of certain biological products (e.g., Albumin, Plasma Protein Fraction, and therapeutic biological products) that are known to have lot-to-lot consistency, official lot release is not normally required. However, submissions of samples and protocols of

these products may still be required for surveillance, licensing, and export purposes, or in the event that FDA obtains information that the manufacturing process may not result in consistent quality of the product.

The following burden estimate is for the protocols required to be submitted with each sample. The collection of samples is not a collection of information under 5 CFR 1320.3(h)(2). Respondents to the collection of information under § 610.2 are manufacturers of licensed biological products. Respondents to the collection of information under §§ 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers of the specific products referenced previously in this document. The estimated number of respondents for each regulation is based on the annual number of manufacturers that submitted samples and protocols for biological products, including submissions for lot release, surveillance, licensing, or export. Based on information obtained from FDA's database system, approximately 75 manufacturers submitted samples and protocols in fiscal year (FY) 2020 under the regulations cited previously in this document. FDA estimates that approximately 72 manufacturers submitted protocols under § 610.2, and 3 manufacturers submitted protocols under the regulation (§ 660.6) for the other specific product. FDA received no submissions under §§ 660.36 or 660.46; however, FDA is using the estimate of one protocol submission under each regulation in the event that protocols are submitted in the future.

The estimated total annual responses are based on FDA's final actions completed in FY 2020 for the various submission requirements of samples and protocols for the licensed biological products. The average burden per response is based on information provided by industry. The burden estimates provided by industry ranged from 1 hour to 5.5 hours. Under § 610.2, the hours per response are based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the average burden per response is based on the higher end of the estimate (rounded to 5 or 6 hours) because more information is generally required to be submitted in the other protocols than under § 610.2.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
610.2, Requests for Samples and Protocols; Official Release	72	82.972	5,974	3	17,922
660.6(b), Protocols	3	4	12	5	60
660.36(a)(2) and (b), Samples and Protocols	1	1	1	6	6
660.46(b), Protocols	1	1	1	5	5
Total	77	5,988	17,993

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall decrease of 1,463 hours and a corresponding decrease of 491 responses. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-05367 Filed 3-15-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1127]

Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notice entitled “Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments” that appeared in the **Federal Register** of June 1, 2020. The notice announced the establishment of a docket to solicit comments on the listing of patent information in the FDA publication “Approved Drug Products With Therapeutic Equivalence Evaluations” (commonly known as the “Orange Book”). The Agency is taking this action in response to the recently enacted Orange Book Transparency Act of 2020, which was signed into law on January 5, 2021.

DATES: FDA is reopening the comment period for the notice published on June

1, 2020 (85 FR 33169). Submit either electronic or written comments by April 15, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 15, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 15, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-2020-N-1127 for “Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments; Reopening of Comment Period.” 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.

FOR FURTHER INFORMATION CONTACT: Nicole Park, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Rm. 1670, Silver Spring, MD 20993-0002, 240-402-7764.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 1, 2020 (85 FR 33169), FDA published a notice with a 90-day comment period to solicit comments on the listing of patent information in the FDA publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book"), including comments on the types of patent information that should be included in the Orange Book. In the **Federal Register** of October 16, 2020 (85 FR 65819), FDA reopened the comment period for the public docket for an additional 30 days in response to a request for an extension to allow interested persons additional time to submit comments.

On January 5, 2021, the President signed into law the Orange Book Transparency Act of 2020 (Pub. L. 116-290). Section 2(e) of the Orange Book Transparency Act of 2020 requires the Agency to solicit public comment regarding the types of patent information that should be included on, or removed from, the Orange Book and to transmit to Congress a summary of such comments and actions the Agency is considering taking, if any, in response to such public comment by January 5, 2022.

In accordance with section 2(e) of the Orange Book Transparency Act of 2020, FDA is reopening the comment period for the public docket for 30 days, until April 15, 2021, to allow interested persons time to submit any additional comments regarding the types of patent information that should be included on, or removed from, the Orange Book. The

Agency believes that an additional 30 days will allow adequate time for interested persons to submit comments.

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-05327 Filed 3-15-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-P-1678]

Determination That NIPRIDE RTU (Sodium Nitroprusside), 10 Milligrams/50 Milliliters (0.2 Milligrams/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 NIPRIDE RTU (sodium nitroprusside), 10 milligrams (mg)/50 milliliters (mL) (0.2 mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for sodium nitroprusside, 10 mg/50 mL (0.2 mg/mL), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Michael Bernstein, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6240, Silver Spring, MD 20993-0002, 301-796-3478, michael.bernstein@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which 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.

NIPRIDE RTU (sodium nitroprusside), 10 mg/50 mL (0.2 mg/mL), is the subject of NDA 209387, held by Exela Pharma Sciences, LLC, and initially approved on March 8, 2017. NIPRIDE RTU is indicated for immediate reduction of blood pressure of adult and pediatric patients in hypertensive crises; induction and maintenance of controlled hypotension in adults and children during surgery, to reduce bleeding; and treatment of acute heart failure to reduce left ventricular end-diastolic pressure, pulmonary capillary wedge pressure, peripheral vascular resistance, and mean arterial blood pressure.

NIPRIDE RTU (sodium nitroprusside), 10 mg/50 mL (0.2 mg/mL), is currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Cardinal Health Regulatory Sciences submitted a citizen petition dated July 15, 2020 (Docket No. FDA-2020-P-1678), under 21 CFR 10.30, requesting that the Agency determine whether NIPRIDE RTU (sodium nitroprusside), 10 mg/50 mL (0.2 mg/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 NIPRIDE RTU (sodium nitroprusside), 10 mg/50 mL (0.2 mg/mL), was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other

information suggesting that NIPRIDE RTU (sodium nitroprusside), 10 mg/50 mL (0.2 mg/mL), was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NIPRIDE RTU (sodium nitroprusside), 10 mg/50 mL (0.2 mg/mL), from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NIPRIDE RTU (sodium nitroprusside), 10 mg/50 mL (0.2 mg/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. ANDAs that refer to NIPRIDE RTU (sodium nitroprusside), 10 mg/50 mL (0.2 mg/mL), may 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: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-05324 Filed 3-15-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-2347]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Cosmetic Export Certificate Application Process

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information,

including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions associated with export certificate applications for FDA-regulated human food and cosmetic products.

DATES: Submit either electronic or written comments on the collection of information by May 17, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 17, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 17, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-2014-N-2347 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Cosmetic Export Certificate Application Process.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food and Cosmetic Export Certificate Application Process

OMB Control Number 0910–0793—Extension

Some countries may require manufacturers of FDA-regulated products to provide certificates for products they wish to export to that country. Accordingly, firms exporting products from the United States often ask FDA to provide such a “certificate.” In many cases, foreign governments are seeking official assurance that products exported to their countries can be marketed in the United States, or that they meet specific U.S. requirements. In some cases, review of an FDA export certificate may be required as part of the process to register or import a product into another country. An export certificate generally indicates that the particular product is marketed in the United States or otherwise eligible for export and that the particular manufacturer has no unresolved enforcement actions pending before, or taken by, FDA.

FDA’s Center for Food Safety and Applied Nutrition (CFSAN) issues export certificates for human food and cosmetic products. Interested persons may request a certificate electronically via the CFSAN Export Certification Application and Tracking System (CFSAN eCATS) or Certificate Application Process (CAP), components of the FDA Industry Systems, or by contacting CFSAN for assistance. Health certificates are the exception and are requested via email. To facilitate the application process, we have eliminated paper-based forms. For food products, respondents are able to identify facilities using their Food Facility Registration, an FDA Establishment Identifier number, or a Data Universal Numbering System number. The system uses these identifiers to locate and autopopulate name and address information, eliminating the need for users to manually enter this information and reducing the time to complete the application. For some applications, respondents can also upload product information via a spreadsheet, which reduces the time needed to enter product information, particularly for

applications that include multiple products.

All information is entered using electronic Forms FDA 3613d, 3613e, and 3613k and used to evaluate certificate requests. The eCATS Module is Form 3613k, where 3613e is the Certificate of Free Sale (<https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food>). All “forms” are electronic and part of the eCATS or CAP portal accessed via <https://www.access.fda.gov>. To view representations of the forms, you have to download the instructions, which are accessible from the following links: <https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics> and <https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food>.

While burden associated with information collection activities for export certificates issued for other FDA-regulated products is approved under OMB control number 0910–0498, this collection specifically supports export certificates issued by CFSAN. Also, because we have eliminated paper-based forms, respondents who require assistance with completing export certificate applications online may contact CFSAN directly by email (CFSANExportCertification@fda.hhs.gov) or telephone (240–402–2307). Instructions for requesting export certificates for cosmetics (Form FDA 3613d) are available online at <https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics> and instructions for requesting export certificates for food (Forms FDA 3613e and Form 3613k) are available online at <https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food>.

Description of Respondents: The respondents to this collection of information are firms interested in exporting U.S.-manufactured human food and cosmetic products to foreign countries that require export certificates.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Type of respondent	Form No. ²	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Cosmetics	FDA 3613d	113	3	339	0.5 (30 minutes)	170
Food	FDA 3613e, 3613k	468	9	4,212	0.5 (30 minutes)	2,106

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

Type of respondent	Form No. ²	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Total	2,276

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² All forms are submitted electronically via FDA Industry Systems.

Based on a review of the information collection since our last OMB approval, we have reduced our burden estimate. The burden estimate has been lowered due to a reduced number of respondents. We base our estimates on our experience with certificate applications received in the past 3 fiscal years.

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–05369 Filed 3–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0770]

Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products; Draft Guidance for Industry; Availability; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is reopening the comment period for the notice entitled “Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products; Draft Guidance for Industry; Availability” that appeared in the **Federal Register** of December 9, 2020. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for the notice published on December 9, 2020 (85 FR 79187). Submit either electronic or written comments on the draft guidance by June 14, 2021 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–2020–D–0770 for “Best Practices in Developing Proprietary Names for Human Nonprescription Drug 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 Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building,

4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Danielle Harris, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4461, Silver Spring, MD 20993–0002, 301–796–4590; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 9, 2020 (85 FR 79187), FDA published a notice with a 60-day comment period to request comments on the draft guidance for industry entitled “Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products.”

The Agency has received a request for an extension of the comment period for the draft guidance to ensure that the Agency considers additional comments on the draft guidance before it begins work on the final version of the guidance. FDA has considered the request and is reopening the comment period until June 14, 2021. The Agency believes that an additional 90 days will allow adequate time for interested persons to submit comments.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: March 10, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–05323 Filed 3–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–1935]

Determination of Regulatory Review Period for Purposes of Patent Extension; OCS LUNG SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined the regulatory review period for OCS LUNG SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by May 17, 2021. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 13, 2021. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 17, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 17, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2019–E–1935 for “Determination of Regulatory Review Period for Purposes of Patent Extension; OCS LUNG SYSTEM.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and continues until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award

(for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device OCS LUNG SYSTEM. OCS LUNG SYSTEM is a portable organ perfusion, ventilation, and monitoring medical device indicated for the preservation of standard criteria donor lungs in a near physiologic, ventilated, and perfused state for double-lung transplantation. Subsequent to this approval, the USPTO received a patent term restoration application for OCS LUNG SYSTEM (U.S. Patent No. 6,100,082) from TransMedics, Inc., and the USPTO requested FDA’s assistance in determining this patent’s eligibility for patent term restoration. In a letter dated June 21, 2019, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of OCS LUNG SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for OCS LUNG SYSTEM is 2,341 days. Of this time, 1,672 days occurred during the testing phase of the regulatory review period, while 669 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption for this device, under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), became effective:* October 26, 2011. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective on March 8, 2012. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on October 26, 2011, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* May 23, 2016. The applicant claims April 28, 2016, as the date the premarket approval application (PMA) for OCS LUNG SYSTEM (PMA P160013) was initially submitted. However, FDA records indicate that

PMA P160013 was submitted on May 23, 2016.

3. *The date the application was approved:* March 22, 2018. FDA has verified the applicant’s claim that PMA P160013 was approved on March 22, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,687 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-05372 Filed 3-15-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0127]

Potential Medication Error Risks With Investigational Drug Container Labels; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled “Potential Medication Error Risks With Investigational Drug Container Labels.” This public meeting is being convened and supported by a partnership between the Reagan-Udall Foundation and FDA. The purpose of the public meeting is to solicit input from stakeholders (e.g., sponsors, clinical sites, entities that supply or otherwise label investigational drugs) on the risk of medication errors potentially related to the content and format of information on investigational drug container labels, the prevalence and nature of such errors, and to gather information on practices that minimize the potential for medication errors.

DATES: The public meeting will be held virtually and broadcast via webcast on May 18, 2021, from 1 p.m. to 4 p.m. (Eastern Time), and May 19, 2021, from 10 a.m. to 1 p.m. (Eastern Time). Submit either electronic or written comments on this public meeting by June 18, 2021. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this public meeting via an online teleconferencing platform.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 18, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 18, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–N–0127 for “Potential Medication Error Risks With Investigational Drug Container Labels.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Jo Wyeth, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4326, Silver Spring, MD 20993, 301–796–1985, Jo.Wyeth@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the public meeting announced in this notice is to solicit input from stakeholders (e.g., sponsors, investigators, clinical sites, contract research organizations and other entities that supply or otherwise label investigational drugs, regulators, professional organizations, and study participants) on the risk of medication errors potentially related to the content and format of the information on investigational drug container labels, the prevalence and nature of such errors, and to gather information on practices that minimize the potential for medication errors.

For the purpose of this meeting, an investigational drug means a drug or

biological product that is used in a clinical investigation under an investigational new drug application. FDA definitions and requirements related to investigational new drug applications are provided in 21 CFR part 312. The requirements for labeling an investigational new drug include: (1) The immediate package of an investigational new drug intended for human use shall bear a label with the statement “Caution: New Drug—Limited by Federal (or United States) law to investigational use” and (2) the label or labeling of an investigational new drug shall not bear any statement that is false or misleading in any particular and shall not represent that the investigational new drug is safe or effective for the purposes for which it is being investigated (21 CFR 312.6). While not a regulatory requirement, some investigational new drug container labels may include additional information such as the protocol/clinical trial number, concentration and/or strength, dosage form (e.g., tablets, injection), quantity per container, storage requirements, and lot number. Sponsors of an investigational new drug application are required to report to FDA any suspected adverse reaction that is both serious and unexpected (21 CFR 312.32(c)(1)(i))¹. Adverse reactions that are not serious or unexpected or medication errors that do not result in adverse reactions may be reported in the annual report, or not reported at all. FDA is aware that globally, other regulatory agencies have varying requirements related to investigational drug labeling and safety reporting (Refs. 1 to 3).

The incidence and scope (e.g., error type; stage in the medication use system where the error occurred; actual, or potential for, adverse events; reporting practices) of medication errors associated with investigational drugs is unknown. FDA recognizes that clinical research is conducted globally (Ref. 4). Published literature from outside the United States has pointed to the container labels as a contributing factor for potential medication errors with investigational drugs and recommended global harmonization of the information on the labels (Refs. 5 and 6). For example, a Canadian study that included labels from blinded protocols provided by European and American sponsors found almost half of the labels affixed to investigational drug containers were missing important information (usually the expiration date,

sponsor address, or storage conditions) (Ref. 5). The study also found other factors that may contribute to medication errors, including the use of small font sizes (less than 8 point), variable formats for expiration dates and lot numbers, the presence of error-prone abbreviations, limited use of color or other differentiation techniques, and highly similar product or protocol identification numbers (Ref. 5). A French simulation study using investigational drug container labels found an error rate of approximately 12 percent (most errors were related to dosage unit, trial code, drug confusion, or expiration date) (Ref. 6).

Best practice guidelines, such as those released by the American Society of Health System Pharmacists, have recommended specific content and format for investigational drug container labels (Ref. 7). In 2018, the Institute for Safe Medication Practices (ISMP) published two reports on medication error risks with investigational drugs (Refs. 8 and 9). The first report (published in April 2018) explored reported risks with investigational drug nomenclature, labeling, and packaging, which included unlabeled containers and look-alike product identifiers, confusing or missing information (e.g., container labels missing, route of administration, dosage form, or net quantity) to support safe use, small unreadable text, and the use of codes and error-prone abbreviations on container labels (Ref. 9). The second report (published in May 2018) recommended error mitigation strategies for clinical sites, sponsors, and other entities that supply investigational drugs and included the recommendation to standardize the content and format of information on investigational drug container labels (Ref. 8).

FDA reviewed additional reports of medication error concerns related to unlabeled or poorly labeled investigational drug container labels (Refs. 10 to 13). The design of container labels can impact the ability of healthcare providers to readily locate and understand critical information for product use (Ref. 14), which in turn may threaten the integrity of clinical investigations and impact the safety and protection of subjects who participate in these investigations.

II. Topics for Discussion at the Public Meeting

During the public meeting, speakers and participants will cover a range of issues related to medication errors and investigational drugs. Discussion topics related to the format and content of

information on investigational drug container labels include: (1) The prevalence and types of medication errors attributed to container labels; (2) the impact of such errors on clinical investigations; (3) information that should always be on the container label, and how that information should be presented to facilitate safe use; (4) entities responsible for labeling containers; (5) existing processes for reporting and analyzing medication errors and complaints related to container labels; and (6) global regulatory convergence and differences for the information on container labels.

III. Participating in the Public Meeting

Registration: To register for the public meeting, complete the registration form at <https://reaganudall.org/news-and-events/events/investigational-drug-labels>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Registration is free.

If you need special accommodations due to a disability, please contact Jo Wyeth (see **FOR FURTHER INFORMATION CONTACT**) no later than May 5, 2021.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments and requests to participate in the focused sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. All requests to make oral presentations must be received by April 28, 2021. We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by May 3, 2021. If selected for presentation, any presentation materials must be emailed to Jo Wyeth (see **FOR FURTHER INFORMATION CONTACT**) no later than May 10, 2021. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will be webcast. Persons interested in participating in the webcast are encouraged to register in advance (see **Registration**). The webcast will also be available on the day of the event without preregistration. Detailed

¹ Sponsors have additional investigational new drug safety reporting requirements that may apply (see 21 CFR 312.32(c)(1)(ii) through (iv)).

information for participating in the webcast is available at the following website: <https://reaganudall.org/news-and-events/events/investigational-drug-labels>.

Registered participants will be sent technical system requirements in advance of the event. It is recommended that you review these technical system requirements before joining the streaming web conference of the public meeting.

FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://reaganudall.org/news-and-events/events/investigational-drug-labels>.

IV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

- * 1. European Commission, "EU Guidelines to Good Manufacturing Practice; Medicinal Products for Human and Veterinary Use," Public release date: February 3, 2010 (available at https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/2009_06_annex13.pdf).
2. Smith-Gick, J., N. Barnes, R. Barone, et al., "The Near-Term Viability and Benefits of eLabels for Patients, Clinical Sites, and Sponsors," *Therapeutic Innovation and Regulatory Science*, vol. 52(5), pp. 537–545, 2018.
- * 3. Health Canada, Good Clinical Practices Guidance Document, "Annex 13 to the Current Edition of the Good Manufacturing Practices Guidelines Drugs Used in Clinical Trials," August 7, 2009 (available at https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/annex-13-good-manufacturing-practices-guidelines-drugs-clinical-trials-0036.html#a8_7).
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- * 9. ISMP, "Investigational Drugs: Product-Related Issues Pose Significant Challenges (Part I)," Public release date: April 19, 2018 (available at <https://www.ismp.org/resources/investigational-drugs-product-related-issues-pose-significant-challenges-part-i>).
10. Cruz, J.L. and J.N. Brown, "Safety Risks With Investigational Drugs: Pharmacy Practices and Perceptions in the Veterans Affairs Health System," *Therapeutic Advances in Drug Safety*, vol. 6(3), pp. 103–109, 2015.
11. Grissinger, M., "Reducing the Potential for Mistakes With Investigational Drugs," *Pharmacy and Therapeutics*, vol. 36(3), pp. 120–138, 2011.
12. Brown, J.N., S.R. Britnell, A.P. Stivers, et al., "Medication Safety in Clinical Trials: Role of the Pharmacist in Optimizing Practice, Collaboration, and Education To Reduce Errors," *Yale Journal of Biology and Medicine*, vol. 90(1), pp. 125–133, 2017.
- * 13. ISMP, "Remdesivir Investigational Drug Labeling Confusion," *Acute Care*, vol. 25(9), 2020.
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medication-errors). When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

Dated: March 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–05370 Filed 3–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: <http://www.hrsa.gov/vaccinecompensation/index.html>.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.*, provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each

proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa-12(b)(2), requires that “[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.” Set forth below is a list of petitions received by HRSA on February 1, 2021, through February 28, 2021. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master “shall afford all interested persons an opportunity to submit relevant, written information” relating to the following:

1. The existence of evidence “that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,” and

2. Any allegation in a petition that the petitioner either:

a. “[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by” one of the vaccines referred to in the Table, or

b. “[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or

significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine” referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the United States Court of Federal Claims at the address listed above (under the heading “For Further Information Contact”), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, Maryland 20857. The Court’s caption (Petitioner’s Name v. Secretary of HHS) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

Diana Espinosa,

Acting Administrator.

List of Petitions Filed

1. Makaylah Kelly, Englewood, Colorado Court of Federal Claims No: 21-0827V
2. Evelyn Ashford, Washington, District of Columbia, Court of Federal Claims No: 21-0828V
3. David K. McQuinn, Washington, District of Columbia, Court of Federal Claims No: 21-0829V
4. Laura O’Hara, Spring, Texas, Court of Federal Claims No: 21-0830V
5. Peter Weil, Madison, Wisconsin, Court of Federal Claims No: 21-0831V
6. Lisa Carter, Woodbridge, Virginia, Court of Federal Claims No: 21-0832V
7. Laurie Marowski on behalf of A. M., Phoenix, Arizona, Court of Federal Claims No: 21-0834V
8. Jason Gaskin and Tabitha Gaskin on behalf of Jason Gaskin, Jr., Deceased, Rancho Santa Margarita, California, Court of Federal Claims No: 21-0835V
9. Laurie Blake, Washington, District of Columbia, Court of Federal Claims No: 21-0837V
10. Jason Groves, Port Angeles, Washington, Court of Federal Claims No: 21-0838V
11. Denise Oldoni, Augusta, Georgia, Court of Federal Claims No: 21-0839V
12. Tony Moye, Madisonville, Texas, Court of Federal Claims No: 21-0841V
13. Hema Mullur, Austin, Texas, Court of Federal Claims No: 21-0842V
14. Barbara Langburt, Washington, District of Columbia, Court of Federal Claims No: 21-0843V
15. Paul Longo, Washington, District of Columbia, Court of Federal Claims No: 21-0844V
16. Joseph Ned Martinez, Washington, District of Columbia, Court of Federal Claims No: 21-0845V
17. Kimberly Albury, Tampa, Florida, Court of Federal Claims No: 21-0846V
18. Oscar Garner, Milwaukee, Wisconsin, Court of Federal Claims No: 21-0847V
19. Phillip Herrera, Milwaukee, Wisconsin, Court of Federal Claims No: 21-0849V
20. Ivan Boyd, Boston, Massachusetts, Court of Federal Claims No: 21-0850V
21. James D. Woodcock, Greenfield, Indiana, Court of Federal Claims No: 21-0851V
22. Rosalind Paaswell, Boston, Massachusetts, Court of Federal Claims No: 21-0853V
23. Virginia McGee, Boston, Massachusetts, Court of Federal Claims No: 21-0854V
24. Beverly Dye, Newtown, Pennsylvania, Court of Federal Claims No: 21-0855V
25. Yolanda Henderson, Dresher, Pennsylvania, Court of Federal Claims No: 21-0857V
26. Anna Miller and Matthew Miller on behalf of A. M., San Diego, California, Court of Federal Claims No: 21-0858V
27. Alexis Lainez on behalf of Noah Greyson Montoya, Deceased, Apple Valley, California, Court of Federal Claims No: 21-0859V
28. Celeste Bodenbender, Washington, District of Columbia, Court of Federal Claims No: 21-0860V
29. Phyllis K. Alexander, Greensboro, North Carolina, Court of Federal Claims No: 21-0861V
30. Adelyn Diaz De La Rocha, Washington, District of Columbia, Court of Federal Claims No: 21-0862V
31. Ana Rivera Rodriguez, San Juan, Puerto Rico, Court of Federal Claims No: 21-0865V
32. Naomi DeLeon on behalf of N. R., Austin, Texas, Court of Federal Claims No: 21-0866V
33. Allen Bickel, Boston, Massachusetts, Court of Federal Claims No: 21-0867V
34. Darlene Cucinotta, Clermont, Florida, Court of Federal Claims No: 21-0868V
35. Dawn Maxfield, Palm Bay, Florida, Court of Federal Claims No: 21-0869V
36. Dominick Vanore, Reno, Nevada, Court of Federal Claims No: 21-0870V
37. Michelle Mason, Pompano Beach, Florida, Court of Federal Claims No: 21-0871V
38. David Titus, Washington, District of Columbia, Court of Federal Claims No: 21-0875V
39. Mike Rodriguez, Las Vegas, Nevada, Court of Federal Claims No: 21-0876V
40. Jerry D. Keller, Richmond, Kentucky, Court of Federal Claims No: 21-0879V
41. Gina Schueler, Richmond, Kentucky, Court of Federal Claims No: 21-0880V
42. Zehra Rizvi, Irmo, South Carolina, Court of Federal Claims No: 21-0881V
43. Douglas Arricale, Phoenix, Arizona, Court of Federal Claims No: 21-0882V
44. Graham Wilkinson, Washington, District of Columbia, Court of Federal Claims No: 21-0883V
45. Sherry Jeffries Compton on behalf of Joyce E. Jeffries, Memphis, Tennessee, Court of Federal Claims No: 21-0884V
46. Dennis Franklin, Springfield, Minnesota, Court of Federal Claims No: 21-0885V
47. Emilia Ostrowska, Houston, Texas, Court of Federal Claims No: 21-0886V

- of Federal Claims No: 21–0886V
48. Krystal Layman, Chillicothe, Ohio, Court of Federal Claims No: 21–0887V
 49. Margaret Craig, Madisonville, Texas, Court of Federal Claims No: 21–0889V
 50. Paul Bishop, Rochester, New York, Court of Federal Claims No: 21–0891V
 51. Abraham Scott, Flowood, Mississippi, Court of Federal Claims No: 21–0892V
 52. Frank Mares, West Covina, California, Court of Federal Claims No: 21–0893V
 53. Kathleen G. McKenna, Spokane, Wisconsin, Court of Federal Claims No: 21–0895V
 54. Arlene Bourne, Washington, District of Columbia, Court of Federal Claims No: 21–0899V
 55. Della McKeehan, Collierville, Tennessee, Court of Federal Claims No: 21–0900V
 56. Margot Meissner, Boston, Massachusetts, Court of Federal Claims No: 21–0901V
 57. Ingraham Hanahan, Washington, District of Columbia, Court of Federal Claims No: 21–0902V
 58. Brandy Romeo, Dresher, Pennsylvania, Court of Federal Claims No: 21–0903V
 59. Muhand Haddad, Downers Grove, Illinois, Court of Federal Claims No: 21–0904V
 60. Samantha Brotman, New York, New York, Court of Federal Claims No: 21–0905V
 61. Carol Cabral, Girard, Pennsylvania, Court of Federal Claims No: 21–0906V
 62. Sandra Williams, Woodbridge, Virginia, Court of Federal Claims No: 21–0907V
 63. Patricia Merrill, Charlotte, North Carolina, Court of Federal Claims No: 21–0908V
 64. Brenda White, North Lincoln, Kansas, Court of Federal Claims No: 21–0909V
 65. Jennifer Hamilton, Memphis, Tennessee, Court of Federal Claims No: 21–0910V
 66. Kayla Brown, Chesapeake, Virginia, Court of Federal Claims No: 21–0912V
 67. Barbara Kelly, Gainesville, Georgia, Court of Federal Claims No: 2, Colleen Marie Medlock, Hillsboro, Oregon, Court of Federal Claims No: 21–0915V
 69. Diane Blouin, Boston, Massachusetts, Court of Federal Claims No: 21–0919V
 70. Amy Lalla, Cortland, New York, Court of Federal Claims No: 21–0920V
 71. Michael R. Lueck, Greenfield, Wisconsin, Court of Federal Claims No: 21–0923V
 72. Christian M. Gatto, Linwood, New Jersey, Court of Federal Claims No: 21–0924V
 73. Juan F. Ruiz, Jr., Boscobel, Wisconsin, Court of Federal Claims No: 21–0927V
 74. Carissa Feters, Phoenix, Arizona, Court of Federal Claims No: 21–0928V
 75. Amy Congilose, Matthews, North Carolina, Court of Federal Claims No: 21–0929V
 76. Jennifer Kane, Boalsburg, Pennsylvania, Court of Federal Claims No: 21–0930V
 77. Marc Clodfelter, Washington, District of Columbia, Court of Federal Claims No: 21–0931V
 78. Hawke M. Strickland, Waupin, Wisconsin, Court of Federal Claims No: 21–0932V
 79. Kimberly A. MacFeggan, Collierville, Tennessee, Court of Federal Claims No: 21–0933V
 80. Claudia Garcia on behalf of G. G., Oklahoma City, Oklahoma, Court of Federal Claims No: 21–0934V
 81. Katherine O'Brien, Tinton Falls, New Jersey, Court of Federal Claims No: 21–0936V
 82. Robert Willis, Bluffton, South Carolina, Court of Federal Claims No: 21–0938V
 83. Es Mae Rose, Pendleton, Oregon, Court of Federal Claims No: 21–0939V
 84. Jeannie Lowery, Greensboro, North Carolina, Court of Federal Claims No: 21–0940V
 85. Gwendolyn Pilgrim, Washington, District of Columbia, Court of Federal Claims No: 21–0941V
 86. Vienna Giglio, Eastchester, New York, Court of Federal Claims No: 21–0942V
 87. James Russell, Allen Park, Michigan, Court of Federal Claims No: 21–0943V
 88. Sharon Dewyea, Washington, District of Columbia, Court of Federal Claims No: 21–0944V
 89. Justin Hock, Baltimore, Maryland, Court of Federal Claims No: 21–0945V
 90. Clemmie L. Johnson, Boscobel, Wisconsin, Court of Federal Claims No: 21–0946V
 91. Antonio J. Smith, Boscobel, Wisconsin, Court of Federal Claims No: 21–0947V
 92. James Cantafio, Danbury, Connecticut, Court of Federal Claims No: 21–0948V
 93. Emma Fox, Exton, Pennsylvania, Court of Federal Claims No: 21–0949V
 94. Tammy Bosford, Queensbury, New York, Court of Federal Claims No: 21–0950V
 95. Thom Demicco, Loma Linda, California, Court of Federal Claims No: 21–0951V
 96. Debra White, Pacific Grove, California, Court of Federal Claims No: 21–0952V
 97. Tremayne D. Edwards, Milwaukee, Wisconsin, Court of Federal Claims No: 21–0954V
 98. Debra Law, St. Louis, Missouri, Court of Federal Claims No: 21–0956V
 99. Isaiah Jacobs, Scottsdale, Arizona, Court of Federal Claims No: 21–0957V
 100. Glorianna Rennish, Sheboygan, Wisconsin, Court of Federal Claims No: 21–0959V
 101. Jeffrey Flynn, Sunnyside, New York, Court of Federal Claims No: 21–0960V
 102. Steven Marshall, Ruckersville, Virginia, Court of Federal Claims No: 21–0961V
 103. Margaret Spencer, Washington, District of Columbia, Court of Federal Claims No: 21–0962V
 104. Elizabeth Fagan, Beverly Hills, California, Court of Federal Claims No: 21–0963V
 105. Nancy Stolze, Beverly Hills, California, Court of Federal Claims No: 21–0964V
 106. Andera Smith, Beverly Hills, California, Court of Federal Claims No: 21–0965V
 107. Thomas K. O'Connor, New York, New York, Court of Federal Claims No: 21–0966V
 108. Alberto S. Galvan, Waupun, Wisconsin, Court of Federal Claims No: 21–0967V
 109. Felicia Sanchez, Dallas, Texas, Court of Federal Claims No: 21–0968V
 110. Jacqueline Clancy, Ellicott City, Maryland, Court of Federal Claims No: 21–0969V
 111. Magdalena Fernandez, Dallas, Texas, Court of Federal Claims No: 21–0970V
 112. Todd Katz, Dallas, Texas, Court of Federal Claims No: 21–0971V
 113. Kathaleen Lang, Dallas, Texas, Court of Federal Claims No: 21–0972V
 114. Ulrike Mathilde Mueller-Sprout, Dallas, Texas, Court of Federal Claims No: 21–0973V
 115. Sandra Camacho, Dallas, Texas, Court of Federal Claims No: 21–0974V
 116. Andres Visconde, Washington, District of Columbia, Court of Federal Claims No: 21–0977V
 117. Liza Orban, Utica, Michigan, Court of Federal Claims No: 21–0978V
 118. Kimberly Axelrod, Arlington, Virginia, Court of Federal Claims No: 21–0980V
 119. Yazmin Soto, New York, New York, Court of Federal Claims No: 21–0981V
 120. Chih-Jung Chen, Rochester, New York, Court of Federal Claims No: 21–0982V
 121. Kevin Lange, Buffalo, New York, Court of Federal Claims No: 21–0983V
 122. Jillian C. Beccia, Farmington Hills, Michigan, Court of Federal Claims No: 21–0984V
 123. Pamela Clemente, Pittsburgh, Pennsylvania, Court of Federal Claims No: 21–0985V
 124. John W. Vance, Conway, Arkansas, Court of Federal Claims No: 21–0986V
 125. Teresa Scarborough, Tustin, California, Court of Federal Claims No: 21–0987V
 126. Wolfgang R. Moenig and Martina Moenig on behalf of M. M., Farmington Hills, Michigan, Court of Federal Claims No: 21–0993V
 127. Steve Marshall, Englewood, New Jersey, Court of Federal Claims No: 21–0997V
 128. Esperanza Perez, Englewood, New Jersey, Court of Federal Claims No: 21–0998V
 129. Lacy Cloud, Cheyenne, Wyoming, Court of Federal Claims No: 21–0999V
 130. Ashley Parmer, Phoenix, Arizona, Court of Federal Claims No: 21–1000V
 131. Brenna Benjamin on behalf of L. J. R., Ellicott City, Maryland, Court of Federal Claims No: 21–1001V
 132. Jillian Fishburn, Phoenix, Arizona, Court of Federal Claims No: 21–1002V
 133. Evelyn Gonzalez, Woodbridge, Illinois, Court of Federal Claims No: 21–1003V
 134. Aryel Vezzose, Phoenix, Arizona, Court of Federal Claims No: 21–1004V
 135. Beverly Williams, Richardson, Texas, Court of Federal Claims No: 21–1006V

[FR Doc. 2021–05350 Filed 3–15–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Voluntary Partner Surveys To Implement Executive Order 12862 in the Health Resources and Services Administration

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than April 15, 2021.

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 Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Voluntary Partner Surveys to Implement Executive Order 12862 in the Health Resources and Services Administration, OMB No. 0915-0212—Extension.

Abstract: In response to Executive Order 12862, HRSA is proposing to conduct voluntary customer surveys of its partners to assess strengths and weaknesses in program services and processes. HRSA partners are typically state or local governments, health care facilities, health care consortia, health care providers, and researchers. HRSA is requesting continued approval of a generic clearance from OMB to conduct the partner surveys.

Partner surveys to be conducted by HRSA might include, for example, mail, electronic, and/or telephone surveys of grantees to determine satisfaction with grant processes or technical assistance provided by a contractor, or in-class or virtual evaluation forms completed by providers who receive training from HRSA grantees to measure satisfaction with the training experience. Results of these surveys will be used to plan and redirect resources and efforts as needed to improve services and processes.

Focus groups may also be used to gain partner input that will inform the design of mail, electronic and/or telephone surveys. Focus groups, in-class evaluation forms, mail surveys, electronic surveys, and telephone surveys are expected to be the preferred data collection methods for this information collection.

A generic approval allows HRSA to conduct a limited number of partner surveys without a full-scale OMB review of each survey. If this generic information collection request receives continued approval, information on each individual partner survey will not be published in the **Federal Register**.

A 60-day notice published in the **Federal Register** on December 15, 2020, vol. 85, No. 241; pp. 81210-11. There were no public comments.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
In-class evaluations	40,000	1	40,000	.05	2,000
Mail/Telephone surveys	12,000	1	12,000	.25	3,000
Focus groups	250	1	250	1.50	375
Total	52,250	52,250	5,375

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021-05349 Filed 3-15-21; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19

ACTION: Notice of amendment.

SUMMARY: The Acting Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer covered countermeasures under section VI of this Declaration.

DATES: This amendment to the Declaration is effective as of March 11, 2021.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; 202–260–0365, paige.ezernack@hhs.gov.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving “willful misconduct” as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, section 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013 and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

On January 31, 2020, the former Secretary, Alex M. Azar II, declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation’s health care community to the COVID–19 outbreak. Pursuant to section 319 of the PHS Act, the Secretary renewed that declaration effective on April 26, 2020, July 25,

2020, October 23, 2020, and January 21, 2021.

On March 10, 2020, former Secretary Azar issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198, Mar. 17, 2020) (the Declaration). On April 10, the former Secretary amended the Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, the former Secretary amended the Declaration to clarify that covered countermeasures under the Declaration include qualified countermeasures that limit the harm COVID–19 might otherwise cause. (85 FR 35100, June 8, 2020). On August 19, the former Secretary amended the declaration to add additional categories of Qualified Persons and amend the category of disease, health condition, or threat for which he recommended the administration or use of the Covered Countermeasures. (85 FR 52136, August 24, 2020). On December 3, 2020, the former Secretary amended the declaration to incorporate Advisory Opinions of the General Counsel interpreting the PREP Act and the Secretary’s Declaration and authorizations issued by the Department’s Office of the Assistant Secretary for Health as an Authority Having Jurisdiction to respond; added an additional category of qualified persons under Section V of the Declaration; made explicit that the Declaration covers all qualified pandemic and epidemic products as defined under the PREP Act; added a third method of distribution to provide liability protections for, among other things, private distribution channels; made explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and the Declaration’s liability protections; made explicit that there are substantive Federal legal and policy issues and interests in having a unified whole-of-nation response to the COVID–19 pandemic among Federal, state, local, and private-sector entities; revised the effective time period of the Declaration; and republished the declaration in full. (85 FR 79190, December 9, 2020). On February 2, 2021, the Acting Secretary Norris Cochran amended the Declaration to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are covered countermeasures under the Declaration (86 FR 7872, February 2, 2021). On

February 16, 2021, the Acting Secretary amended the Declaration to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are covered countermeasures under the Declaration (86 FR 9516, February 16, 2021) and on February 22, 2021, the Department filed a notice of correction to the February 2 and February 16 notices correcting effective dates stated in the Declaration, and correcting the description of qualified persons added by the February 16, 2021 amendment. (86 FR 10588, February 22, 2021).

The Acting Secretary now amends section V of the Declaration to revise subsection (f) to clarify that observers should be experienced in administering intramuscular injections; delete subsection (g), change the prior subsection (h) to subsection (g) and add a new subsection (h) to add additional categories of qualified persons covered under the PREP Act, and thus authorizes: (h) The following healthcare professionals and students in a healthcare profession training program subject to the requirements of this paragraph:

1. Any midwife, paramedic, advanced or intermediate emergency medical technician (EMT), physician assistant, respiratory therapist, dentist, podiatrist, optometrist or veterinarian licensed or certified to practice under the law of any state who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered;

2. Any physician, advanced practice registered nurse, registered nurse, practical nurse, pharmacist, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, respiratory therapist, dentist, physician assistant, podiatrist, optometrist, or veterinarian who has held an active license or certification under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is

administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General;

3. Any medical, nursing, pharmacy, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, physician assistant, respiratory therapy, dental, podiatry, optometry or veterinary student with appropriate training in administering vaccines as determined by his or her school or training program and supervision by a currently practicing healthcare professional experienced in administering intramuscular injections who administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered;

Subject to the following requirements:

- i. The vaccine must be authorized, approved, or licensed by the FDA;
- ii. Vaccination must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s);
- iii. The healthcare professionals and students must have documentation of completion of the Centers for Disease Control and Prevention COVID-19 Vaccine Training Modules and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID-19 vaccines;
- iv. The healthcare professionals and students must have documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering intramuscular injections is in their ordinary scope of practice, who confirms competency of the healthcare provider or student in preparation and administration of the COVID-19 vaccine(s) to be administered and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID-19 vaccines;
- v. The healthcare professionals and students must have a current certificate

in basic cardiopulmonary resuscitation;¹

vi. The healthcare professionals and students must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine; and

vii. The healthcare professionals and students comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

Description of This Amendment by Section

Section V. Covered Persons

Under the PREP Act and the Declaration, a "qualified person" is a "covered person." Subject to certain limitations, a covered person is immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure. "Qualified person" includes (A) a licensed health professional or other

¹ This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase "current certificate in basic cardiopulmonary resuscitation," when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. See Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, Oct. 20, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf> (last visited Jan. 24, 2021).

individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) "a person within a category of persons so identified in a declaration by the Secretary" under subsection (b) of the PREP Act. 42 U.S.C. 247d-6d(i)(8).

By this amendment to the Declaration, the Acting Secretary identifies an additional categories of persons who are qualified persons under section 247d-6d(i)(8)(B): licensed healthcare professionals who may not ordinarily prescribe, dispense or administer vaccines, additional healthcare providers with recently expired licenses, and students in a healthcare profession training program, subject to appropriate training, supervision, and other specified requirements. The Acting Secretary anticipates that significantly more vaccines will be available to the public in the spring and summer of 2021, and wants to ensure that states have the greatest flexibility in mobilizing the workforce they will need to engage in the largest vaccination effort in our Nation's history. This amendment thus expands the pool of vaccinators to individuals who have or can obtain training and the capability to administer vaccines even if prescribing, dispensing and administering vaccines is not within the scope of their license or usual responsibilities, allowing States, Territories, local areas and Tribes to use these individuals in their vaccination programs.

The Acting Secretary has determined that there is an urgent need to expand the pool of available COVID-19 vaccinators in order to respond effectively to the pandemic. As vaccine supply is made more widely available over the coming months, health care system capacity and the vaccination workforce are likely to become increasingly strained throughout the Nation.

As qualified persons, these healthcare professionals and students in healthcare profession training programs will be afforded liability protections in accordance with the PREP Act and the terms of this amended Declaration. Second, to the extent that any State law that would otherwise prohibit the healthcare professionals and students in healthcare profession training programs who are a "qualified person" from prescribing, dispensing, or administering COVID-19 vaccines or other Covered Countermeasures, such law is preempted. On May 19, 2020, the Office of the General Counsel issued an advisory opinion concluding that, because licensed pharmacists are

“qualified persons” under this declaration, the PREP Act preempts state law that would otherwise prohibit such pharmacists from ordering and administering authorized COVID-19 diagnostic tests.² The opinion relied in part on the fact that the Congressional delegation of authority to the Secretary under the PREP Act to specify a class of persons, beyond those who are authorized to administer a covered countermeasure under State law, as “qualified persons” would be rendered a nullity in the absence of such preemption. This opinion is incorporated by reference into this declaration. Based on the reasoning set forth in the May 19, 2020 advisory opinion, any State law that would otherwise prohibit a member of any of the classes of “qualified persons” specified in this declaration from administering a covered countermeasure is likewise preempted. In accordance with section 319F-3(i)(8)(A) of the Public Health Service Act, a State remains free to expand the universe of individuals authorized to administer covered countermeasures within its jurisdiction under State law.

The plain language of the PREP Act makes clear that there is preemption of state law as described above. Furthermore, preemption of State law is justified to respond to the nation-wide public health emergency caused by COVID-19 as it will enable States to quickly expand the vaccination workforce with additional qualified healthcare professionals where State or local requirements might otherwise inhibit or delay allowing these healthcare professionals to participate in the COVID-19 vaccination program.

Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID-19.

Section V of the March 10, 2020 Declaration under the PREP Act for medical countermeasures against COVID-19, as amended April 10, 2020, June 4, 2020, August 19, 2020, as amended and republished on December

3, 2020, and as amended on February 2, 2021, is further amended pursuant to section 319F-3(b)(4) of the PHS Act as described below. All other sections of the Declaration remain in effect as republished at 85 FR 79190 (December 9, 2020).

1. Covered Persons, section V, delete in full and replace with:

V. Covered Persons

42 U.S.C. 247d-6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are “manufacturers,” “distributors,” “program planners,” “qualified persons,” and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States. “Order” as used herein and in guidance issued by the Office of the Assistant Secretary for Health³ means a provider medication order, which includes prescribing of vaccines, or a laboratory order, which includes prescribing laboratory orders, if required. In addition, I have determined that the following additional persons are qualified persons:

(a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an Emergency, as that term is defined in Section VII of this Declaration;⁴

³ See Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf> (last visited Jan. 24, 2021); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/authorized-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021).

⁴ See, e.g., Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf> (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, OASH, Aug. 31, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-coverage-for-screening-in-congregate-settings.pdf> (last visited Jan. 24, 2021); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/authorized-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021).

(b) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act;

(c) Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act;

(d) A State-licensed pharmacist who orders and administers, and pharmacy interns who administer (if the pharmacy intern acts under the supervision of such pharmacist and the pharmacy intern is licensed or registered by his or her State board of pharmacy),⁵ (1) vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule or (2) FDA authorized or FDA licensed COVID-19 vaccines to persons ages three or older. Such State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if the following requirements are met:

- i. The vaccine must be authorized, approved, or licensed by the FDA;
- ii. In the case of a COVID-19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s);

www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/authorized-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, Oct. 20, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf> (last visited Jan. 24, 2021); PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, Oct. 29, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf> (last visited Jan. 24, 2021) (collectively, OASH PREP Act Authorizations). Nothing herein shall suggest that, for purposes of the Declaration, the foregoing are the only persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction.

⁵ Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, “State-licensed or registered intern” (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but need not, take the form of a license from, or registration with, the State board of pharmacy. See Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, Oct. 20, 2020 at 2, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf> (last visited Jan. 24, 2021).

² Department of Health and Human Services General Counsel Advisory Opinion on the Public Readiness and Emergency Preparedness Act, May 19, 2020, available at: <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf> (last visited Jan. 24, 2021). See also, Department of Justice Office of Legal Counsel Advisory Opinion for Robert P. Charrow, General Counsel of the Department of Health and Human Services, January 12, 2021, available at: <https://www.justice.gov/sites/default/files/opinions/attachments/2021/01/19/2021-01-19-prep-act-preemption.pdf> (last visited Jan. 24, 2021).

iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule;

iv. The licensed pharmacist must have completed the immunization training that the licensing State requires for pharmacists to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. Such a training program must include hands on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

v. The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

vi. The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation;⁶

vii. The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period;

viii. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care

provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine;

ix. The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate; and

x. The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

(e) Healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are licensed or otherwise permitted to practice. When ordering and administering Covered Countermeasures by means of telehealth to patients in a state where the healthcare personnel are not already permitted to practice, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients by means of telehealth in the state where the healthcare personnel are permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures by means of telehealth is preempted.⁷ Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services;

(f) Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State as of the effective date of this amendment, or as authorized under the section V(d) of this Declaration, who

prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, in association with a COVID-19 vaccination effort by a federal, State, local Tribal or territorial authority or by an institution in the State in which the COVID-19 vaccine covered countermeasure is administered, so long as the license or certification of the healthcare professional has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to: (i) Documentation of completion of the Centers for Disease Control and Prevention COVID-19 (CDC) Vaccine Training Modules⁸ and, for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering intramuscular injections is in their ordinary scope of practice, who confirms competency of the healthcare provider in preparation and administration of the COVID-19 vaccine(s) to be administered;

(g) Any member of a uniformed service (including members of the National Guard in a Title 32 duty status) (hereafter in this paragraph "service member") or Federal government, employee, contractor, or volunteer who prescribes, administers, delivers, distributes or dispenses a Covered Countermeasure. Such Federal government service members, employees, contractors, or volunteers are qualified persons if the following requirement is met: the executive department or agency by or for which the Federal service member, employee, contractor, or volunteer is employed, contracts, or volunteers has authorized or could authorize that service member, employee, contractor, or volunteer to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of the duties or responsibilities of that service member, employee, contractor, or volunteer, even if those authorized duties or responsibilities ordinarily would not extend to members of the

⁶ This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase "current certificate in basic cardiopulmonary resuscitation," when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. See Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, Oct. 20, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf> (last visited Jan. 24, 2021).

⁷ See, e.g., Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf> (last visited Jan. 24, 2021).

⁸ See COVID-19 Vaccine Training Modules, available at <https://www.cdc.gov/vaccines/covid-19/training.html>.

public or otherwise would be more limited in scope than the activities such service member, employees, contractors, or volunteers are authorized to carry out under this declaration; and

(h) The following healthcare professionals and students in a healthcare profession training program subject to the requirements of this paragraph:

1. Any midwife, paramedic, advanced or intermediate emergency medical technician (EMT), physician assistant, respiratory therapist, dentist, podiatrist, optometrist or veterinarian licensed or certified to practice under the law of any state who prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered;

2. Any physician, advanced practice registered nurse, registered nurse, practical nurse, pharmacist, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, respiratory therapist, dentist, physician assistant, podiatrist, optometrist, or veterinarian who has held an active license or certification under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General;

3. Any medical, nursing, pharmacy, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, physician assistant, respiratory therapy, dental, podiatry, optometry or veterinary student with appropriate training in administering vaccines as determined by his or her school or training program and supervision by a

currently practicing healthcare professional experienced in administering intramuscular injections who administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered;

Subject to the following requirements:

i. The vaccine must be authorized, approved, or licensed by the FDA;

ii. Vaccination must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s);

iii. The healthcare professionals and students must have documentation of completion of the Centers for Disease Control and Prevention COVID-19 Vaccine Training Modules and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID-19 vaccines;

iv. The healthcare professionals and students must have documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering vaccinations is in their ordinary scope of practice, who confirms competency of the healthcare provider or student in preparation and administration of the COVID-19 vaccine(s) to be administered and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID-19 vaccines;

v. The healthcare professionals and students must have a current certificate in basic cardiopulmonary resuscitation;⁹

⁹ This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase "current certificate in basic cardiopulmonary resuscitation," when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. See Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, Oct. 20, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf> (last visited Jan. 24, 2021).

vi. The healthcare professionals and students must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine; and

vii. The healthcare professionals and students comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa-10 *et seq.* are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such covered countermeasures.

2. Effective Time Period, section XII, delete in full and replace with:

Liability protections for any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, through the means of distribution identified in Section VII(a) of this Declaration, begin on March 27, 2020 and extend through October 1, 2024.

Liability protections for all other Covered Countermeasures identified in Section VI of this Declaration, through means of distribution identified in Section VII(a) of this Declaration, begin on February 4, 2020 and extend through October 1, 2024.

Liability protections for all Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction, as

www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf (last visited Jan. 24, 2021).

identified in Section VII(b) of this Declaration, begin with a Declaration of Emergency as that term is defined in Section VII (except that, with respect to qualified persons who order or administer a routine childhood vaccination that ACIP recommends to persons ages three through 18 according to ACIP's standard immunization schedule, liability protections began on August 24, 2020), and last through (a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first.

Liability protections for all Covered Countermeasures identified in Section VII(c) of this Declaration begin on December 9, 2020 and last through (a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first.

Liability protections for Qualified Persons under section V(f) of the declaration begin on February 2, 2021, and last through October 1, 2024.

Liability protections for Qualified Persons under section V(g) of the declaration begin on February 16, 2021, and last through October 1, 2024.

Liability protections for Qualified Persons who are physicians, advanced practice registered nurses, registered nurses, or practical nurses under section V(h) of the declaration begins on February 2, 2021 and last through October 1, 2024, with additional conditions effective as of March 11, 2021 and liability protections for all other Qualified persons under section V(h) begins on March 11, 2021 and last through October 1, 2024.

Authority: 42 U.S.C. 247d–6d.

Norris Cochran,
Acting Secretary, Department of Health and Human Services.

[FR Doc. 2021–05401 Filed 3–11–21; 4:15 pm]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and

evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

Date: May 18–19, 2021.

Time: 9:00 a.m. to 4:15 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alicia J. Dombroski, Ph.D., Director, Division of Extramural Activities, Natl Inst of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD 20892.

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: March 10, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–05351 Filed 3–15–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0046]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Interagency Alien Witness and Informant Record

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

ACTION: 60-day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated

burden (*i.e.*, the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until May 17, 2021.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0046 in the body of the letter, the agency name and Docket ID USCIS–2006–0062. Submit comments via the Federal eRulemaking Portal website at <https://www.regulations.gov> under e-Docket ID number USCIS–2006–0062. USCIS is limiting communications for this Notice as a result of USCIS' COVID–19 response actions.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721–3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at <https://www.uscis.gov>, or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: <https://www.regulations.gov> and entering USCIS–2006–0062 in the search box. All submissions will be posted, without change, to the Federal eRulemaking Portal at <https://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of <https://www.regulations.gov>.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) 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;

(2) 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;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Interagency Alien Witness and Informant Record.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I-854A and I-854B; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Federal Government. The Form I-854 will enable the U.S. Immigration and Customs Enforcement (ICE) to fulfill those responsibilities. A law enforcement agency may request S nonimmigrant classification for an essential witness or informant by completing this form, which requires certifications by both the law enforcement agency (e.g., that it will collect the alien's statutorily-required quarterly reports and oversee the alien's departure, if that becomes necessary) and the alien. The law enforcement agency files a properly completed Form I-854 with the Criminal Division, Department of Justice, which may certify the law enforcement agency request to the U.S. Citizenship and Immigration Services (USCIS).

(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 respondents for the information collection I-854A is 10 and the estimated hour burden per response is 3 hours. The estimated total number of respondents for the information collection I-854B is 30 and the

estimated hour burden per response is 1 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 is 60 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.

Dated: March 9, 2021.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2021-05393 Filed 3-15-21; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0044]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Application for Action on an Approved Application or Petition

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

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until April 15, 2021.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at <http://www.regulations.gov> under e-Docket ID number USCIS-2007-0012. All submissions received must include the OMB Control Number 1615-0044 in the body of the letter, the agency name and Docket ID USCIS-2007-0012.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy,

Regulatory Coordination Division, Samantha Deshommes, Chief, Telephone number (240) 271-3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at <http://www.uscis.gov>, or call the USCIS Contact Center at (800) 375-5283; TTY (800) 767-1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on September 29, 2020, at 85 FR 61020, allowing for a 60-day public comment period. USCIS did not receive any comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: <http://www.regulations.gov> and enter USCIS-2007-0012 in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) 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;

(2) 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

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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 Request:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application for Action on an Approved Application or Petition.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I-824; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. This information collection is used to request a duplicate approval notice, as well as to notify and to verify the U.S. Consulate that a petition has been approved or that a person has been adjusted to permanent resident status.

(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 respondents for the information collection I-824 is 10,571 and the estimated hour burden per response is 0.42 hour.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 4,440 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 \$1,361,016.

Dated: March 9, 2021.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2021-05392 Filed 3-15-21; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-6248-N-01]

Section 8 Housing Assistance Payments Program—Fiscal Year (FY) 2021 Inflation Factors for Public Housing Agency (PHA) Renewal Funding

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: This notice establishes Renewal Funding Inflation Factors (RFIFs) to adjust Fiscal Year (FY) 2021 renewal funding for the Housing Choice Voucher (HCV) Program of each public housing agency (PHA), as required by the Consolidated Appropriations Act, 2021. The notice apportions the expected percent change in national Per Unit Cost (PUC) for the HCV program, 5.80 percent, to each PHA based on the change in Fair Market Rents (FMRs) for their operating area to produce the FY 2021 RFIFs. HUD's FY 2021 methodology is the same as that which was used in FY 2020.

DATES: *Effective Date:* March 16, 2021.

FOR FURTHER INFORMATION CONTACT:

Miguel A. Fontanez, Director, Housing Voucher Financial Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, telephone number 202-402-4212; or Adam Bibler, Program Parameters and Research Division, Office of Policy Development and Research, telephone number 202-402-6057, for technical information regarding the development of the schedules for specific areas or the methods used for calculating the inflation factors. Their mailing address is: Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410. Hearing- or speech-impaired persons may contact the Federal Relay Service at 800-877-8339 (TTY). (Other than the "800" TTY number, the above-listed telephone numbers are not toll free.)

SUPPLEMENTARY INFORMATION:

I. Background

Division L, Title II of the Consolidated Appropriations Act, 2021 requires that the HUD Secretary, for the calendar year 2021 funding cycle, provide renewal funding for each public housing agency (PHA) based on validated voucher management system (VMS) leasing and cost data for the prior calendar year and by applying an inflation factor as established by the Secretary, by notice published in the **Federal Register**. This

notice announces the availability of the FY 2021 inflation factors and describes the methodology for calculating them. Tables in PDF and Microsoft Excel formats showing Renewal Funding Inflation Factors (RFIFs) by HUD Fair Market Rent Area are available electronically from the HUD data information page at: <https://www.huduser.gov/portal/datasets/rfif/rfif.html>.

II. Methodology

RFIFs are used to adjust the allocation of Housing Choice Voucher (HCV) program funds to PHAs for local changes in rents, utility costs, and tenant incomes. To calculate the RFIFs, HUD first forecasts a national inflation factor, which is the annual change in the national average Per Unit Cost (PUC). HUD then calculates individual area inflation factors, which are based on the annual changes in the two-bedroom Fair Market Rent (FMR) for each area. Finally, HUD adjusts the individual area inflation factors to be consistent with the national inflation factor.

HUD's forecast of the national average PUC is based on forecasts of gross rent and tenant income. Each forecast is produced using historical and forecasted macroeconomic data as independent variables, where the forecasts are consistent with the Economic Assumptions of the Administration's FY 2022 Budget. The forecast of gross rent is itself based on forecasts of the Consumer Price Index (CPI) Rent of Primary Residence Index and the CPI Fuels and Utilities Index. Forecasted values of these series are applied to the FY 2021 national average two-bedroom FMR to produce a CY 2021 value. A "notional" PUC is calculated as the difference between gross rent value and 30 percent of tenant income (the standard for tenant rent contribution in the voucher program). The change between the forecasted CY 2021 notional PUC and the CY 2020 notional PUC is the expected national change in PUC, or 5.80 percent. HUD uses a notional PUC as opposed to the actual PUC to project costs that are consistent with PHAs leasing the same number and quality of units. For more information on HUD's forecast methodology, see 82 FR 26710.

The inflation factor for an individual geographic area is based on the annualized change in the area's FMR between FY 2020 and FY 2021. These changes in FMRs are then scaled such that the voucher-weighted average of all individual area inflation factors is equal to the national inflation factor, i.e., the expected annual change in national PUC

from CY 2020 to CY 2021, and such that no area has a factor less than one. For PHAs operating in multiple FMR areas, HUD calculates a voucher-weighted average inflation factor based on the count of vouchers in each FMR area administered by the PHA as captured in HUD administrative data as of December 31, 2020.

III. The Use of Inflation Factors

HUD subsequently applies the calculated individual area inflation factors to eligible renewal funding for each PHA based on VMS leasing and cost data for the prior calendar year.

IV. Geographic Areas and Area Definitions

As explained above, inflation factors based on area FMR changes are produced for all FMR areas and applied to eligible renewal funding for each PHA. The tables showing the RFIFs, available electronically from the HUD data information page, list the inflation factors for each FMR area on a state-by-state basis. The inflation factors use the same OMB metropolitan area definitions, as revised by HUD, that are used in the FY 2021 FMRs. PHAs should refer to the Area Definitions Table on the following web page to make certain that they are referencing the correct inflation factors: http://www.huduser.org/portal/datasets/rfif/FY2021/FY2021_RFIF_FMR_AREA_REPORT.pdf. The Area Definitions Table lists areas in alphabetical order by state, and the counties associated with each area. In the six New England states, the listings are for counties or parts of counties as defined by towns or cities. HUD is also releasing the data in Microsoft Excel format to assist users who may wish to use these data in other calculations. The Excel file is available at <https://www.huduser.gov/portal/datasets/rfif/rfif.html>. Note that, as described earlier, the actual renewal funding inflation factor applied to agency funding will be the voucher-weighted average of the FMR area factors when the PHA operates in multiple areas.

VI. Environmental Impact

This notice involves a statutorily required establishment of a rate or cost determination which does not constitute a development decision affecting the physical condition of specific project areas or building sites. Accordingly, under 24 CFR 50.19(c)(6), this notice is categorically excluded from environmental review under the

National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Todd Richardson,

General Deputy Assistant Secretary for Policy, Development and Research.

[FR Doc. 2021-05365 Filed 3-15-21; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-709]

Bulk Manufacturer of Controlled Substances Application: Cambridge Isotope Lab; Correction

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application; correction.

SUMMARY: The Drug Enforcement Administration (DEA) published a document in the **Federal Register** of September 14, 2020, concerning a notice of application. The document contained a misspelling (Isotype vs. Isotope).

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of September 14, 2020, in FR Doc. 2020-20160 (85 FR 56633), on page 56633-56634, correct all instances of the registrant name to read Cambridge Isotope Lab.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021-05358 Filed 3-15-21; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-805]

Importer of Controlled Substances Application: Purisys, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Purisys, LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before April 15, 2021. Such persons

may also file a written request for a hearing on the application on or before April 15, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on February 17, 2021, Purisys, LLC, 1550 Olympic Drive, Athens, Georgia 30601, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Noroxymorphone	7379	II
Phenylacetone	8501	II
Levorphanol	9220	II
Thebaine	9333	II
Poppy Straw Concentrate	9670	II
Tapentadol	9780	II

The company plans to import drug code 8501, Phenylacetone and drug code 9670, Poppy Straw Concentrate to bulk manufacture other controlled substances for distribution to its customers. The company plans to import impurities of buprenorphine that have been determined by DEA to be captured under drug code 9333, Thebaine. In reference to drug codes 73760, Marihuana and 7370, Tetrahydrocannabinols the company plans to import a Synthetic Cannabidiol and a Synthetic Tetrahydrocannabinol. No other activity for these drug codes is authorized for this registration. Placement of these drug codes on the company's registration does not translate into automatic approval of subsequent permit applications to import controlled substances.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-

approved finished dosage forms for commercial sale.

William T. McDermott,
Assistant Administrator.

[FR Doc. 2021-05356 Filed 3-15-21; 8:45 am]

BILLING CODE 4410-09-P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act Meetings

TIME AND DATE: 10:00 a.m., Thursday, March 18, 2021.

PLACE: Due to the COVID-19 Pandemic, the meeting will be open to the public via live webcast only. Visit the agency's homepage (www.ncua.gov) and access the provided webcast link.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

1. NCUA Rules and Regulations, Central Liquidity Facility.
2. NCUA Rules and Regulations, Asset Thresholds Pertaining to Large Credit Unions.
3. Board Briefing, NCUA Guaranteed Note and Asset Management Estates Programs.

CONTACT PERSON FOR MORE INFORMATION: Melane Conyers-Ausbrooks, Secretary of the Board, Telephone: 703-518-6304.

Melane Conyers-Ausbrooks,
Secretary of the Board.

[FR Doc. 2021-05468 Filed 3-12-21; 11:15 am]

BILLING CODE 7535-01-P

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meeting

TIME AND DATE: 9:30 a.m., Tuesday, April 6, 2021.

PLACE: Virtual.

STATUS: The one item may be viewed by the public through webcast only.

MATTER TO BE CONSIDERED:

66392 2021-2022 Most Wanted List of Transportation Safety Improvements Proposal.

FOR MORE INFORMATION CONTACT: Candi Bing at (202) 590-8384 or by email at bing@ntsb.gov.

Media Information Contact: Chris O'Neil by email at chris.oneil@ntsb.gov (202) 314-6100.

This meeting will take place virtually. The public may view it through a live or archived webcast by accessing a link under "Webcast of Events" on the NTSB home page at www.ntsb.gov.

There may be changes to this event due to the evolving situation concerning

the novel coronavirus (COVID-19). Schedule updates, including weather-related cancellations, are also available at www.nts.gov.

The National Transportation Safety Board is holding this meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b).

Dated: March 12, 2021.

Candi R. Bing,

Federal Register Liaison Officer.

[FR Doc. 2021-05551 Filed 3-12-21; 4:50 pm]

BILLING CODE 7533-01-P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-289 and 50-320; NRC-2021-0069]

**Exelon Generation Company, LLC;
TMI-2 Solutions, LLC; Three Mile Island
Nuclear Station, Units 1 and 2**

AGENCY: Nuclear Regulatory
Commission.

ACTION: Exemptions; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued exemptions in response to a request to reduce the required level of primary offsite liability insurance from \$450 million to \$100 million and to eliminate the requirement to carry secondary financial protection for Three Mile Island Nuclear Station, Unit 1 and to reduce the required level of primary offsite liability insurance in the event of an extraordinary nuclear occurrence from \$200 million to \$100 million for Three Mile Island Nuclear Station, Unit 2.

DATES: The exemptions were issued on March 9, 2021.

ADDRESSES: Please refer to Docket ID NRC-2021-0069 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-2021-0069. 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 individual 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.

- **Attention:** The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at pdr.resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Theodore Smith, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6721, email: Theodore.Smith@nrc.gov.

SUPPLEMENTARY INFORMATION: The text of the exemptions is attached.

Dated: March 11, 2021.

For the Nuclear Regulatory Commission.

Bruce A. Watson,

*Chief, Reactor Decommissioning Branch,
Division of Decommissioning, Uranium
Recovery and Waste Programs, Office of
Nuclear Material Safety and Safeguards.*

Attachment—Exemption

NUCLEAR REGULATORY COMMISSION

Docket Nos. 50-289 and 50-320

Exelon Generation Company, LLC

TMI-2 Solutions, LLC

**Three Mile Island Nuclear Station,
Units 1 and 2 Exemptions**

I. Background

By letter dated June 20, 2017 (Agencywide Documents Access and Management System [ADAMS] Accession No. Main Library [ML] ML17171A151), Exelon Generation Company, LLC (Exelon) certified to the U.S. Nuclear Regulatory Commission (NRC, the Commission) that it planned to permanently cease power operations at Three Mile Island Nuclear Station, Unit 1 (TMI-1) on or about September 30, 2019. On September 20, 2019, Exelon permanently ceased power operations at TMI-1. By letter dated September 26, 2019 (ADAMS Accession No. ML19269E480), Exelon certified to the NRC that the fuel was permanently removed from the TMI-1 reactor vessel and placed in the spent fuel pool (SFP) as of September 26, 2019. Accordingly,

pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.82(a)(2), the TMI-1 renewed facility operating license no longer authorizes operation of the reactor or emplacement or retention of fuel in the reactor vessel. The facility is still authorized to possess and store irradiated (*i.e.*, spent) nuclear fuel. Spent fuel is currently stored onsite at the TMI-1 facility in the SFP.

Three Mile Island Nuclear Station, Unit 2 (TMI-2) was a 2,770 megawatts thermal pressurized light-water reactor supplied by Babcock & Wilcox that was issued an operating license on February 8, 1978 and began commercial operations on December 30, 1978. On March 28, 1979, TMI-2 experienced an accident that resulted in severe damage to the reactor core. Subsequently, approximately 99 percent of the fuel and damaged core material was removed from the TMI-2 reactor vessel and associated systems and shipped to the U.S. Department of Energy Idaho National Laboratory. After the completion of accident recovery operations, TMI-2 was placed in a Post-Defueling Monitored Storage (PDMS) state on September 14, 1993, with a possession only license that authorizes the possession of byproduct and special nuclear materials but not the operation of the reactor.

Following the TMI-2 accident, in 1982, the NRC granted an exemption from the requirements of 10 CFR 140.11(a)(4) for TMI-1 and TMI-2 (ML19141A211). The exemption allowed the licensees to provide two endorsements to meet the financial protection requirements of subsection 170 of the Atomic Energy Act of 1954, as amended. The first endorsement, Endorsement No. 43, restored the limits of liability to the amounts listed in other endorsements upon an “extraordinary nuclear occurrence” (ENO) being declared by the NRC arising out of the ownership, operation, maintenance, or use of TMI-1 and/or TMI-2. The second endorsement, Endorsement No. 44, increased the TMI-1 liability limit to the NRC limit in effect at the time for any bodily injury or property damages caused by a nuclear energy hazard, but increased the TMI-2 liability limit only in the event the NRC declared an ENO on or after May 1, 1979. Subsequently, in 1994, the NRC granted TMI-2 an exemption from participation in secondary financial protection (ADAMS Accession No. 9408050260 [Legacy Library]). The exemptions herein do not impact the exemptions already in place.

II. Request/Action

By letter dated January 3, 2020 (ADAMS Accession No. ML20003E096),

Exelon requested an exemption from 10 CFR 140.11(a)(4) to reduce the required level of primary offsite liability insurance from \$450 million to \$100 million and to eliminate the requirement to carry secondary financial protection for TMI-1 and TMI-2 Solutions, LLC (TMI-2 Solutions) ¹ requested an exemption from 10 CFR 140.11(a)(4) to reduce the required level of primary offsite liability insurance in the event of an ENO ² from \$200 million to \$100 million for TMI-2.

The regulation at 10 CFR 140.11(a)(4) requires each licensee to have and maintain primary financial protection in an amount of \$450 million. In addition, the licensee is required to participate in an industry retrospective rating plan (secondary financial protection) that commits each licensee to pay into an insurance pool to be used for damages that may exceed primary insurance coverage. Participation in the industry retrospective rating plan will subject the licensee to deferred premium charges up to a maximum total deferred premium of \$131,056,000 with respect to any nuclear incident at any operating nuclear power plant and up to a maximum annual deferred premium of \$20,496,000 per incident.

Many of the accident scenarios postulated in the updated safety analysis reports for operating power reactors involve failures or malfunctions of systems, which could affect the fuel in the reactor core and, in the most severe postulated accidents, would involve the release of large quantities of fission products. With the permanent cessation of power operations at TMI-1 and the permanent removal of the fuel from the reactor vessel, and the PDMS state of TMI-2 with no fuel assemblies in the TMI-2 reactor or the TMI-2 SFP, many accidents are no longer possible. Similarly, the associated risk of offsite liability damages that would require insurance or indemnification is commensurately lower for such plants. Therefore, Exelon requested an exemption from 10 CFR 140.11(a)(4) to permit a reduction in primary offsite liability insurance and to withdraw from participation in the industry retrospective rating plan for TMI-1. Additionally, TMI-2 Solutions requested an exemption from 10 CFR 140.11(a)(4) to permit a reduction in primary offsite liability insurance to \$100 million in the event of an ENO for TMI-2.

¹ The TMI-2 license was transferred to TMI-2 Solutions on December 18, 2020 (ADAMS Accession No. ML20352A381).

² Pursuant to 10 CFR 140.83, if the Commission determines that both of the criteria set forth in 10 CFR 140.84 and 140.85 have been met, it will make the determination that there has been an ENO.

III. Discussion

Pursuant to 10 CFR 140.8, “Specific exemptions,” the Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in 10 CFR part 140 when the exemptions are authorized by law and are otherwise in the public interest. The NRC staff has reviewed the licensees’ request for exemptions from 10 CFR 140.11(a)(4) and has concluded that the requested exemptions are authorized by law and are otherwise in the public interest.

The Price Anderson Act of 1957 (PAA) requires that nuclear power reactor licensees have insurance to compensate the public for damages arising from a nuclear incident. Specifically, the PAA requires licensees of facilities with a “rated capacity of 100,000 electrical kilowatts or more” to maintain the maximum amount of primary offsite liability insurance commercially available (currently \$450 million) and a specified amount of secondary insurance coverage (currently up to \$131,056,000 per reactor). In the event of an accident causing offsite damages in excess of \$450 million, each licensee would be assessed a prorated share of the excess damages, up to \$131,056,000 per reactor, for a total of approximately \$13 billion per nuclear incident. The NRC’s regulations at 10 CFR 140.11(a)(4) implement these PAA insurance requirements and set forth the amount of primary and secondary insurance each power reactor licensee must have.

As noted above, the PAA requirements with respect to primary and secondary insurance and the implementing regulations at 10 CFR 140.11(a)(4) apply to licensees of facilities with a “rated capacity of 100,000 electrical kilowatts or more.” In accordance with 10 CFR 50.82(a)(2), the license for a power reactor no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor vessel upon the docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel, or when a final legally effective order to permanently cease operations has come into effect. Therefore, the reactor cannot be used to generate power.

Accordingly, a reactor that is undergoing decommissioning has no “rated capacity.” Thus, the NRC may take the reactor licensee out of the category of reactor licensees that are required to maintain the maximum available insurance and to participate in

the secondary retrospective insurance pool.

The financial protection limits of 10 CFR 140.11(a)(4) were established to require a licensee to maintain sufficient insurance, as specified under the PAA, to satisfy liability claims by members of the public for personal injury, property damage, and the legal cost associated with lawsuits as the result of a nuclear accident at an operating reactor with a rated capacity of 100,000 kilowatts electric or greater. Thus, the insurance levels established by this regulation, as required by the PAA, were associated with the risks and potential consequences of an accident at an operating reactor with a rated capacity of 100,000 kilowatts electric or greater.

The legal and associated technical basis for granting exemptions from 10 CFR part 140 is set forth in SECY-93-127, "Financial Protection Required of Licensees of Large Nuclear Power Plants During Decommissioning," dated May 10, 1993 (ADAMS Accession No. ML12257A628). The legal analysis underlying SECY-93-127 concluded that, upon a technical finding that lesser potential hazards exist after permanent cessation of power operations (and the reactor having no "rated capacity"), the Commission has the discretion under the PAA to reduce the amount of insurance required of a licensee undergoing decommissioning.

As a technical matter, the fact that a reactor has permanently ceased power operations is not itself determinative as to whether a licensee may cease providing the offsite liability coverage required by the PAA and 10 CFR 140.11(a)(4). In light of the presence of freshly discharged irradiated fuel in the SFP at a recently shut down reactor, the potential for an offsite radiological release from a zirconium fire with consequences comparable in some respects to an operating reactor accident remains. That risk is very low at the time of reactor shut down because of design provisions that prevent a significant reduction in coolant inventory in the SFP under normal and accident conditions and becomes no longer credible once the continual reduction in decay heat provides ample time to restore coolant inventory and permits air-cooling in a drained SFP. After that time, the probability of a large offsite radiological release from a zirconium fire is negligible for permanently shut down reactors, but the SFP is still operational and an inventory of radioactive materials still exists onsite. Therefore, an evaluation of the potential for offsite damage is necessary to determine the appropriate level of offsite insurance post shut down, in

accordance with the Commission's discretionary authority under the PAA to establish an appropriate level of required financial protection for such permanently shut down facilities.

The NRC staff has conducted an evaluation and concluded that, aside from the handling, storage, and transportation of spent fuel and radioactive materials for a permanently shut down and defueled reactor, no reasonably conceivable potential accident exists that could cause significant offsite damage. During normal power reactor operations, the forced flow of water through the reactor coolant system (RCS) removes heat generated by the reactor. The RCS transfers this heat away from the reactor core by converting reactor feedwater to steam, which then flows to the main turbine generator to produce electricity. Most of the accident scenarios postulated for operating power reactors involve failures or malfunctions of systems that could affect the fuel in the reactor core, which in the most severe postulated accidents would involve the release of large quantities of fission products. With the permanent cessation of reactor operations at the TMI site and the permanent removal of the fuel from the reactor core, such accidents are no longer possible. The reactor, RCS, and supporting systems no longer operate and have no function related to the storage of the irradiated fuel. Therefore, postulated accidents involving failure or malfunction of the reactor, RCS, or supporting systems are no longer applicable.

During reactor decommissioning, the principal radiological risks are associated with the storage of spent fuel onsite. On a case-by-case basis, licensees undergoing decommissioning have been granted permission to reduce the required amount of primary offsite liability insurance coverage from \$450 million to \$100 million and to withdraw from the secondary insurance pool. One of the technical criteria for granting the exemption is that the possibility of a design-basis event that could cause significant offsite damage has been eliminated.

In its exemption request, Exelon described both design-basis and beyond-design-basis events involving irradiated fuel stored in the TMI-1 SFP. Exelon stated, and the NRC staff agrees, that while spent fuel remains in the SFP, the only postulated design-basis accident that would remain applicable to TMI-1 in the permanently defueled condition that could contribute a significant dose is a fuel handling accident (FHA) in the Reactor Building, where the SFP is located. For completeness, the NRC staff

also evaluated the applicability of other design-basis accidents documented in the TMI-1 Updated Final Safety Analysis Report (UFSAR) (ADAMS Package Accession No. ML18117A343) to ensure that these accidents would not have consequences that could potentially exceed the 10 CFR 50.67 dose limits and Regulatory Guide 1.183, "Alternative Radiological Source Terms for Evaluating Design Basis Accidents at Nuclear Power Reactors," dose acceptance criteria or approach the U.S. Environmental Protection Agency (EPA) early phase protective action guides (PAGs).

In the TMI-1 UFSAR, the licensee has determined that 365 days after shut down, the FHA doses would decrease to a level that would not warrant protective actions under the EPA early phase PAG framework, notwithstanding meeting the dose limit requirements under 10 CFR 50.67 and dose acceptance criteria under Regulatory Guide 1.183. The NRC staff notes that the doses from an FHA are dominated by the isotope Iodine-131. TMI-1 permanently ceased power operations on September 20, 2019. With 488 days of decay, the thyroid dose from an FHA would be negligible and the only isotope remaining in significant amounts, among those postulated to be released in a design-basis FHA, would be Krypton-85. Since Krypton-85 primarily decays by beta emission, the calculated skin dose from an FHA analysis would make an insignificant contribution to the total effective dose equivalent, which is the parameter of interest in the determination of the EPA early phase PAGs for sheltering or evacuation. The NRC staff concludes that the dose consequence from an FHA for the permanently shut down TMI-1 would not approach the EPA early phase PAGs. Therefore, any offsite consequence from a design-basis radiological release is highly unlikely and, thus, a significant amount of offsite liability insurance coverage is not required.

The only beyond design-basis event that has the potential to lead to a significant radiological release at a permanently shut down and defueled reactor is a zirconium fire. The zirconium fire scenario is a postulated, but highly unlikely, accident scenario that involves the loss of water inventory from the SFP resulting in a significant heat up of the spent fuel and culminating in substantial zirconium cladding oxidation and fuel damage. The probability of a zirconium fire scenario is related to the decay heat of the irradiated fuel stored in the SFP. Therefore, the risks from a zirconium

fire scenario continue to decrease as a function of the time that TMI-1 has been permanently shut down.

In the analysis provided in Attachment 2, “Three Mile Island Nuclear Station Zirconium Fire Analysis for Drained Spent Fuel Pool (Calculation C-1101-202-E410-476, Revision 1),” to the letter dated July 1, 2019 (ADAMS Accession No. ML19182A104), the licensee compared the conditions for the hottest fuel assembly stored in the SFP to a criterion proposed in SECY-99-168, “Improving Decommissioning Regulations for Nuclear Power Plants,” dated June 30, 1999 (ADAMS Accession No. ML12265A598), applicable to offsite emergency response for the unit in the decommissioning process. This criterion considers the time for the hottest assembly to heat up from 30 degrees Celsius (°C) to 900 °C adiabatically. If the heat up time is greater than 10 hours, then offsite emergency preplanning involving the plant is not necessary. Based on the limiting fuel assembly for decay heat and adiabatic heat up analysis presented in Attachment 2, at 488 days (approximately 16 months) after permanent cessation of power operations, the time for the hottest fuel assembly to reach 900 °C is 10 hours after the assemblies have been uncovered. As stated in NUREG-1738, “Technical Study of Spent Fuel Pool Accident Risk at Decommissioning Nuclear Power Plants,” dated February 2001 (ADAMS Accession No. ML010430066), 900 °C is an acceptable temperature to use for assessing onset of fission product release under transient conditions to establish the critical decay time for determining the availability of 10 hours for deployment of mitigation equipment and, if necessary, for offsite agencies to take appropriate action to protect the health and safety of the public if fuel and cladding oxidation occurs in air.

The NRC staff reviewed the calculation to verify that important physical properties of materials were within acceptable ranges and the results were accurate. The NRC staff determined that physical properties were appropriate and completed independent confirmatory calculations that produced similar results. Therefore, the NRC staff found that after 488 days of decay, at least 10 hours would be available before a significant offsite release could begin. The NRC staff concluded that the adiabatic heat up calculation provided an acceptable method for determining the minimum time available for deployment of mitigation equipment and, if necessary,

implementing measures under a comprehensive general emergency plan.

In this regard, one technical criterion for relieving decommissioning reactor licensees from the insurance obligations applicable to an operating reactor is a finding that the heat generated by the SFP has decayed to the point where the possibility of a zirconium fire is highly unlikely. This was addressed in SECY-93-127, where the NRC staff concluded that there was a low likelihood and reduced short-term public health consequences of a zirconium fire once a decommissioning plant’s spent fuel has sufficiently decayed. In its Staff Requirements Memorandum, “Financial Protection Required of Licensees of Large Nuclear Power Plants during Decommissioning,” dated July 13, 1993 (ADAMS Accession No. ML003760936), the Commission approved a policy that authorized, through the exemption process, withdrawal from participation in the secondary insurance layer and a reduction in commercial liability insurance coverage to \$100 million when a licensee is able to demonstrate that the spent fuel could be air-cooled if the SFP was drained of water.

The NRC staff has used this technical criterion to grant similar exemptions to other decommissioning reactors (*e.g.*, Maine Yankee Atomic Power Station, published in the **Federal Register** (FR) on January 19, 1999 (64 FR 2920); Zion Nuclear Power Station, published in the **Federal Register** on December 28, 1999 (64 FR 72700); Kewaunee Power Station, published in the **Federal Register** on March 24, 2015 (80 FR 15638); Crystal River Unit 3 Nuclear Generation Plant, published in the **Federal Register** on May 6, 2015 (80 FR 26100); Oyster Creek Nuclear Generating Station, published in the **Federal Register** on December 28, 2018 (83 FR 67365); and Pilgrim Nuclear Power Station, published in the **Federal Register** on January 13, 2020 (85 FR 1827)).

Additional discussions of other decommissioning reactor licensees that have received exemptions to reduce their primary insurance level to \$100 million are provided in SECY-96-256, “Changes to the Financial Protection Requirements for Permanently Shutdown Nuclear Power Reactors, 10 CFR 50.54(w) and 10 CFR 140.11,” dated December 17, 1996 (ADAMS Accession No. ML15062A483). These prior exemptions were based on the licensee demonstrating that the SFP could be air-cooled consistent with the technical criterion discussed above.

The NRC staff has evaluated the issue of zirconium fires in SFPs and presented an independent evaluation of

an SFP subject to a severe earthquake in NUREG-2161, “Consequence Study of a Beyond-Design-Basis Earthquake Affecting the Spent Fuel Pool for a U.S. Mark I Boiling Water Reactor,” dated September 2014 (ADAMS Accession No. ML14255A365). This evaluation concluded that, for a representative boiling-water reactor, fuel in a dispersed high-density configuration would be adequately cooled by natural circulation air flow within several months after discharge from a reactor if the pool was drained of water.

In its exemption request, Exelon compared TMI-1 fuel storage parameters with those used in NRC generic evaluations of fuel cooling included in NUREG/CR-6451, “A Safety and Regulatory Assessment of Generic BWR [Boiling-Water Reactor] and PWR [Pressurized-Water Reactor] Permanently Shut down Nuclear Power Plants,” dated August 1997 (ADAMS Accession No. ML082260098). The analysis described in NUREG/CR-6451 determined that natural air circulation would adequately cool fuel that has decayed for 17 months after operation in a typical PWR, which is a slightly longer decay time than the zirconium fire period of 488 days on which the TMI-1 exemption request is based. In order to evaluate if the TMI-1 decay period was conservative, Exelon examined the decay heat at TMI-1 and determined that the average fuel assembly decay heat for the most recently offloaded TMI-1 spent fuel at 488 days after shut down will be approximately 3 percent less than the decay heat for the average fuel assembly at 519 days for the representative PWR plant in NUREG/CR-6451.

A comparison of the parameters for the fuel assembly power, power density, and hydraulic resistance of the 15x15 fuel assemblies at TMI-1 indicated that these parameters are less than those of the 17x17 fuel assemblies modeled in NUREG/CR-6451. Therefore, the NUREG/CR-6451 fuel assembly model is conservative for TMI-1. The SFP rack configuration was also evaluated and found to be conservative for TMI-1. The configuration/hydraulic resistance of the TMI-1 downcomers and plenum underneath the SFP storage racks is bounded by that modeled in NUREG/CR-6451. Additionally, the hydraulic resistance of the SFP rack loaded cells is less than that of the SFP rack configuration modeled in NUREG/CR-6451. The bottom orifices on all TMI-1 SFP racks are equal to or larger than those modeled in NUREG/CR-6451, which also makes the estimates for TMI-1 more conservative.

As a result of the comparison, Exelon concluded that the TMI-1 SFP conditions are bounded by the NUGREG/CR-6451 benchmark and that the TMI-1 spent fuel would be air-coolable at 488 days after permanent shut down. Therefore, at 16 months after permanent shut down, the NRC staff has reasonable assurance that fuel stored in the TMI-1 SFP would be adequately air-cooled in the unlikely event the SFP completely drained.

In SECY-00-0145, "Integrated Rulemaking Plan for Nuclear Power Plant Decommissioning," dated June 28, 2000, and SECY-01-0100, "Policy Issues Related to Safeguards, Insurance, and Emergency Preparedness Regulations at Decommissioning Nuclear Power Plants Storing Fuel in Spent Fuel Pools," dated June 4, 2001 (ADAMS Accession Nos. ML003721626 and ML011450420, respectively), the NRC staff discussed additional information concerning SFP zirconium fire risks at decommissioning reactors and associated implications for offsite insurance. Analyzing when the spent fuel stored in the SFP is capable of adequate air-cooling is one measure that demonstrates when the probability of a zirconium fire would be exceedingly low.

In addition, the licensee performed adiabatic heat up analyses to determine a dose rate curve at the Exclusion Area Boundary (EAB) and Control Room. Although the analysis described above demonstrated that a significant release of radioactive material from the spent fuel in the absence of water cooling is not possible after 488 days following permanent cessation of power operations, the potential exists for radiation exposure to an offsite individual in the event that shielding of the fuel is lost. The site-specific offsite and Control Room radiological impacts of a postulated complete loss of SFP water were assessed in TMI-1 Technical Evaluation 623073, "TMI Spent Fuel Pool Drindown Shine Dose Rate Evaluation, Revision 0." With a decay of 365 days from shut down, the dose rate at the EAB would be 4.04×10^{-1} mrem/hour not crediting the shielding from the Fuel Handling Building (FHB) roof. Crediting the FHB roof structure, the dose rate at the EAB would be 4.6×10^{-10} mrem/hour.

The licensee's adiabatic heat up analyses demonstrate that 16 months after the permanent cessation of operations, there would be at least 10 hours to take mitigative actions in response to events that could lead to a zirconium fire. In addition, the TMI-1 SFP conditions were determined to be bounded by the analysis of the NUREG/

CR-6451 benchmark demonstrating that the SFP would be air-coolable at 488 days after permanent cessation of operations.

In its exemption request, Exelon furnished the following information: "Because of the length of time it would take for the adiabatic heat up to occur, there is ample time to respond (≥ 10 hours) to any drain down event that might cause such an occurrence by restoring [SFP] cooling or makeup or providing [SFP] spray. As a result, the likelihood that such a scenario would progress to a zirconium fire is not deemed credible."

In the NRC staff's evaluation contained in SECY-20-0041, "Request by Exelon Generation Company, LLC for Exemptions from Certain Emergency Planning Requirements for the Three Mile Island Nuclear Station," dated May 5, 2020 (ADAMS Accession No. ML19311C763), the NRC staff assessed the Exelon accident analyses associated with the radiological risks from a zirconium fire at a permanently shut down and defueled TMI site. For the highly unlikely beyond design-basis accident scenario where the SFP coolant inventory is lost in such a manner that all methods of heat removal from the spent fuel are no longer available, the NRC staff found that there will be a minimum of 10 hours from the initiation of the accident until the cladding reaches a temperature where offsite radiological release might occur. The NRC staff finds that 10 hours is sufficient time to support deployment of mitigation equipment, consistent with plant conditions, to prevent the zirconium cladding from reaching a point of rapid oxidation.

The NRC staff has determined that the licensee's proposed reduction in primary offsite liability coverage to a level of \$100 million and the licensee's proposed withdrawal from participation in the secondary insurance pool for offsite financial protection are consistent with the policy established in SECY-93-127 and subsequent insurance considerations resulting from zirconium fire risks, as discussed in SECY-00-0145 and SECY-01-0100. The NRC has previously determined in SECY-00-0145 that the minimum offsite financial protection requirement may be reduced to \$100 million and that secondary insurance is not required once it is determined that the spent fuel in the SFP is no longer thermal-hydraulically capable of sustaining a zirconium fire based on a plant-specific analysis. In addition, the NRC staff notes that similar exemptions from these insurance requirements have been granted to other permanently shut down

and defueled power reactors upon satisfactory demonstration that zirconium fire risk from the irradiated fuel stored in the SFP is of negligible concern.

As provided in SECY-93-127, the NRC staff included in its recommendations that using the standards set forth in SECY-93-127, primary financial protection could be reduced to \$100 million for nuclear power plants that have had the requisite spent fuel cooling period. However, as specifically mentioned in SECY-93-127 (Note 5), for TMI-2 "primary financial protection covering the site will remain at \$200 million [the full required regulatory value at the time of the issuance of SECY-93-127] because there is at least one other operating reactor on [the] site." Since TMI-1 is no longer authorized to operate, there is no longer at least one other operating reactor on the TMI site. Therefore, TMI-2 Solutions requested a corresponding exemption from 10 CFR 140.11(a)(4) for TMI-2 to permanently reduce the required level of primary offsite liability insurance for ENOs from \$200 million to \$100 million. As discussed above, TMI-2 is maintained in a PDMS state with a possession only license that authorizes the possession of byproduct and special nuclear materials but not the operation of the reactor.

The NRC staff evaluated the applicability of a waste gas tank rupture as documented in the TMI-1 UFSAR, and the applicability of any unanticipated releases as documented in the Unanticipated Events Analysis in the TMI-2 Post-Defueling Monitored Storage Safety Analysis Report (ADAMS Package Accession No. ML17236A295), to ensure that these accidents would not have consequences that could potentially exceed the 10 CFR 50.67 dose limits and Regulatory Guide 1.183 dose acceptance criteria or approach the EPA early phase PAGs. Exelon stated that the bounding event for TMI-2 is a fire in the Reactor Building with the Reactor Building Purge System in operation. The NRC staff reviewed the assumptions, inputs, and methods used by Exelon to assess the radiological impacts of the requested exemption. The NRC staff concludes that Exelon has demonstrated that the dose consequences for postulated accidents at the permanently defueled TMI facility would not have consequences that could potentially exceed the applicable dose limits in 10 CFR 100.11, "Determination of exclusion area, low population zone, and population center distance," and 10 CFR 50.67, and the dose acceptance criteria in Regulatory Guide 1.183. The analysis demonstrates

that 365 days after permanent cessation of power operations, the radiological consequences of the analyzed design-basis accidents will not exceed the limits of the EPA early phase PAGs at the EAB. Therefore, the NRC staff finds the requested exemption to be acceptable from a dose consequence perspective.

The most significant accident sequence for a permanently defueled and shut down reactor involves the complete loss of water from the spent fuel pool. As the NRC previously recognized when issuing an exemption for TMI-2 from the requirement to participate in secondary financial protection, this accident scenario is not credible or reasonably conceivable at TMI-2 since the spent fuel pool is drained and no spent fuel is stored in the pool. Since TMI-2 is being maintained in a PDMS state with the reactor defueled and no fuel in the TMI-2 SFP, TMI-2 meets the criterion established in SECY-93-127 for relief from the requirements to maintain primary offsite liability insurance for ENOs at a level above \$100 million. As discussed previously, TMI-2 has already received an exemption from participation in the secondary retrospective insurance pool. Because the criteria presented in SECY-93-127 for removal from the secondary financial protection requirement are identical to those for reducing the primary offsite liability insurance, there is precedent for allowing the reduction of offsite liability insurance for TMI (as a site), once TMI-1 has met the criteria in SECY-93-127. In addition, the NRC staff notes that similar exemptions from these insurance requirements have been granted to other permanently shut down and defueled power reactors, upon satisfactory demonstration that zirconium fire risk from the irradiated fuel stored in the SFP is of negligible concern.

A. The Exemptions Are Authorized by Law

The PAA and its implementing regulations in 10 CFR 140.11(a)(4) require licensees of nuclear reactors that have a rated capacity of 100,000 kilowatts electric or more to have and maintain \$450 million in primary financial protection and to participate in a secondary retrospective insurance pool. In accordance with 10 CFR 140.8, the Commission may grant exemptions from the regulations in 10 CFR part 140 as the Commission determines are authorized by law. The legal and associated technical basis for granting exemptions from 10 CFR part 140 are set forth in SECY-93-127. The legal

analysis underlying SECY-93-127 concluded that, upon a technical finding that lesser potential hazards exist after permanent cessation of operations, the Commission has the discretion under the PAA to reduce the amount of insurance required of a licensee undergoing decommissioning.

Based on its review of the exemption requests, the NRC staff concludes that the technical criteria for relieving Exelon and TMI-2 Solutions from their existing primary and/or secondary insurance obligations have been met. As explained above, the NRC staff found that no reasonably conceivable design-basis accident exists that could cause an offsite release greater than the EPA PAGs and, therefore, that any offsite consequence from a design-basis radiological release is highly unlikely and the need for a significant amount of offsite liability insurance coverage is unwarranted. Additionally, the NRC staff determined that, after 16 months decay, the fuel stored in the TMI-1 SFP will be capable of being adequately cooled by air in the highly unlikely event of pool drainage. Moreover, in the highly unlikely beyond design-basis accident scenario where the SFP coolant inventory is lost in such a manner that all methods of heat removal from the spent fuel are no longer available, the NRC staff has determined that at least 10 hours would be available and is sufficient time to support deployment of mitigation equipment, consistent with plant conditions, to prevent the zirconium cladding from reaching a point of rapid oxidation. Thus, the NRC staff concludes that the fuel stored in the TMI-1 SFP will have decayed sufficiently by the requested effective date for the exemptions of 16 months after permanent cessation of power operations to support a reduction in the required insurance consistent with SECY-00-0145. Moreover, since the criteria presented in SECY-93-127 for removal from the secondary financial protection requirement are identical to those for reducing the primary offsite liability insurance, there is precedent for allowing the reduction of offsite liability insurance for TMI (as a site), once TMI-1 has met the criteria in SECY-93-127.

The NRC staff has determined that granting the licensees' proposed exemptions will not result in a violation of the Atomic Energy Act of 1954, Section 170, or other laws, as amended, which require licensees to maintain adequate financial protection. Accordingly, consistent with the legal standard presented in SECY-93-127, under which decommissioning reactor licensees may be relieved of the

requirements to carry the maximum amount of insurance available and to participate in the secondary retrospective premium pool where there is sufficient technical justification, the NRC staff concludes that the requested exemptions are authorized by law.

B. The Exemptions Are Otherwise in the Public Interest

The financial protection limits of 10 CFR 140.11 were established to require licensees to maintain sufficient offsite liability insurance to ensure adequate funding for offsite liability claims following an accident at an operating reactor. However, the regulation does not consider the reduced potential for and consequence of nuclear incidents at permanently shut down and decommissioning reactors.

The basis provided in SECY-93-127, SECY-00-0145, and SECY-01-0100 allows licensees of decommissioning plants to reduce their primary offsite liability insurance and to withdraw from participation in the retrospective rating pool for deferred premium charges. As discussed in these documents, once the zirconium fire concern is determined to be negligible, possible accident scenario risks at permanently shut down and defueled reactors are greatly reduced when compared to the risks at operating reactors and the associated potential for offsite financial liabilities from an accident are commensurately less. The licensee analyzed and the NRC staff confirmed that the risks of accidents that could result in an offsite radiological risk are minimal, thereby justifying the proposed reductions in offsite primary liability insurance and withdrawal from participation in the secondary retrospective rating pool for deferred premium charges.

Additionally, participation in the secondary retrospective rating pool could potentially have adverse consequences on the safe and timely completion of decommissioning. If a nuclear incident sufficient to trigger the secondary insurance layer occurred at another nuclear power plant, the licensee could incur financial liability of up to \$131,056,000. However, because TMI is permanently shut down, it cannot produce revenue from electricity generation sales to cover such a liability. Therefore, such liability if subsequently incurred could significantly affect the ability of the facility to conduct and complete timely radiological decontamination and decommissioning activities. In addition, as SECY-93-127 concluded, the shared financial risk exposure to the licensee is greatly disproportionate to the

radiological risk posed by TMI when compared to operating reactors. The reduced overall risk to the public at decommissioning power plants does not warrant that the licensee be required to carry full operating reactor insurance coverage after the requisite spent fuel cooling period has elapsed following final reactor shut down. The licensee's proposed financial protection limits will maintain a level of liability insurance coverage commensurate with the risk to the public. These changes are consistent with previous NRC policy as discussed in SECY-00-0145 and exemptions approved for other decommissioning reactors. Thus, the underlying purpose of the regulations will not be adversely affected by the reductions in insurance coverage. Accordingly, an exemption from participation in the secondary insurance pool (for TMI-1) and a reduction in the primary insurance to \$100 million (for TMI-1 and TMI-2), a value more in line with the potential consequences of accidents, would be in the public interest in that this ensures that there will be adequate funds to address any of those consequences and helps to ensure the safe and timely decommissioning of the reactor.

Therefore, the NRC staff has concluded that the requested exemptions from 10 CFR 140.11(a)(4) at the requested effective date of 16 months after the permanent cessation of power operations, are in the public interest.

C. Environmental Considerations

The NRC's approval of an exemption from insurance or indemnity requirements belongs to a category of actions that the Commission, by rule or regulation, has declared to be a categorical exclusion after first finding that the category of actions does not individually or cumulatively have a significant effect on the human environment. Specifically, the exemption is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement in accordance with 10 CFR 51.22(c)(25).

Under 10 CFR 51.22(c)(25), granting of an exemption from the requirements of any regulation of Chapter I to 10 CFR is a categorical exclusion provided that: (i) There is no significant hazards consideration; (ii) there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (iii) there is no significant increase in individual or cumulative public or occupational radiation exposure; (iv) there is no significant construction impact; (v) there is no significant increase in the

potential for or consequences from radiological accidents; and (vi) the requirements from which an exemption is sought involve surety, insurance, or indemnity requirements.

As the Director, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards, I have determined that approval of the exemption request involves no significant hazards consideration, as defined in 10 CFR 50.92, because reducing a licensee's offsite liability requirements at TMI does not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The exempted financial protection regulation is unrelated to the operation of TMI or site activities. Accordingly, there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite and no significant increase in individual or cumulative public or occupational radiation exposure. The exempted regulation is not associated with construction so there is no significant construction impact. The exempted regulation does not concern the source term (*i.e.*, potential amount of radiation in an accident) nor any activities conducted at the site. Therefore, there is no significant increase in the potential for, or consequences of, a radiological accident. In addition, there would be no significant impacts to biota, water resources, historic properties, cultural resources, or socioeconomic conditions in the region resulting from issuance of the requested exemptions. The requirement for offsite liability insurance involves surety, insurance, or indemnity matters only.

Therefore, pursuant to 10 CFR 51.22(b) and 51.22(c)(25), no environmental impact statement or environmental assessment need be prepared in connection with the approval of this exemption request.

IV. Conclusions

Accordingly, the Commission has determined that, pursuant to 10 CFR 140.8, the requested exemptions are authorized by law and are otherwise in the public interest. Therefore, the Commission hereby grants Exelon and TMI-2 Solutions exemptions from the requirements of 10 CFR 140.11(a)(4) for the TMI site. TMI-1 permanently ceased power operations on September 20, 2019. The exemptions from 10 CFR

140.11(a)(4) permit TMI-1 to reduce the required level of primary financial protection from \$450 million to \$100 million and to withdraw from participation in the secondary layer of financial protection 16 months after the permanent cessation of power operations. Further, the exemptions permit TMI-2 relief from the requirements to maintain primary offsite liability insurance for ENOs at a level above \$100 million.

The exemptions are effective as of 16 months after permanent cessation of power operations.

Dated, this 9th day of March, 2021.

For the Nuclear Regulatory Commission.
Patricia K. Holahan,
*Director, Division of Decommissioning,
Uranium Recovery, and Waste Programs,
Office of Nuclear Material Safety and
Safeguards.*

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91290; File No. SR-ICEEU-2021-007]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to the ICE Clear Europe Futures and Options Risk Policy and Futures and Options Risk Procedures and Retirement of the Futures and Options Concentration Charge Policy

March 10, 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 March 3, 2021, ICE Clear Europe Limited ("ICE Clear Europe" or the "Clearing House") filed with the Securities and Exchange Commission ("Commission") the proposed rule changes described in Items I, II, and III below, which Items have been prepared primarily by ICE Clear Europe. ICE Clear Europe filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f)(4)(ii)⁴ thereunder, such that the proposed rule was immediately effective upon filing with the Commission. The Commission is publishing this notice to solicit

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(a).

⁴ 17 CFR 240.19b-4(f)(4)(iii).

comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed amendments is for ICE Clear Europe to (i) modify its Futures and Options Risk Policy (the "F&O Risk Policy") and Futures and Options Risk Procedures (the "F&O Risk Procedures" or the "Procedures") to update certain aspects of the F&O initial margin methodology, including with respect to the capital to margin ratio, use of delivery margin, calculation of net liquidating value and certain buffers, and (ii) retire its Futures and Options Concentration Charge Policy ("F&O Concentration Charge Policy") once such proposed amendment are made, as such policy would be made redundant as a result of the proposed amendments.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe 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. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICE Clear Europe is proposing to revise the F&O Policy to remove the description of the capital to margin ratio as a basis for requesting additional initial margin or a reduction in positions to reduce the required initial margin level.

ICE Clear Europe is also proposing to amend its F&O Procedures to (i) update certain processes, escalations and controls with respect to the review of the IRM margin rate parameters, (ii) update the existing descriptions of review and testing processes for additional margin calculation methodologies, (iii) add a description of the Clearing House's use of delivery margin, net liquidating value, intraday buffers, overnight buffers, and ad hoc buffers as margin calculation methodologies and (iv) make various other drafting clarifications and improvements. These proposed

amendments would result in the retiring of ICE Clear Europe's F&O Concentration Charge Policy as the F&O Risk Policy and F&O Risk Procedures (as amended) would render such Future and Options Concentration Charge Policy redundant.

I. Futures and Options Risk Policy

The Policy would be revised to remove section 2.2.6, which describes the capital to margin ratio, from the additional margin requirements discussion. The description is being removed as the ratio is not in itself necessarily the basis of additional margin requirements and is addressed in other existing ICE Clear Europe policies and procedures. This amendment does not reflect a change in Clearing House practice or margin methodology. Certain minor non-substantive typographical updates would also be made to the Policy.

II. F&O Risk Procedures

IRM Margin Rate Parameters

Amendments to the Procedures would update the standard parameters for daily calculation of the calibrated IM rate (the so-called "Autopilot" or "AP" rate) to reference inter-contract volatility spreads. The amendments would update and clarify certain processes for the routine periodic review of the production margin rate (which is the actual rate used in the margin calculation generating CMC's Core IM requirements, and is typically based on the Autopilot rate). Specifically, the amendments would clarify that details of proposed parameters and margin impact along with justification for any manual overrides from the Autopilot rate would need to be approved by the CRO and the President of ICEU or their deputies. The amendments would provide that the CRD can inform exchange staff (instead of sales staff) at its discretion for information about the margin update. The amendments would also remove a process for the CRD to receive feedback on proposed parameters by sales staff or management, which the Clearing House views as unnecessary in light of the procedures for senior management approval.

Furthermore, the amendments would provide that upon review and approval of specific Senior Management Team members, the CRD would promote the rates into the risk system. The CRD would refresh the Product Report to perform a check on the rates to go live. One such check would be to ensure no cross-asset class inter-commodity spread (ICS) parameters are larger than

80%. Any correction to the promoted rates would be made at such point. The summary table of the review and promotion process for IRM margin rate parameters would be updated to reflect the Clearing House's current practices with respect to the testing and frequency of testing for such IRM margin rate parameters. Specifically, daily checks flagging any difference between production rate and AP rate using a threshold of 20% where AP is larger than production would be used. Additionally, monthly checks would flag any difference between production rate and AP rate for material parameters using a threshold of 20% relative difference where AP is larger than production scanning rate, and 20% absolute difference where production is larger than AP ICS rate.

Parameter Review and Recalibration

The amendments would clarify that exceptions driving an ad hoc review and parameter recalibration would be subject to notification to the Risk Oversight Department ("ROD") in addition to Senior CRD (director or above) decision. This clarification would be made throughout the Procedures with respect to parameter review and recalibration.

IRM Parameterization

This section would be amended to correctly reference relevant model documentation. The summary of the review process would be updated to add that ad hoc reviews would be triggered by large deviations in the daily sensitivity report.

Additional Initial Margin

Amendments to the section of the Procedures relating to concentration charges would update the testing frequency for product review and group mapping requirements from at least annually to monthly for a subset of products, and otherwise quarterly.

With respect to the Stress Margin or Stress Loss Charge ("SLC") additional Initial Margin calculation methodology, the Procedures would update the testing and frequency with respect to the SLC process from no specific test to provide for Daily Cover 1 and Cover 2 tests where the largest uncollateralized stress loss of a single member and pair of members, respectively, is determined. Any SLC top up would be called from the member. Furthermore, with respect to the SLC process for stress scenarios and proxy mapping, the amendments would update the frequency of review to provide that PCA EVT scenarios (*i.e.*, those combining principal component analysis and extreme value theory)

would be reviewed at least quarterly. Monthly testing with respect to PCA EVT monitoring would be reported to the MOC.

The amendments would update the description of F&O guarantee fund (GF) requirements to clarify that GF size corresponds to the maximum of the largest cover 2 loss over the last month or the average cover two losses over the last three months plus one standard deviation. This change conforms to current practice and does not reflect a change in methodology.

Regarding the Clearing House's Wrong-Way Risk (WWR) Requirements, the amendments would update the testing/frequency of the WWR process to add that index weights would be reviewed quarterly.

With respect to the EMIR add-on calculation methodology, the testing frequency would be updated to provide for monthly backtesting on benchmark products using a one-day margin period of risk and a daily check for benchmark products using a two-day margin period of risk. Ad hoc review would be dependent on test results, margin behavior during high volatility periods, and market expert feedback, rather than being only applicable for H and F accounts.

The updates to the procedures would add a new section addressing "Delivery Margins", which would add a description of the Clearing House's existing use of delivery margins to mitigate any payment or delivery risks during the delivery timeline of physically delivered products. Such delivery margins include: (i) Delivery margin, which is designed to cover any price movement on the product in delivery, (ii) buyer security, which is the notional value of the prompt portion of the contract in delivery, (iii) seller security, which is the additional charge on the seller to cover the situation where the seller is unable to deliver agreed product, and (iv) contingent variation margin, collected against difference between spot price and end of day settlement price between the last trading day and collection of buyer's security. The amended Procedures would also include a summary table that describes details of the delivery margin, buyer/seller security, and contingent variation margin.

The amendments to the Procedures would also add a new section describing the Clearing House's existing practices regarding net liquidating value of certain "equity-style" margined F&O options. For such options, the option premium must be paid/received at inception of the trade and the daily option value held as a credit or debit

against the margin account for the remainder of the open position. The level of NLV credit/debit would be recalculated each day according to the option settlement price and any top up would be called the following day. A summary table of the details of the NLV determination would be included.

The updates to the Procedures would add a new section regarding "Intraday and Overnight Buffer", which would summarize the existing ability of Clearing Members to post an additional buffer each day to offset intraday margin shortfall. The provisions would reference existing descriptions of intraday and overnight buffers in the Procedures. A summary table of the intraday and overnight buffers would also be included.

Finally, the updates to the Procedures would add a new section describing "Ad-Hoc Buffer", which would state that Clearing Members may be requested to post additional buffers for various risks not otherwise covered in the Procedures. Such requirements would be set by the Risk Senior Management and the Credit Risk team. A summary table of the ad-hoc buffer would be included. The amendments are intended to describe more clearly an existing authority of the Clearing House.

Other General Drafting Clarifications and Improvements

The amendments would define previously undefined terms such as "CRO" (Chief Risk Officer). Various typographical and similar corrections would also be made throughout the Procedures.

(b) Statutory Basis

ICE Clear Europe believes that the proposed amendments to the F&O Risk Policy and the F&O Risk Procedures are consistent with the requirements of Section 17A of the Act⁵ and the regulations thereunder applicable to it. In particular, Section 17A(b)(3)(F) of the Act⁶ requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest.

The proposed changes to the F&O Procedures and F&O Policy are designed to strengthen ICE Clear Europe's tools to

manage the risk of losses resulting from defaulting Clearing Members' portfolios. The amendments would update and clarify the processes, controls and escalations with respect to the testing and reviewing Clearing Members' Initial Margin requirements and related parameters. The amendments would also more clearly describe certain types of additional margin and calculation methodologies, and clarify the procedures for the testing and review thereof. Through better managing risks in default scenarios and promoting market stability, the proposed amendments would promote the stability of the Clearing House and the prompt and accurate clearance and settlement of cleared contracts. The enhanced risk management is therefore also generally consistent with the protection of investors and the public interest in the safe operation of the Clearing House. (ICE Clear Europe would not expect the amendments to affect the safeguarding of securities and funds in ICE Clear Europe's custody or control or for which it is responsible.) Accordingly, the amendments satisfy the requirements of Section 17A(b)(3)(F).⁷

The amendments are also consistent with relevant provisions of Rule 17Ad-22. Rule 17Ad-22(e)(3)(i)⁸ requires clearing agencies to maintain a sound risk management framework that identifies, measures, monitors and manages the range of risks that it faces. The amendments to the F&O Risk Policy and the F&O Risk Procedures are intended to better reflect margin and guaranty fund methodologies that calibrate resources held by ICE Clear Europe to the risks faced by the Clearing House, through improvements to the description and review and testing of relevant methodologies. The amendments will thus strengthen the management of default risks, and risk management more generally. In ICE Clear Europe's view, the amendments are therefore consistent with the requirements of Rule 17Ad-22(e)(3)(i).⁹

Rule 17Ad-22(e)(6)(i)¹⁰ requires a covered clearing agency to consider and produce margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market. The proposed amendments update the existing descriptions of calculation methodologies for additional margin to provide further detail, including with respect to ongoing testing and review processes. The

⁷ 15 U.S.C. 78q-1(b)(3)(F).

⁸ 17 CFR 240.17 Ad-22(e)(3)(i).

⁹ 17 CFR 240.17 Ad-22(e)(3)(i).

¹⁰ 17 CFR 240.17Ad-22(e)(6)(i).

⁵ 15 U.S.C. 78q-1.

⁶ 15 U.S.C. 78q-1(b)(3)(F).

amendments further add a description of the Clearing House's existing use of delivery margin, net liquidating value, intraday buffers, overnight buffers, and ad hoc buffers. These amendments thus enhance the clarity of ICE Clear Europe's overall margin framework and documentation, and facilitate compliance with the requirements of Rule 17Ad-22(e)(6)(i).¹¹

Rule 17Ad-22(e)(6)(vi)(A) and (B)¹² requires that a clearing agency cover its credit exposures to its participants by establishing a risk-based margin system that is monitored by management and regularly reviewed by "(A) [c]onducting backtests of its margin model at least once each day using standard predetermined parameters and assumptions" and "(B) [c]onducting a sensitivity analysis of its margin model and a review of its parameters and assumptions for backtesting on at least a monthly basis . . ." The proposed amendments describing the EMIR margin add-on methodology provide for monthly backtesting on 1-day margin period of risk benchmark products using predetermined parameters and a daily check for other products. In ICE Clear Europe's view, these amendments are therefore consistent with the requirements of Rule 17Ad-22(e)(6)(vi)(A) and (B).¹³

Rule 17Ad-22(e)(4)(v)¹⁴ requires a covered clearing agency to maintain financial resources that would at a minimum enable it to cover a wide range of foreseeable stress scenarios that include, but are not limited to, the default of the two participant families that would potentially cause the largest aggregate credit exposure for the covered clearing agency in extreme but plausible market conditions. The amendments to the Procedures are consistent with this requirement by providing that the GF size corresponds to the maximum of the largest cover 2 loss over the last month or the average cover 2 two losses over the last three months plus one standard deviation. In ICE Clear Europe's view, these amendments are therefore consistent with the requirements of Rule 17Ad-22(e)(4)(v).¹⁵

Rule 17Ad-22(e)(2)¹⁶ requires clearing agencies to establish reasonably designed policies and procedures to provide for governance arrangements that are clear and transparent and specify clear and direct lines of

responsibility. The proposed amendments to the Procedures would update the processes for the review of the relevant parameters to clarify the role of the CRD and deputies of the Chief Risk Officer and the President of the Clearing House. They would also describe for the role of Senior Management Team members and the Risk Oversight Department in this process. In ICE Clear Europe's view, the amendments are therefore consistent with the requirements of Rule 17Ad-22(e)(2).¹⁷

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed amendments would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The amendments are being adopted to update and clarify the F&O Risk Policy and the F&O Risk Procedures and will apply to all F&O Clearing Members. The proposed amendments are not expected to materially change F&O Guaranty Fund Contributions or margin requirements for F&O Clearing Members. ICE Clear Europe does not believe the amendments would affect the costs of clearing, the ability to market participants to access clearing, or the market for clearing services generally. Therefore, ICE Clear Europe does not believe the proposed rule change imposes any burden on competition that is inappropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any written comments received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁸ and paragraph (f) of Rule 19b-4¹⁹ 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.

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-ICEEU-2021-007 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-ICEEU-2021-007. 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 filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at <https://www.theice.com/notices/Notices.shtml?regulatoryFilings>.

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-ICEEU-2021-007

¹¹ 17 CFR 240.17Ad-22(e)(6)(i).

¹² 17 CFR 240.17Ad-22(e)(6)(vi)(A) and (B).

¹³ 17 CFR 240.17Ad-22(e)(6)(vi)(A) and (B).

¹⁴ 17 CFR 240.17 Ad-22(e)(4)(v).

¹⁵ 17 CFR 240.17 Ad-22(e)(4)(v).

¹⁶ 17 CFR 240.17 Ad-22(e)(2).

¹⁷ 17 CFR 240.17 Ad-22(e)(2).

¹⁸ 15 U.S.C. 78s(b)(3)(A).

¹⁹ 17 CFR 240.19b-4(f).

and should be submitted on or before April 6, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

J. Mathew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-05339 Filed 3-15-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91295; File No. SR-ISE-2021-03]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange's Pricing Schedule at Options 7, Section 3

March 10, 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 March 2, 2021, Nasdaq ISE, LLC ("ISE" or "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 amend the Exchange's Pricing Schedule at Options 7, Section 3 (Regular Order Fees and Rebates), as described further below.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/ise/rules>, 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 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 purpose of the proposed rule change is to amend the Exchange's Pricing Schedule at Options 7, Section 3 (Regular Order Fees and Rebates) to: (i) Decrease the Priority Customer³ taker fee in Select Symbols,⁴ and (ii) increase the Non-Priority Customer⁵ maker fee in Select Symbols.

The Exchange initially filed the proposed pricing changes on March 1, 2021 (SR-ISE-2021-02). On March 2, 2021, the Exchange withdrew that filing and submitted this filing.

Today, Priority Customers are charged a taker fee of \$0.41 per contract for regular orders in Select Symbols. The Exchange now proposes to decrease this fee to \$0.37 per contract for Priority Customers.

Today, all Non-Priority Customers are charged a maker fee of \$0.11 per contract for regular orders in Select Symbols. The Exchange now proposes to increase this fee to \$0.18 per contract for all Non-Priority Customers.⁶

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁷ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,⁸ in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair

³ A "Priority Customer" is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Nasdaq ISE Options 1, Section 1(a)(37).

⁴ "Select Symbols" are options overlying all symbols listed on the Nasdaq ISE that are in the Penny Interval Program.

⁵ "Non-Priority Customers" include Market Makers, Non-Nasdaq ISE Market Makers, Firm Proprietary/Broker Dealers, and Professional Customers.

⁶ The Exchange notes that under this proposal, Market Makers that qualify for Market Maker Plus in Select Symbols will continue to receive the applicable Market Maker Plus rebates in Select Symbols set forth in note 5 of Options 7, Section 3, and will not pay the proposed \$0.18 per contract maker fee.

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(4) and (5).

discrimination between customers, issuers, brokers, or dealers.

The Exchange's proposed changes to its Pricing Schedule are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for options securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition v. Securities and Exchange Commission*, the D.C. Circuit stated as follows: "[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'"⁹

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system "has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies."¹⁰

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for options security transaction services. The Exchange is only one of sixteen options exchanges to which market participants may direct their order flow. Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules. As such, the proposal represents a reasonable attempt by the Exchange to increase its liquidity and market share relative to its competitors.

⁹ *NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782-83 (December 9, 2008) (SR-NYSEArca-2006-21)).

¹⁰ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) ("Regulation NMS Adopting Release").

²⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

The Exchange believes that the proposed decrease for the Priority Customer taker fee in Select Symbols is reasonable, equitable, and not unfairly discriminatory. As discussed above, this fee will decrease from \$0.41 to \$0.37 per contract for Priority Customers. The Exchange seeks to incentivize Priority Customer participation, in particular, Priority Customer activity to remove liquidity in Select Symbols, with the proposed change. As amended, Priority Customers will continue to be charged the lowest taker fee in Select Symbols.¹¹ The Exchange believes that it is equitable and not unfairly discriminatory to charge Priority Customers a lower taker fee than other market participants as the Exchange has historically offered lower execution fees to Priority Customers. Furthermore, Priority Customer order flow enhances liquidity on the Exchange for the benefit of all market participants by providing more trading opportunities, which in turn attracts Market Makers and other market participants who may interact with this order flow.

The Exchange believes that the proposed increase for the Non-Priority Customer maker fees in Select Symbols is reasonable, equitable, and not unfairly discriminatory. As discussed above, this fee will increase from \$0.11 to \$0.18 per contract for all Non-Priority Customers. While the maker fee is increasing for Non-Priority Customers, the proposed increase is intended to offset the cost of decreasing the Priority Customer taker fee proposed above. Furthermore, the Exchange notes that the proposed maker fees remain lower than maker fees at another options exchange.¹²

The Exchange believes that the proposed maker fees in Select Symbols is equitable and not fairly discriminatory because they will be increased uniformly for all Non-Priority Customers. Priority Customers will continue to be assessed no maker fees in Select Symbols under this proposal. For the same reasons discussed above for the proposed Priority Customer taker fees, the Exchange believes that it is equitable and not unfairly discriminatory to continue offering a

lower rate to Priority Customers compared to other market participants.

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 not necessary or appropriate in furtherance of the purposes of the Act. In terms of intra-market competition, the Exchange does not believe that its proposal will place any category of market participant at a competitive disadvantage. The proposed Select Symbol taker fee will be decreased for Priority Customers, who will continue to be charged at a lower rate than all other market participants for removing liquidity on the Exchange. The proposed Select Symbol maker fee will be increased uniformly for all Non-Priority Customers, while Priority Customers will continue to be assessed no fee for adding liquidity on the Exchange. As discussed above, the Exchange has historically charged lower rates to Priority Customers compared to other market participants. The Exchange believes that this incentivizes increased Priority Customer order flow, which enhances liquidity on the Exchange for the benefit of all market participants by providing more trading opportunities, which in turn attracts Market Makers and other market participants who may interact with this order flow.

In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other options exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. For example, while the Exchange is increasing the maker fees for Non-Priority Customers in Select Symbols under this proposal, the Exchange does not believe this will cause an undue burden on inter-market competition as the proposed fees remain lower than similar fees charged by other options exchanges such as Phlx.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act¹³ and Rule 19b-4(f)(2)¹⁴ 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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) 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 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-ISE-2021-03 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-ISE-2021-03. 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

¹¹ Today, the Exchange charges all Non-Priority Customers (except Market Makers) a taker fee of \$0.46 per contract in Select Symbols. Market Makers are currently charged a taker fee of \$0.45 per contract in Select Symbols.

¹² See, e.g., Nasdaq PHLX ("Phlx") Pricing Schedule at Options 7, Section 4, which assesses Lead Market Makers and Market Makers an electronic options transaction charge of \$0.22 per contract in Penny Symbols, and Professionals, Broker-Dealers, and Firms an electronic options transaction charge of \$0.48 per contract in Penny Symbols.

¹³ 15 U.S.C. 78s(b)(3)(A)(ii).

¹⁴ 17 CFR 240.19b-4(f)(2).

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-ISE-2021-03 and should be submitted on or before April 6, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-05342 Filed 3-15-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270-222, OMB Control No. 3235-0233]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Extension:

Form 2-E, Report pursuant to rule 609 of Regulation E

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the "Commission") has submitted to the Office of Management and Budget ("OMB") a request for extension of the previously approved collection of information discussed below.

Rule 609 (17 CFR 230.609) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) requires small business investment companies and business development companies that have engaged in offerings of securities that are exempt from registration pursuant to Regulation E under the Securities Act of 1933 (17

CFR 230.601 to 610a) to report semi-annually on Form 2-E (17 CFR 239.201) the progress of the offering. The form solicits information such as the dates an offering commenced and was completed (if completed), the number of shares sold and still being offered, amounts received in the offering, and expenses and underwriting discounts incurred in the offering. The information provided on Form 2-E assists the staff in monitoring the progress of the offering and in determining whether the offering has stayed within the limits set for an offering exempt under Regulation E.

The Commission estimates that, on average, approximately one respondent submits a Form 2-E filing each year. The Commission further estimates that this information collection imposes an annual burden of four hours and imposes an annual external cost burden of zero.

The collection of information under Form 2-E is mandatory. The information provided by the form will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The public may view the background documentation for this information collection at the following website, www.reginfo.gov. Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: Lindsay.M.Abate@omb.eop.gov; and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549 or send an email to: PRA_Mailbox@sec.gov. 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.

Dated: March 11, 2021.

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-05377 Filed 3-15-21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91286; File Nos. SR-NASDAQ-2020-081; SR-NASDAQ-2020-082]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Amendments No. 1 and Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Changes, as Modified by Amendments No. 1, To Adopt Listing Rules Related to Board Diversity and To Offer Certain Listed Companies Access to a Complimentary Board Recruiting Solution To Help Advance Diversity on Company Boards

March 10, 2021.

I. Introduction

On December 1, 2020, The Nasdaq Stock Market LLC ("Nasdaq" or "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 listing rules related to board diversity ("Board Diversity Proposal"). The proposed rule change was published for comment in the **Federal Register** on December 11, 2020.³ On January 19, 2021, pursuant to Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁵ On February 26, 2021, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change as originally filed.⁶

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 90574 (December 4, 2020), 85 FR 80472 (SR-NASDAQ-2020-081). Comments received on the Board Diversity Proposal are available on the Commission's website at: <https://www.sec.gov/comments/sr-nasdaq-2020-081/srnasdaq2020081.htm>.

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 90951, 86 FR 7135 (January 26, 2021). The Commission designated March 11, 2021 as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

⁶ In Amendment No. 1, the Exchange amended the Board Diversity Proposal to: (1) Add a defined term for "Two or More Races or Ethnicities" to proposed Rule 5605(f)(1); (2) modify the application of proposed Rule 5605(f) to Foreign Issuers and clarify the scope of Exempt Companies; (3) provide a lower diversity objective for a company with five or fewer members on its board; (4) modify the

¹⁵ 17 CFR 200.30-3(a)(12).

On December 1, 2020, the Exchange also filed with the Commission, pursuant to Section 19(b)(1) of the Act⁷ and Rule 19b-4 thereunder,⁸ a proposed rule change to offer certain listed companies access to a complimentary board recruiting solution to help advance diversity on company boards (“Board Recruiting Service Proposal”). The proposed rule change was published for comment in the **Federal Register** on December 10, 2020.⁹ On January 19, 2021, pursuant to Section 19(b)(2) of the Act,¹⁰ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.¹¹ On February 26, 2021, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change as originally filed.¹²

disclosures required by proposed Rule 5606; (5) modify the process by which a company may provide public disclosure if it does not meet the applicable board diversity objectives of proposed Rule 5605(f)(2) and similarly conform the process for providing the public disclosures under proposed Rule 5606; (6) modify the phase-in periods for companies subject to proposed Rules 5605(f) and 5606; (7) provide a grace period for a company that no longer meets the board diversity objectives of proposed Rule 5605(f)(2) due to a vacancy on its board and clarify the cure period for a company that does not satisfy proposed Rule 5605(f); (8) modify the effective dates and transition periods applicable to proposed Rules 5605(f) and 5606; (9) make conforming and clarifying changes throughout the description of the proposed rule change and the proposed rule text; and (10) provide additional justification and support for the proposed rule change. The full text of Amendment No. 1 to the Board Diversity Proposal is available on the Commission’s website at: <https://www.sec.gov/comments/sr-nasdaq-2020-081/srnasdaq2020081-8425992-229601.pdf>.

⁷ 15 U.S.C. 78s(b)(1).

⁸ 17 CFR 240.19b-4.

⁹ See Securities Exchange Act Release No. 90571 (December 4, 2020), 85 FR 79556 (SR-NASDAQ–2020–082). Comments received on the Board Recruiting Service Proposal are available on the Commission’s website at: <https://www.sec.gov/comments/sr-nasdaq-2020-082/srnasdaq2020082.htm>.

¹⁰ 15 U.S.C. 78s(b)(2).

¹¹ See Securities Exchange Act Release No. 90952, 86 FR 7148 (January 26, 2021). The Commission designated March 10, 2021 as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

¹² In Amendment No. 1, the Exchange amended the Board Recruiting Service Proposal to: (1) Make conforming changes to the proposal based on Amendment No. 1 to the Board Diversity Proposal; (2) specify the application of the proposal to a company with five or fewer members on its board; (3) provide additional justification for the proposal to allow eligible companies until December 1, 2022 to begin using the complimentary board recruiting solution; and (4) make additional clarifying changes throughout the description of the proposed rule change. The full text of Amendment No. 1 to the Board Recruiting Service Proposal is available on the Commission’s website at: <https://www.sec.gov/>

The Commission is publishing this notice and order to solicit comments on the proposed rule changes, as modified by Amendments No. 1, from interested persons and to institute proceedings pursuant to Section 19(b)(2)(B) of the Act¹³ to determine whether to approve or disapprove the proposed rule changes, as modified by Amendments No.1.

II. Description of the Proposed Rule Changes, as Modified by Amendments No. 1

A. The Board Diversity Proposal

1. Proposed Rule 5605(f)

The Exchange proposes to adopt new Rule 5605(f)(2), which would require each Nasdaq-listed company (other than a Foreign Issuer, Smaller Reporting Company, or Company with a Smaller Board, as discussed below) to have, or explain why it does not have, at least two members of its board of directors who are Diverse,¹⁴ including at least one Diverse director who self-identifies as Female and at least one Diverse director who self-identifies as an Underrepresented Minority or LGBTQ+. Pursuant to proposed Rule 5605(f)(1), “Diverse” would be defined to mean an individual who self-identifies in one or more of the following categories: (i) Female, (ii) Underrepresented Minority, or (iii) LGBTQ+. Also pursuant to proposed Rule 5605(f)(1), “Female” would be defined to mean an individual who self-identifies her gender as a woman, without regard to the individual’s designated sex at birth; “Underrepresented Minority” would be defined to mean an individual who self-identifies as one or more of the following: Black or African American,

[comments/sr-nasdaq-2020-082/srnasdaq2020082-8425987-229599.pdf](https://www.sec.gov/comments/sr-nasdaq-2020-082/srnasdaq2020082-8425987-229599.pdf).

¹³ 15 U.S.C. 78s(b)(2)(B).

¹⁴ The Exchange states that it has published an FAQ on its Listing Center clarifying that “two members of its board of directors who are Diverse” would exclude emeritus directors, retired directors, and members of an advisory board. See Amendment No. 1 to the Board Diversity Proposal at 73 n.187.

¹⁵ See proposed Rule 5605(f)(2)(A). The Exchange also states that it does not intend for the Board Diversity Proposal to preclude companies from considering additional diverse attributes, such as nationality, disability, or veteran status, in selecting board members; however, the company would still have to provide the required disclosure under proposed Rule 5605(f)(3) if the company does not meet the diversity objectives of proposed Rule 5605(f)(2). See Amendment No. 1 to the Board Diversity Proposal at 64. The Exchange also states that, although non-binary is included as a category in the Board Diversity Matrix under proposed Rule 5606 (as discussed in Section II.A.2 below), a company would not satisfy the diversity objectives in proposed Rule 5605(f)(2) to have a minimum number of Diverse directors if a director self-identifies solely as non-binary. See *id.* at 66 n.173.

Hispanic or Latinx, Asian, Native American or Alaska Native, Native Hawaiian or Pacific Islander, or Two or More Races or Ethnicities;¹⁶ and “LGBTQ+” would be defined to mean an individual who self-identifies as any of the following: Lesbian, gay, bisexual, transgender, or as a member of the queer community.¹⁷

The Exchange proposes to define a Foreign Issuer under proposed Rule 5605(f)(1) as: (a) A Foreign Private Issuer (as defined in Rule 5005(a)(19));¹⁸ or (b) a company that (i) is considered a “foreign issuer” under Rule 3b-4(b) under the Act¹⁹ and (ii)

¹⁶ “Black or African American” would be defined to mean a person having origins in any of the Black racial groups of Africa (not of Hispanic or Latinx origin). See Amendment No. 1 to the Board Diversity Proposal at 327. “Hispanic or Latinx” would be defined to mean a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. See *id.* “Asian” would be defined to mean a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. See *id.* “Native American or Alaska Native” would be defined to mean a person having origins in any of the original peoples of North and South America (including Central America) and who maintains cultural identification through tribal affiliation or community recognition. See *id.* “Native Hawaiian or Pacific Islander” would be defined to mean a person having origins in any of the peoples of Hawaii, Guam, Samoa, or other Pacific Islands. See *id.* “Two or More Races or Ethnicities” would be defined to mean a person who identifies with more than one of the following categories: White (not of Hispanic or Latinx origin), Black or African American, Hispanic or Latinx, Asian, Native American or Alaska Native, Native Hawaiian or Pacific Islander. See *id.*; proposed Rule 5605(f)(1). “White (not of Hispanic or Latinx origin)” would be defined to mean a person having origins in any of the original peoples of Europe, the Middle East, or North Africa. See Amendment No. 1 to the Board Diversity Proposal at 327.

¹⁷ See proposed Rule 5605(f)(1). The Exchange states that the categories it has proposed to comprise an Underrepresented Minority are consistent with the categories reported to the Equal Employment Opportunity Commission (“EEOC”) through the Employer Information Report EEO-1 Form (“EEO-1”) and should be construed in accordance with the EEOC’s definitions. See Amendment No. 1 to the Board Diversity Proposal at 9–10, 61. The Exchange also states that, while the EEO-1 report refers to “Hispanic or Latino” rather than “Latinx,” the Exchange proposes to use the term “Latinx” to apply broadly to all gendered and gender-neutral forms that may be used by individuals of Latin American heritage, including individuals who self-identify as Latino/a/e. See *id.* at 61 n.160. The Exchange further states that the terms in the proposed definition of LGBTQ+ are similar to the identities defined in California’s A.B. 979, but have been expanded to include the queer community. See *id.* at 61.

¹⁸ Under Rule 5005(a)(19), the term Foreign Private Issuer has “the same meaning as under Rule 3b-4 under the Act.”

¹⁹ See 17 CFR 240.3b-4(b) (“The term foreign issuer means any issuer which is a foreign government, a national of any foreign country or a corporation or other organization incorporated or organized under the laws of any foreign country.”).

has its principal executive offices located outside of the United States.²⁰ For Foreign Issuers, the Exchange proposes to define “Diverse” to mean an individual who self-identifies as one or more of the following: Female, LGBTQ+, or an underrepresented individual based on national, racial, ethnic, indigenous, cultural, religious, or linguistic identity in the country of the company’s principal executive offices as reported on the company’s Form F–1, 10–K, 20–F, or 40–F (“Underrepresented Individual”).²¹ For a Foreign Issuer that has a two-tiered board system, the Exchange proposes to define “board of directors” to mean the company’s supervisory or non-management board.²² Proposed Rule 5605(f)(2)(B) would require each Foreign Issuer (other than a Company with a Smaller Board, as discussed below) to have, or explain why it does not have, at least two members of its board of directors who are Diverse, including at least one Diverse director who self-identifies as Female. As proposed, the second Diverse director may include an individual who self-identifies as one or more of the following: Female, LGBTQ+, or an Underrepresented Individual.²³

²⁰ According to the Exchange, this definition is designed to recognize that companies that are not Foreign Private Issuers but are headquartered outside of the United States are foreign companies notwithstanding the fact that they file domestic Commission reports, and is designed to exclude companies that are domiciled in a foreign jurisdiction without having a physical presence in that country. See Amendment No. 1 to the Board Diversity Proposal at 83.

²¹ See proposed Rule 5605(f)(2)(B)(i). The Exchange states that its proposed definition of an Underrepresented Individual is based on the United Nations Declaration on the Rights of Persons Belonging to National or Ethnic, Religious and Linguistic Minorities and the United Nations Declaration on the Rights of Indigenous Peoples. See Amendment No. 1 to the Board Diversity Proposal at 69 (citing G.A. Res. 47/135, art. 1.1 (December 18, 1992); G.A. Res. 61/295 (September 13, 2007)). The Exchange also states that, because the EEOC categories of race and ethnicity may not extend to all countries globally since each country has its own unique demographic composition, and because on average women tend to be underrepresented in boardrooms across the globe, proposed Rule 5605(f)(2)(B)(ii) would allow Foreign Issuers to satisfy the diversity objectives by having two Female directors. See *id.* at 81–82.

²² See proposed Rule 5605(f)(2)(B)(i). The Exchange states that this is consistent with Rule 10A–3(e)(2) under the Act. See Amendment No. 1 to the Board Diversity Proposal at 84 (citing 17 CFR 240.10A–3(e)(2)).

²³ The Exchange also proposes to amend Rule 5615 and IM–5615–3, which currently permit a Foreign Private Issuer to follow home country practices in lieu of the requirements set forth in the Rule 5600 series, subject to several exclusions. Specifically, the Exchange proposes to amend Rule 5615 and IM–5615–3 to add proposed Rule 5605(f) to the list of excluded corporate governance rules. The Exchange also proposes to amend Rule 5615 and IM–5615–3 to add proposed Rule 5606 (as

The Exchange proposes to define a Smaller Reporting Company as set forth in Rule 12b–2 under the Act.²⁴ Proposed Rule 5605(f)(2)(C) would require each Smaller Reporting Company (other than a Company with a Smaller Board, as discussed below) to have, or explain why it does not have, at least two members of its board of directors who are Diverse, including at least one Diverse director who self-identifies as Female. As proposed, the second Diverse director may include an individual who self-identifies as one or more of the following: Female, LGBTQ+, or an Underrepresented Minority.²⁵

Proposed Rule 5605(f)(2)(D) would require each company with a board of directors of five or fewer members (“Company with a Smaller Board”) to have, or explain why it does not have, at least one member of its board of directors who is Diverse.²⁶ As proposed, if a company had five members on its board of directors before becoming subject to proposed Rule 5605(f), it would not become subject to the objectives of proposed Rule 5605(f)(2)(A), (B), or (C) to have at least two Diverse directors if it then added

discussed in Section II.A.2 below) to the list of excluded corporate governance rules. However, the Exchange states that Foreign Private Issuers that elect to follow an alternative diversity objective in accordance with home country practices, or are located in jurisdictions that restrict the collection of personal data, may satisfy the requirements of proposed Rule 5605(f) by explaining their reasons for doing so instead of meeting the diversity objectives of the rule. See Amendment No. 1 to the Board Diversity Proposal at 84.

²⁴ See proposed Rule 5605(f)(1). See also 17 CFR 240.12b–2 (defining a Smaller Reporting Company as “an issuer that is not an investment company, an asset-backed issuer . . . , or a majority-owned subsidiary of a parent that is not a smaller reporting company and that: (1) Had a public float of less than \$250 million; or (2) Had annual revenues of less than \$100 million and either: (i) No public float; or (ii) A public float of less than \$700 million”).

²⁵ The Exchange states that, because smaller companies may not have the resources necessary to compensate an additional director or engage a search firm to search outside of directors’ networks, it proposes to provide each Smaller Reporting Company with additional flexibility (*i.e.*, proposed Rule 5605(f)(2)(C) would allow these companies to satisfy the objective to have two Diverse directors by having two Female directors). See Amendment No. 1 to the Board Diversity Proposal at 84–85.

²⁶ The Exchange proposes this alternative diversity objective for Companies with a Smaller Board because, according to the Exchange, these companies may face similar resource constraints to those of Smaller Reporting Companies, but not all Companies with a Smaller Board are Smaller Reporting Companies, and therefore the alternative diversity objective that would be provided to Smaller Reporting Companies may not be available to them. See *id.* at 86. The Exchange further states that Companies with a Smaller Board may be disproportionately impacted by the proposed rule change if they plan to satisfy proposed Rule 5605(f)(2) by adding additional directors, which may impose additional costs in the form of director compensation and D&O insurance. See *id.*

one director to its board in order to satisfy proposed Rule 5605(f)(2)(D), thereby becoming a six-member board.²⁷ However, a Company with a Smaller Board would become subject to proposed Rule 5605(f)(2)(A), (B), or (C) if it subsequently expands its board.²⁸

If a company elects to satisfy the requirements of proposed Rule 5605(f)(2) by disclosing why it does not meet the applicable diversity objectives of proposed Rule 5605(f)(2), proposed Rule 5605(f)(3) would require the company to: (i) Specify the requirements of proposed Rule 5605(f)(2) that are applicable (*e.g.*, the applicable subparagraph and the applicable diversity objectives); and (ii) explain the reasons why it does not have two Diverse directors (or one Diverse director for a Company with a Smaller Board).²⁹ The disclosure must be provided in advance of the company’s next annual meeting of shareholders: (a) In any proxy statement or any information statement (or, if a company does not file a proxy, in its Form 10–K or 20–F); or (b) on the company’s website.³⁰ If the company provides the disclosure on its website, the company must submit such disclosure concurrently with the filing made pursuant to (a) above and submit a URL link to the disclosure through the Nasdaq Listing Center, within one business day after such posting.³¹

Proposed Rule 5605(f)(5) would specify the phase-in period for any

²⁷ See proposed Rule 5605(f)(2)(D). The Exchange proposes this exception to avoid complexity for Companies with a Smaller Board that attempt to satisfy the diversity objectives by adding a Diverse director to their board, and to prevent such companies from thereby being subject to a higher threshold (*i.e.*, that of proposed Rule 5605(f)(2)(A), (B), or (C)) as a result. See Amendment No. 1 to the Board Diversity Proposal at 86–87.

²⁸ See proposed Rule 5605(f)(2)(D).

²⁹ As proposed, a company would not need to provide any public disclosures pursuant to proposed Rule 5605(f) if the company demonstrates under proposed Rule 5606 (as discussed in Section II.A.2 below) that it meets the applicable diversity objectives of proposed Rule 5605(f)(2); however, if a company does not meet its applicable diversity objectives, it would be required to provide the additional public disclosure explaining why it does not meet the applicable objectives. See Amendment No. 1 to the Board Diversity Proposal at 73.

³⁰ See proposed Rule 5605(f)(3).

³¹ See *id.* The Exchange states that it would not evaluate the substance or merits of a company’s explanation provided pursuant to proposed Rule 5605(f)(3), but would verify that the company has provided one at the time it files its proxy statement or information statement (or, if the company does not file a proxy, at the time it files its Form 10–K or 20–F). See Amendment No. 1 to the Board Diversity Proposal at 74. If the company does not meet the applicable diversity objectives and has not provided any explanation, or has provided an explanation that does not satisfy proposed Rule 5605(f)(3)(i) and (ii), the company will be considered deficient with the requirements of proposed Rule 5605(f)(3). See *id.* at 74–75.

company newly listing on the Exchange that was not previously subject to a substantially similar requirement of another national securities exchange (including through an initial public offering, direct listing, transfer from another exchange or the over-the-counter market, in connection with a spin-off or carve-out from a company listed on the Exchange or another exchange, or through a merger with an acquisition company listed under IM-5101-2 (“acquisition company”)) and any company that ceases to be a Foreign Issuer, a Smaller Reporting Company, or an Exempt Company.³²

As proposed, any newly-listed company on the Nasdaq Global Select Market (“NGS”) or Nasdaq Global Market (“NGM”) would be permitted to satisfy the requirement of proposed Rule 5605(f)(2) to have, or explain why it does not have: (i) At least one Diverse director by the later of (a) one year from the date of listing or (b) the date the company files its proxy statement or information statement (or, if the company does not file a proxy, its Form 10-K or 20-F) for the company’s first annual meeting of shareholders subsequent to the company’s listing; and (ii) at least two Diverse directors by the later of (a) two years from the date of listing or (b) the date the company files its proxy statement or information statement (or, if the company does not file a proxy, its Form 10-K or 20-F) for the company’s second annual meeting of shareholders subsequent to the company’s listing.³³ In addition, any newly-listed company on the Nasdaq Capital Market (“NCM”) would be permitted to satisfy the requirement of proposed Rule 5605(f)(2) to have, or explain why it does not have, at least two Diverse directors by the later of: (i) Two years from the date of listing; or (ii) the date the company files its proxy statement or information statement (or, if the company does not file a proxy, its Form 10-K or 20-F) for the company’s second annual meeting of shareholders subsequent to the company’s listing.³⁴ As proposed, any newly listed Company with a Smaller Board would be permitted to satisfy the requirement of proposed Rule 5605(f)(2) to have, or explain why it does not have, at least one Diverse director by the later of: (i) Two years from the date of listing, or (ii) the date the company files its proxy statement or information statement (or, if the company does not file a proxy, its Form 10-K or 20-F) for the company’s

second annual meeting of shareholders subsequent to the company’s listing.³⁵

Proposed Rule 5605(f)(5)(C) would provide that any company that ceases to be a Foreign Issuer, Smaller Reporting Company, or Exempt Company would be permitted to satisfy the requirements of proposed Rule 5605(f) by the later of: (i) One year from the date that the company no longer qualifies as a Foreign Issuer, Smaller Reporting Company, or Exempt Company; or (ii) the date the company files its proxy statement or information statement (or, if the company does not file a proxy, its Form 10-K or 20-F) for the company’s first annual meeting of shareholders subsequent to such event.

Proposed Rule 5605(f)(6)(A) would provide that if a company (i) does not meet the applicable diversity objectives under proposed Rule 5605(f)(2) and fails to provide the disclosure required by proposed Rule 5605(f)(3), or (ii) fails to hold an annual meeting of shareholders during the applicable periods in proposed Rule 5605(f)(5) or (7) and therefore fails to meet, or explain why it does not meet, the diversity objectives of proposed Rule 5605(f)(2), the Exchange’s Listing Qualifications Department would promptly notify the company and inform it that it has until the later of its next annual shareholders meeting or 180 days from the event that caused the deficiency to cure the deficiency.³⁶ If a company does not regain compliance within the applicable cure period, the Listings Qualifications Department would issue a Staff Delisting Determination Letter.³⁷

Moreover, proposed Rule 5605(f)(6)(B) would provide that a company that has satisfied the diversity objectives of proposed Rule 5605(f)(2) within the timeframes set forth in proposed Rule 5605(f)(7), but later ceases to meet the diversity objectives of proposed Rule 5605(f)(2) due to a vacancy on its board of directors, would have until the later of (i) one year from the date of vacancy or (ii) the date the company files its proxy statement or its information statement (or, if the company does not file a proxy, its Form 10-K or 20-F) in the calendar year following the year of

the date of vacancy, to satisfy proposed Rule 5605(f)(2) or (3). As proposed, in lieu of providing the disclosure required by proposed Rule 5605(f)(3), a company relying on this rule may publicly disclose that it is relying on the grace period provided by proposed Rule 5605(f)(6)(B).³⁸ This disclosure must be provided in advance of the company’s next annual meeting of shareholders: (a) In any proxy statement or any information statement (or, if the company does not file a proxy, in its Form 10-K or 20-F); or (b) on the company’s website.³⁹ If the company provides such disclosure on its website, then the company must submit such disclosure concurrently with the filing made pursuant to (a) and submit a URL link to the disclosure through the Nasdaq Listing Center, within one business day after such posting.⁴⁰

Proposed Rule 5605(f)(7) would specify the transition period for the implementation of the requirements of proposed Rule 5605(f). As proposed, each company listed on the Exchange (including a Company with a Smaller Board) would be required to have, or explain why it does not have, at least one Diverse director by the later of: (i) Two calendar years after the approval date of the proposal (“First Effective Date”); or (ii) the date the company files its proxy statement or information statement (or, if the company does not file a proxy, its Form 10-K or 20-F) for the company’s annual shareholders meeting during the calendar year of the First Effective Date.⁴¹ In addition, each company listed on NGS or NGM must have, or explain why it does not have, at least two Diverse directors by the later of: (i) Four calendar years after the approval date of the proposal (“Second NGS/NGM Effective Date”); or (ii) the date the company files its proxy statement or information statement (or, if the company does not file a proxy, its Form 10-K or 20-F) for the company’s annual shareholders meeting during the calendar year of the Second NGS/NGM Effective Date.⁴² Moreover, each company listed on NCM must have, or explain why it does not have, at least two Diverse directors by the later of: (i) Five calendar years after the approval date of the proposal (“Second NCM Effective Date”); or (ii) the date the company files its proxy statement or information statement (or, if the company does not file a proxy, its Form 10-K or 20-F) for the company’s annual

³⁵ See proposed Rule 5605(f)(5)(D).

³⁶ The Exchange proposes to add a similar provision as Rule 5810(c)(3)(F). The Exchange also proposes to renumber existing Rules 5810(c)(3)(F) and (G) as Rules 5810(c)(3)(G) and (H), respectively, and to make a non-substantive change in Rule 5810(c)(2)(A)(iv) to clarify that Rule 5250(b)(3) is related to “Disclosure of Third Party Director and Nominee Compensation.”

³⁷ See Rule 5810(c)(3). A company that receives a Staff Delisting Determination Panel through the process set forth in Rule 5815. See Amendment No. 1 to the Board Diversity Proposal at 88.

³⁸ See proposed Rule 5605(f)(6)(B).

³⁹ See *id.*

⁴⁰ See *id.*

⁴¹ See proposed Rule 5605(f)(7)(A).

⁴² See proposed Rule 5605(f)(7)(B).

³² See *infra* note 46 and accompanying text (describing Exempt Companies).

³³ See proposed Rule 5605(f)(5)(A).

³⁴ See proposed Rule 5605(f)(5)(B).

shareholders meeting during the calendar year of the Second NCM Effective Date.⁴³ As proposed, a company would not be required to comply with the requirements of proposed Rule 5605(f) prior to the end of the phase-in periods under proposed Rule 5605(f)(5), if applicable.⁴⁴ Furthermore, a company listed on NCM that transfers to NGS or NCM after the approval date but prior to the end of the transition periods set forth in proposed Rule 5605(f)(7) would be required to satisfy the requirements of proposed Rule 5605(f) by the later of: (i) The periods set forth in proposed Rule 5605(f)(7)(C); or (ii) one year from the date of transfer.⁴⁵

Proposed Rule 5605(f)(4) would exempt the following types of companies from the requirements of proposed Rule 5605(f) (“Exempt Companies”): (1) Acquisition companies; (2) asset-backed issuers and other passive issuers (as set forth in Rule 5615(a)(1)); (3) cooperatives (as set forth in Rule 5615(a)(2)); (4) limited partnerships (as set forth in Rule 5615(a)(4)); (5) management investment companies (as set forth in Rule 5615(a)(5)); (6) issuers of non-voting preferred securities, debt securities, and derivative securities (as set forth in Rule 5615(a)(6)) that do not have equity securities listed on the Exchange; and (7) issuers of securities listed under the Rule 5700 series.⁴⁶

⁴³ See proposed Rule 5605(f)(7)(C).

⁴⁴ See proposed Rule 5605(f)(7)(D). A company listing after the approval date, but prior to the end of the periods set forth in proposed Rule 5605(f)(7) would be required to fully satisfy the requirements of proposed Rule 5605(f) by the later of the periods under proposed Rule 5605(f)(7) or the two year phase-in periods under proposed Rule 5605(f)(5). See proposed Rule 5605(f)(7)(E). According to the Exchange, the proposed transition and phase-in periods are intended to provide newly-listed public companies with additional time to meet the diversity objectives of proposed Rule 5605(f)(2), as newly-listed public companies may have unique governance structures, such as staggered boards or director seats held by venture capital firms, that require additional timing considerations when adjusting the board’s composition. See Amendment No. 1 to the Board Diversity Proposal at 79. The Exchange further states that the proposed transition and phase-in periods are intended to provide additional flexibility to companies listed on NCM, as such companies are typically smaller and may face additional challenges and resource constraints when identifying additional director nominees who self-identify as Diverse. See *id.* The Exchange also states that its proposed phase-in periods are consistent with the phase-in periods it provides to companies for other board composition requirements. See *id.* at 81. See also, *e.g.*, Rules 5615(b)(1), 5615(b)(3), and 5620.

⁴⁵ See proposed Rule 5605(f)(7)(F).

⁴⁶ The Exchange states that these companies do not have boards, do not list equity securities, or are not operating companies. See Amendment No. 1 to the Board Diversity Proposal at 90. The Exchange also states that these companies are already exempt from certain corporate governance standards related

The Exchange states that it has published FAQs on its Listing Center to provide guidance to companies on the application of the proposed rules in the Board Diversity Proposal, and represents that it will establish a dedicated mailbox for companies and their counsel to email additional questions to the Exchange regarding the application of such proposed rules.⁴⁷

2. Proposed Rule 5606

The Exchange proposes to adopt new Rule 5606, which would require each Nasdaq-listed company (other than Exempt Companies⁴⁸) to publicly disclose in an aggregated form, to the extent permitted by applicable law, information on the voluntary self-identified gender and racial characteristics and LGBTQ+ status of the company’s board of directors.⁴⁹

Specifically, pursuant to proposed Rule 5606(a), each Nasdaq-listed company would be required to annually disclose its board-level diversity data a substantially similar format⁵⁰ as the “Board Diversity Matrix” provided in proposed Rule 5606(a).⁵¹ As proposed, companies would be required to provide the Board Diversity Matrix information

to board composition, as described in Rule 5615. See *id.* The Exchange also states that, although it is exempting acquisition companies from the requirements of proposed Rule 5605(f), upon such a company’s completion of a business combination with an operating company, the post-business combination entity would be provided the same phase-in period as other newly listed companies to satisfy the requirements of proposed Rule 5605(f). See *id.* at 90–91, 151. The Exchange states that this approach is similar to other phase-in periods currently granted to acquisition companies. See *id.* at 90–91. See also, *e.g.*, Rule 5615(b)(1).

⁴⁷ See Amendment No. 1 to the Board Diversity Proposal at 20.

⁴⁸ See proposed Rule 5606(c).

⁴⁹ The Exchange states that its proposal would not prevent companies from disclosing information related to other diverse attributes of board members beyond those highlighted in the rule if they felt such disclosure would benefit investors. See Amendment No. 1 to the Board Diversity Proposal at 64.

⁵⁰ As proposed, a company may not substantially alter the Board Diversity Matrix. However, a company may supplement its disclosure by providing additional information related to its directors (*e.g.*, a company may choose to provide the information on a director-by-director basis or may choose to include any skills, experience, and attributes of each of its directors that are relevant to the company). Supplemental information may be included below the information required by the Board Diversity Matrix or in a separate table. See *id.* at 326–27.

⁵¹ Following the first year of disclosure of the Board Diversity Matrix, all companies would be required to include the current year and immediately prior year diversity statistics in the disclosure. See proposed Rule 5606(a). If a company publishes the Board Diversity Matrix on its website, the disclosure must remain accessible on the company’s website. See Amendment No. 1 to the Board Diversity Proposal at 326.

at least once per year.⁵² If, within the same year, a company changes its board composition after it publishes the matrix, the company may, but is not required to, publish its updated information.⁵³ In addition, any publication of the information in the Board Diversity Matrix must be included in a searchable format and, if a company uses a graphic or image format (*i.e.*, tif, jpg, gif, or png), the company must also include the same information as searchable text or in a searchable table.⁵⁴

In the proposed Board Diversity Matrix, a company would be required to provide the total number of directors on its board and the company (other than a Foreign Issuer) would include the following information in accordance with the instructions accompanying the Board Diversity Matrix: (1) The number of directors based on gender identity (female, male, or non-binary⁵⁵) and the number of directors who did not disclose gender; (2) the number of directors based on race and ethnicity (African American or Black, Alaskan Native or Native American, Asian, Hispanic or Latinx, Native Hawaiian or Pacific Islander, White, or Two or More Races or Ethnicities⁵⁶), disaggregated by gender identity (or did not disclose gender); (3) the number of directors who self-identify as LGBTQ+; and (4) the number of directors who did not disclose a demographic background under item (2) or (3) above.⁵⁷ In the proposed Board Diversity Matrix, any director who chooses not to disclose a gender would be included in the “Did Not Disclose Gender” category and any director who chooses not to identify as any race or ethnicity or not to identify as LGBTQ+ would be included in the

⁵² See Amendment No. 1 to the Board Diversity Proposal at 326.

⁵³ See *id.* In addition, the Board Diversity Matrix must include the date the information was collected as the “as of date.” See *id.*

⁵⁴ The searchable information could be included, for example, together with the related graphic or in an appendix. See *id.*

⁵⁵ “Non-binary” refers to genders that are not solely man or woman; someone who is non-binary may have more than one gender, have no gender, or their gender may not be in relation to the gender binary. See *id.* at 327.

⁵⁶ If a director self-identifies in the “Two or More Races or Ethnicities” category, the director must also self-identify in each individual category, as appropriate. See *id.* at 66 n.174.

⁵⁷ The Exchange states that defined terms for the race and ethnicity categories in the instructions to the Board Diversity Matrix are substantially similar to the terms and definitions used in the EEO–1 report, as described above. See *supra* note 17. Also, in the instructions to the Board Diversity Matrix, LGTBQ+ is defined similarly to proposed Rule 5605(f)(1) as a person who identifies as any of the following: lesbian, gay, bisexual, transgender, or a member of the queer community.

“Did Not Disclose Demographic Background” category.

A company that qualifies as a Foreign Issuer under proposed Rule 5605(f)(1) may elect to use an alternative Board Diversity Matrix format.⁵⁸ Similar to other companies, a Foreign Issuer would be required to provide the total number of directors on its board. The Foreign Issuer would also be required to provide the following in its Board Diversity Matrix: (1) Its country of principal executive offices; (2) whether it is a Foreign Private Issuer; (3) whether disclosure is prohibited under home country law; (4) the number of directors based on gender identity (female, male, or non-binary) and the number of directors who did not disclose gender; (5) the number of directors who self-identify as Underrepresented Individuals in home country jurisdiction; (6) the number of directors who self-identify as LGBTQ+; and (7) the number of directors who did not disclose the demographic background under item (5) or (6) above.⁵⁹ In the proposed Board Diversity Matrix, any director who chooses not to disclose a gender would be included in the “Did Not Disclose Gender” category and any director who chooses not to identify as an Underrepresented Individual or not to identify as LGBTQ+ would be included in the “Did Not Disclose Demographic Background” category.

Proposed Rule 5606(b) would require each company to provide the disclosure required under proposed Rule 5606 in the same manner as, and concurrently with, the disclosure required by proposed Rule 5605(f)(3).⁶⁰

Proposed Rule 5606(d) would permit a company newly listing on the Exchange that was not previously subject to a substantially similar requirement of another national securities exchange (including through an initial public offering, direct listing, transfer from another exchange or the over-the-counter market, in connection with a spin-off or carve-out from a company listed on the Exchange or another exchange, or through a merger with an acquisition company) to satisfy the requirement of proposed Rule 5606 within one year of listing on the Exchange.

Pursuant to Rule 5606(e), proposed Rule 5606 would become operative one year after a Commission approval of the proposal. A company would be required to be in compliance with proposed Rule 5606 by the later of: (i) One calendar year from the approval date (“Effective

Date”); or (ii) the date the company files its proxy statement or its information statement for its annual meeting of shareholders (or, if the company does not file a proxy or information statement, the date it files its Form 10-K or 20-F) during the calendar year of the Effective Date.

The Exchange proposes to amend Rule 5810(c)(2)(A)(iv) to include a deficiency from the standards of proposed Rule 5606 as a deficiency for which a company may submit a plan of compliance for Exchange staff review. Accordingly, if a company fails to adhere to proposed Rule 5606, the Exchange would notify the company that it is not in compliance with a listing standard and allow the company 45 calendar days to submit a plan to regain compliance and, upon review of such plan, the Exchange may provide the company with up to 180 days to regain compliance.⁶¹ If the company does not submit a plan or regain compliance within the applicable time periods, it would be issued a Staff Delisting Determination, which the company could appeal to a Hearings Panel pursuant to Rule 5815.⁶²

B. The Board Recruiting Service Proposal

In order to help advance diversity on company boards and to help companies prepare for and, if approved, comply with proposed Rules 5605(f) and 5606, the Exchange proposes to provide certain Nasdaq-listed companies with one-year of complimentary access for two users to a board recruiting solution, which would provide access to a network of board-ready Diverse candidates, allowing companies to identify and evaluate Diverse board candidates.⁶³ According to the Exchange, this service has an approximate retail value of \$10,000 per year.⁶⁴

The Exchange proposes to offer this service to any “Eligible Company,” which would be defined to mean a listed company (except as described below) that represents to the Exchange that it does not have: (i) At least one director who self-identifies as Female; and (ii) at least one director who self-identifies as one or more of the following: Black or African American, Hispanic or Latinx, Asian, Native American or Alaska Native, Native Hawaiian or Pacific Islander, or Two or More Races or Ethnicities, or who self-

identifies as lesbian, gay, bisexual, transgender, or as a member of the queer community.⁶⁵ A company that is (i) a Foreign Private Issuer (as defined in Rule 5005(a)(19)), or (ii) considered a foreign issuer under Rule 3b-4(b) under the Act and has its principal executive offices located outside of the United States, would be an Eligible Company if the company represents to the Exchange that it does not have: (i) At least one director who self-identifies as Female; and (ii) at least one director who self-identifies as one or more of the following: Female, an underrepresented individual based on national, racial, ethnic, indigenous, cultural, religious, or linguistic identity in the country of the company’s principal executive offices, or lesbian, gay, bisexual, transgender, or as a member of the queer community.⁶⁶ A company that is a Smaller Reporting Company (as defined in Rule 12b-2 under the Act) would be an Eligible Company if the company represents to the Exchange that it does not have: (i) At least one director who self-identifies as Female, and (ii) at least one director who self-identifies as one or more of the following: Female, Black or African American, Hispanic or Latinx, Asian, Native American or Alaska Native, Native Hawaiian or Pacific Islander, or Two or More Races or Ethnicities, or who self-identifies as lesbian, gay, bisexual, transgender, or as a member of the queer community.⁶⁷

As proposed, until December 1, 2022, any Eligible Company that requests access to this service through the Nasdaq Listing Center will receive complimentary access for one year from the initiation of the service.⁶⁸ The Exchange states that it intends to evaluate the service and the progress made in enhancing diversity and may extend the program prior to its expiration through another proposed rule change filed with the

⁶⁵ See proposed IM-5900-9(a). The Exchange states that, although proposed Rule 5605(f)(2)(D) would require a Company with a Smaller Board to have, or explain why it does not have, at least one Diverse director on its board, such a company would be considered an Eligible Company if it does not have at least one director who self-identifies as female and at least one director who self-identifies as an Underrepresented Minority or LGBTQ+, which the Exchange believes would help promote greater diversity on boards of all sizes. See Amendment No. 1 to the Board Recruiting Service Proposal at 11 n.20.

⁶⁶ See proposed IM-5900-9(b).

⁶⁷ See proposed IM-5900-9(c). The Exchange states that a company that is not an Eligible Company would be able to receive complimentary 90-day access to the board recruiting solution, which is being offered by Nasdaq’s partner to all clients of Nasdaq, Inc., including non-listed companies. See Amendment No. 1 to the Board Recruiting Service Proposal at 12 n.21.

⁶⁸ See proposed IM-5900-9.

⁵⁸ See proposed Rule 5606(a).

⁵⁹ See *id.*

⁶⁰ See *supra* notes 30–31 and accompanying text.

⁶¹ See Rule 5810(c)(2).

⁶² See *id.*

⁶³ See proposed IM-5900-9; Amendment No. 1 to the Board Recruiting Service Proposal at 10–11.

⁶⁴ See proposed IM-5900-9.

Commission.⁶⁹ The Exchange states that no other company would be required to pay higher fees as a result of its Board Recruiting Service Proposal and represents that providing the proposed complimentary service would have no impact on the resources available for its regulatory programs.⁷⁰

III. The Exchange's Arguments in the Proposals and the Comment and Response Letters Received on the Proposals

A. Summary of the Exchange's Arguments in the Proposals

1. The Board Diversity Proposal

In support of the Board Diversity Proposal, the Exchange states that it has reviewed dozens of empirical studies and found that an extensive body of empirical research demonstrates that diverse boards are positively associated with improved corporate governance and company performance.⁷¹ While the Exchange acknowledges that some studies have mixed results on this issue—for example, some studies have found that board gender and ethnic diversity has a non-significant relationship or no relationship with a company's performance⁷²—the Exchange believes that, at a minimum, the academic and empirical studies support the conclusion that board diversity does not have adverse effects on company performance.⁷³

The Exchange also states that there is substantial evidence that board diversity promotes investor protection, including by enhancing the quality of a company's financial reporting, internal controls, public disclosures, and management oversight.⁷⁴ The Exchange states that more than a dozen studies have found

a positive association between gender diversity and important investor protections,⁷⁵ and some academics assert that such findings may extend to other forms of diversity, including racial and ethnic diversity.⁷⁶ The Exchange also states that it has reviewed studies suggesting that board diversity could enhance a company's ability to monitor management by reducing “groupthink” and improving decision-making.⁷⁷

The Exchange states that, while some companies have made progress in diversifying their boardrooms,⁷⁸ the national market system and the public interest would be well-served by a “disclosure-based, business driven” framework for companies to embrace meaningful and multi-dimensional diversification of their boards.⁷⁹ The Exchange states that its discussions with organizational leaders representing a broad spectrum of market participants and stakeholders (including business, investor, governance, legal, and civil rights communities) revealed strong support for disclosure requirements that would standardize the reporting of board diversity statistics.⁸⁰ The

⁷⁵ See *id.* at 29, Section 3.a.III.B. The Exchange states that studies have found that gender-diverse boards or audit committees are associated with: More transparent public disclosures and less information asymmetry; better reporting discipline by management; a lower likelihood of manipulated earnings through earnings management; an increased likelihood of voluntarily disclosing forward-looking information; a lower likelihood of receiving audit qualifications due to errors, non-compliance, or omission of information; and a lower likelihood of securities fraud. See *id.* at 13, Section 3.a.III.B. In addition, the Exchange states that studies found that having at least one woman on the board is associated with a lower likelihood of material weaknesses in internal control over financial reporting and a lower likelihood of material financial restatements. See *id.* at 13, Section 3.a.III.B, Section 3.b.II.B.

⁷⁶ See *id.* at 29, Section 3.a.III.B.

⁷⁷ See *id.* at Section 3.a.III.C.

⁷⁸ The Exchange believes that a supermajority of listed companies have at least one woman on the board and that listed companies are diligently working to add directors with other diverse attributes. See *id.* at 12, 41. The Exchange states that, while gender diversity has improved among U.S. company boards in recent years, the pace of change has been gradual and the U.S. still lags behind jurisdictions that have focused on board diversity. See *id.* at 12, Section 3.a.IV. The Exchange also states that progress toward bringing underrepresented racial and ethnic groups into the boardroom has been slower. See *id.* at 12, Section 3.a.IV.

⁷⁹ See *id.* at 8–9.

⁸⁰ See *id.* at Section 3.a.V. The Exchange also states that the majority of the organizations were in agreement that companies would benefit from a disclosure-based, business-driven framework to drive meaningful and systemic change in board diversity, and that a disclosure-based approach would be more palatable to the U.S. business community than a mandate. See *id.* at 46. According to the Exchange, some in the group pointed out that smaller companies and companies in certain industries may face challenges finding

Exchange further states that such discussions reinforced the notion that if companies recruit by skill set and experience rather than title, they would find that there is more than enough diverse talent to satisfy demand.⁸¹

Moreover, the Exchange states that current reporting of board diversity data is not provided in a consistent manner or on a sufficiently widespread basis and, as such, investors are not able to readily compare board diversity statistics across companies.⁸² In pointing out the “broad latitude” afforded to companies by Commission rules relating to board diversity and proxy disclosure, the Exchange states that the absence of a specific definition of “diversity” for such disclosures has resulted in current reporting of board-level diversity statistics being significantly unreliable and unusable to investors.⁸³ The Exchange states that the lack of transparency creates barriers to investment analysis, due diligence, and academic study, and is impacting investors who are increasingly basing public advocacy, proxy voting, and direct shareholder-company engagement decisions on board diversity considerations.⁸⁴

diverse board members. See *id.* In addition, the Exchange states that leaders from the legal community emphasized that any proposed rule change that imposed additional burdens beyond, or is inconsistent with, existing securities laws would present an additional burden and potentially more legal liability for listed companies. See *id.* at 46–47.

⁸¹ See *id.* at 19–20, 46. According to the Exchange, studies suggest that the traditional director candidate selection process may create barriers to considering qualified diverse candidates for board positions (e.g., directors looking within their own social networks for candidates with previous C-suite experience). See *id.* at 41–44, Section 3.b.II.A.

⁸² See *id.* at 9. The Exchange also states that, while conducting research on the state of board diversity among its listed companies, it encountered multiple key challenges, such as: (1) Inconsistent disclosure and definitions of “diversity” across companies; (2) limited data on diverse characteristics outside of gender; (3) inconsistent or no disclosure of a director's race, ethnicity, or other diversity attributes (e.g., nationality); (4) difficult-to-extract data because statistics are often embedded in graphics; and (5) aggregation of information, making it difficult to separate gender from other categories of diversity. See *id.* at 51. See also *id.* at 59, 107 (stating that the current lack of transparency and consistency makes it difficult for the Exchange and investors to determine the state of diversity among listed companies and each board's philosophy regarding diversity; to the extent investors must obtain this information on their own through an imperfect process, this increases information asymmetries between larger and smaller stakeholders; and a broader definition of diversity may result in certain diverse candidates being overlooked and may hinder meaningful progress on improving diversity related to race, ethnicity, sexual orientation, and gender identity).

⁸³ See *id.* at Sections 3.a.VI.A–B.

⁸⁴ See *id.* at 51–52.

⁶⁹ See Amendment No. 1 to the Board Recruiting Service Proposal at 12.

⁷⁰ See *id.*

⁷¹ See Amendment No. 1 to the Board Diversity Proposal at 13. The Exchange states that studies have identified positive relationships between board diversity and commonly used financial metrics, including higher returns on invested capital, returns on equity, earnings per share, earnings before interest and taxation margin, asset valuation multiples, and credit ratings. See *id.* at 13, Section 3.a.III.A. The Exchange also points to a report that suggests that the relationship between board gender diversity and corporate performance may extend to LGBTQ+ diversity. See *id.* at 25.

⁷² See *id.* at 25–27.

⁷³ See *id.* at 28. The Exchange also states that this is not the first time it has considered whether, on balance, various studies finding mixed results related to board composition and company performance are a sufficient rationale to propose a listing rule. See *id.* The Exchange states that, for example, in 2003, notwithstanding the various findings of studies at the time regarding the relationship between company performance and board independence, it adopted listing rules requiring a majority independent board. See *id.*

⁷⁴ See *id.* at 29.

The Exchange states that it is well positioned to establish practices that would assist in carrying out its mandate to protect investors and remove impediments from the market through the Board Diversity Proposal.⁸⁵ The Exchange believes that it is well within its delegated authority to propose listing rules designed to enhance transparency, provided that they do not conflict with existing federal securities laws.⁸⁶ The Exchange also states that the proposal is related to corporate governance standards for listed companies and is therefore not designed to regulate by virtue of any authority conferred by the Act matters not related to the purposes of the Act or the administration of the Exchange.⁸⁷ While the Exchange recognizes that U.S. states are increasingly proposing and adopting board diversity requirements, the Exchange states that certain of its current corporate governance listing rules relate to areas that are also regulated by states (e.g., quorums, shareholder approval of certain transactions).⁸⁸ The Exchange also states that adopting Exchange rules relating to such matters (and the proposed rule changes described herein) would ensure uniformity of such rules among its listed companies.⁸⁹

The Exchange believes that the disclosure-based framework of proposed Rule 5605(f) may influence corporate conduct if a company chooses to meet the proposed diversity objectives,⁹⁰ and could help increase opportunities for Diverse candidates who otherwise may be overlooked due to the impediments

of the traditional director recruitment process.⁹¹ The Exchange also believes that boards that choose to meet the proposed diversity objectives may experience benefits from diversity that perfect the mechanism of a free and open market and a national market system, and promote investor protection and the public interest.⁹² Moreover, the Exchange believes that, to the extent a company chooses not to meet the proposed diversity objectives, the disclosure under proposed Rule 5605(f)(3) would provide analysts and investors with a better understanding about a company's reasons for not doing so and its philosophy regarding diversity.⁹³ The Exchange believes that this disclosure would enable the investment community to conduct more informed analyses of, and have more informed conversations with, companies, and improve the quality of information available to investors who rely on this information to make informed investment and voting decisions.⁹⁴ In addition, the Exchange believes that the proposed disclosure framework and phase-in and transition periods under Rule 5605(f) recognize the differences (e.g., in demographics or resources) among different types of companies and would not unfairly discriminate among companies.⁹⁵

⁹¹ See *id.* For these reasons, the Exchange believes that proposed Rule 5605(f) is designed to remove impediments to a free and open market and a national market system. See *id.* The Exchange also states that proposed Rule 5605(f) is not designed to create additional impediments to a free and open market and a national market system because it would empower companies to maintain decision-making authority over the composition of their boards. See *id.* at 122.

⁹² See *id.* at Sections 3.b.II.B–C. The Exchange also believes that including diverse directors with a broader range of skills, perspectives, and experiences may help detect and prevent fraudulent and manipulative acts and practices by mitigating “groupthink” and enhancing the functioning of boards, and may reduce the likelihood of insider trading and other fraudulent and manipulative acts and practices. See *id.* at 123–29. In addition, the Exchange states that it recognizes that directors may bring diverse perspectives, skills, and experiences to the board, notwithstanding that they have similar attributes; therefore, the Exchange believes that it is in the public interest to permit a company to choose whether to meet the proposed diversity objectives or explain why it does not. See *id.* at 129–30.

⁹³ See *id.* at 122. The Exchange also believes that the proposal could help lower information asymmetry and reduce the risk of insider trading or opportunistic insider behavior, which would help to make stock prices more informative and enhance stock liquidity, and is therefore designed to protect investors and promote capital formation and efficiency. See *id.* at 135.

⁹⁴ The Exchange believes that, therefore, the proposal is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to promote capital formation and efficiency. See *id.* at 122–23.

⁹⁵ See *id.* at Section 3.b.II.D. See also *id.* at 161–63 (stating that the proposal would not impose any

The Exchange believes that the disclosures required by proposed Rule 5606 and the accompanying format requirements would protect investors by eliminating data collection inaccuracies, decreasing investors' costs, and enhancing investors' ability to utilize the information disclosed.⁹⁶ The Exchange also believes that proposed Rule 5606 would protect investors that view information related to board diversity as material to their investment and voting decisions, and enhance investor confidence by assisting investors in making more informed decisions.⁹⁷ Moreover, the Exchange believes that the proposed annual disclosures would provide consistent information to the public and would enable investors to continually review the board composition of a company to track trends,⁹⁸ as well as simplify or eliminate the need for a company to respond to multiple investor requests for board diversity information.⁹⁹ The Exchange also believes that the proposed timing for the board composition disclosures would align with other governance-related disclosures (e.g., those provided in the proxy) and would make it easier for investors to know where a company has provided the disclosures and give shareholders access to the information

burden on competition among issuers that is not necessary or appropriate in furtherance of the purposes of the Act and would not impose any burden on competition among listing exchanges).

⁹⁶ See *id.* at 110. The Exchange also believes that it would be in the public interest to utilize the Board Diversity Matrix format because it would remove impediments in aggregating and analyzing data across all companies. See *id.* at 113. The Exchange additionally believes that it would be reasonable and in the public interest to allow companies the flexibility of supplementing their disclosure by providing additional information related to their directors (beyond what is required by proposed Rule 5606) in the Board Diversity Matrix. See *id.* The Exchange also states that its proposed definition of “Diverse” would be familiar to most companies and that the proposed Board Diversity Matrix would provide for standardized disclosures. See *id.* at 114. Moreover, the Exchange believes that prohibiting companies from providing the information through graphics and images would allow investors to easily disaggregate the data and track directors with multiple diversity characteristics. See *id.* at 113.

⁹⁷ See *id.* at 110–11. In addition, the Exchange states that the proposed disclosure format would provide a company with a uniform template with the flexibility to include any additional details about its board that the company believes would be useful to investors. See *id.* at 111.

⁹⁸ The Exchange also states that the disclosures under proposed Rule 5606 would provide a means for the Exchange to assess whether companies meet the diversity objectives under proposed Rule 5605(f), which would protect investors and the public interest. See *id.* at 116.

⁹⁹ See *id.* at 112. The Exchange also believes that the proposed disclosures would make information available to investors who otherwise would not be able to obtain individualized disclosures. See *id.*

⁸⁵ See *id.* at 53. The Exchange also states that the Board Diversity Proposal leverages the Exchange's unique ability, as a self-regulatory organization (“SRO”), to influence corporate governance in furtherance of the goal of Section 342 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. See *id.* at 18.

⁸⁶ See *id.* at 58. The Exchange states that, for example, it already requires its listed companies to publicly disclose compensation or other payments by third parties to a company's directors or nominees, notwithstanding that such disclosure is not required by federal securities laws. See *id.* at 58–59. The Exchange also states that it has designed the proposal to avoid a conflict with existing disclosure requirements under Regulation S-K and mitigate additional burdens for companies by providing them with flexibility to provide such disclosure on their website, in their proxy statement or information statement, or, if a company does not file a proxy, in its Form 10-K or 20-F, and by not requiring companies to adopt a diversity policy. See *id.* at 60.

⁸⁷ See *id.* at Section 3.b.II.E.

⁸⁸ See *id.* at 155–56. The Exchange recognizes that several states have enacted or proposed legislation relating to board diversity and that Congress is considering legislation to require Commission-registered companies to provide board diversity statistics and disclose whether they have a board diversity policy. See *id.* at 16.

⁸⁹ See *id.* at 156.

⁹⁰ See *id.* at 121.

prior to a company's annual shareholders meeting.¹⁰⁰ Finally, the Exchange believes that proposed Rule 5606 would provide appropriate flexibility for Foreign Issuers¹⁰¹ and appropriate exceptions for certain types of Nasdaq-listed companies,¹⁰² and would provide reasonable compliance periods because it would impose only a de minimis burden on companies.¹⁰³

2. The Board Recruiting Service Proposal

In support of the Board Recruiting Service Proposal, the Exchange argues that offering a board recruiting solution would assist and encourage listed companies to increase diverse representation on their boards, which the Exchange believes could result in improved corporate governance, strengthening of market integrity, and improved investor confidence.¹⁰⁴ The Exchange further states that offering this service would help companies to achieve compliance with the Board Diversity Proposal, if it were approved.¹⁰⁵ The Exchange also states that utilization of the complimentary board recruiting solution would be optional, and no company would be required to use the service.¹⁰⁶

¹⁰⁰ See *id.* at 115. See also *id.* at 135 (stating a similar belief with respect to the disclosures under proposed Rule 5605(f)). The Exchange also states that proposed Rule 5606(b) would closely align the timing for companies that choose to disclose the Board Diversity Matrix data on their websites and companies that choose to provide the data through a Commission filing. See *id.* at 115.

¹⁰¹ See *id.* at 115–16.

¹⁰² See *id.* at 117–18.

¹⁰³ See *id.* at 118. See also *id.* at 159–60 (stating that the Exchange faces competition in the market for listing services, and the Exchange's belief that there would be a de minimis time and economic burden on listed companies to collect and disclose the diversity statistical data under proposed Rule 5606, and that any burden placed on companies to gather and disclose this information would be counterbalanced by the benefits that the information would provide to a company's investors). In the Board Diversity Proposal, the Exchange also describes the alternatives that it considered, including: (1) Mandate-based and disclosure-based approaches; (ii) higher and lower diversity objectives; (iii) longer and shorter compliance timeframes; and (iv) broader and narrower definitions of "Diverse." See *id.* at Section 3.a.VILD.

¹⁰⁴ See Amendment No. 1 to the Board Recruiting Service Proposal at 10. The Exchange reiterates that, in researching the Board Diversity Proposal, it has reviewed dozens of empirical studies and found that an extensive body of academic and empirical research demonstrates diverse boards are positively associated with improved corporate governance and company performance. See *id.* at 6. Moreover, the Exchange states that investors and investor groups are calling for diversification in the boardroom, and legislators at the federal and state level are increasingly taking action to encourage or mandate corporations to diversify their boards and improve diversity disclosures. See *id.* at 9–10.

¹⁰⁵ See *id.* at 10.

¹⁰⁶ See *id.* at 13.

The Exchange further argues that it is reasonable and not unfairly discriminatory to offer the board recruiting solution only to Eligible Companies because the Exchange believes these companies have the greatest need to identify Diverse board candidates, particularly if these companies elect to meet the diversity objectives in the Board Diversity Proposal, if approved, rather than disclosing why they have not met the objectives.¹⁰⁷ Additionally, the Exchange believes that companies that already have two Diverse directors have demonstrated by their current board composition that they do not need additional assistance provided by the Exchange to identify Diverse candidates for their boards.¹⁰⁸ The Exchange also believes that offering this complimentary service would help it compete to attract and retain listings, particularly in light of the additional requirements in the Board Diversity Proposal that would apply to Exchange-listed companies, if it were approved.¹⁰⁹ The Exchange further represents that individual listed companies would not be given specially negotiated packages of products or services to list, or remain listed.¹¹⁰

B. The Comment and Response Letters Received on the Proposals

The Commission has received comment letters that support the proposals, comment letters that suggest changes to the proposals, and comment letters that oppose the proposals.¹¹¹ The Commission has also received two response letters from the Exchange.¹¹²

¹⁰⁷ See *id.*

¹⁰⁸ See *id.* at 13–14. As described above, although proposed Rule 5605(f)(2)(D) would require a Company with a Smaller Board to have, or explain why it does not have, at least one Diverse director on its board, such a company would be considered an Eligible Company if it does not have at least one director who self-identifies as female and at least one director who self-identifies as an Underrepresented Minority or LGBTQ+, which the Exchange believes would help promote greater diversity on boards of all sizes. See *id.* at 11 n.20.

¹⁰⁹ See *id.* at 14.

¹¹⁰ See *id.* at 15.

¹¹¹ Comments received on the Board Diversity Proposal are available on the Commission's website at: <https://www.sec.gov/comments/sr-nasdaq-2020-081/srnasdaq2020081.htm>. Comments received on the Board Recruiting Service Proposal are available on the Commission's website at: <https://www.sec.gov/comments/sr-nasdaq-2020-082/srnasdaq2020082.htm>.

¹¹² See letter from Stephen J. Kastenbergh, Ballard Spahr LLP, to Vanessa Countryman, Secretary, Commission, dated February 5, 2021 (submitted on behalf of the Exchange by its counsel), available at: <https://www.sec.gov/comments/sr-nasdaq-2020-081/srnasdaq2020081-8343758-228925.pdf>; letter from John A. Zecca, Executive Vice President, Chief Legal Officer, and Chief Regulatory Officer, Nasdaq, to Vanessa A. Countryman, Secretary, Commission,

IV. Proceedings To Determine Whether To Approve or Disapprove SR–NASDAQ–2020–081 and SR–NASDAQ–2020–082, as Modified by Amendments No. 1, and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act¹¹³ to determine whether the proposed rule changes, as modified by Amendments No. 1, should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the issues raised by the proposed rule changes. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide additional comment on the proposed rule changes, as modified by Amendments No. 1, to inform the Commission's analysis of whether to approve or disapprove the proposed rule changes, as modified by Amendments No. 1.

Pursuant to Section 19(b)(2)(B) of the Act,¹¹⁴ the Commission is providing notice of the grounds for disapproval under consideration. As described above, the Exchange proposes in the Board Diversity Proposal to require each of its listed companies, subject to certain exceptions, to: (i) Provide statistical information regarding the diversity characteristics among the members of the company's board of directors; and (ii) if the company does not meet the applicable board diversity objectives, to disclose an explanation as to why. Also as described above, the Exchange proposes in the Board Recruiting Service Proposal to provide certain Nasdaq-listed companies with one-year of complimentary access to a diverse board candidate recruiting solution. In addition, as stated above, the Commission has received comment letters that support the proposals, comment letters that suggest changes to the proposals, and comment letters that oppose the proposals, as well as two response letters from the Exchange. Moreover, on February 26, 2021, the Exchange submitted an amendment to each of the proposals.

The Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the consistency of the proposals, as modified by Amendments

dated February 26, 2021, available at: <https://www.sec.gov/comments/sr-nasdaq-2020-081/srnasdaq2020081-8425992-229601.pdf>.

¹¹³ 15 U.S.C. 78s(b)(2)(B).

¹¹⁴ *Id.*

No. 1, with Section 6(b)(5) of the Act,¹¹⁵ which requires that the rules of a national securities exchange be designed, among other things, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, 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 not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers, or to regulate by virtue of any authority conferred by the Act matters not related to the purposes of the Act or the administration of the exchange; and Section 6(b)(8) of the Act,¹¹⁶ which requires that the rules of a national securities exchange not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Commission is instituting proceedings to also allow for additional analysis of, and input from commenters with respect to, the consistency of the Board Recruiting Service Proposal, as modified by Amendment No. 1, with Section 6(b)(4) of the Act,¹¹⁷ which requires that the rules of a national securities exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities.

V. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposals. In particular, the Commission invites the written views of interested persons concerning whether the proposals, as modified by Amendments No. 1, are consistent with Sections 6(b)(4),¹¹⁸ 6(b)(5)¹¹⁹ and 6(b)(8)¹²⁰ of the Act or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b-4 under the Act,¹²¹ any

request for an opportunity to make an oral presentation.¹²²

Interested persons are invited to submit written data, views, and arguments regarding whether the proposals, as modified by Amendments No. 1, should be approved or disapproved by April 6, 2021. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by April 20, 2021. 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-NASDAQ-2020-081 or SR-NASDAQ-2020-082 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-NASDAQ-2020-081 or SR-NASDAQ-2020-082. 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 changes that are filed with the Commission, and all written communications relating to the proposed rule changes 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

¹²² Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94-29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. See Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

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-NASDAQ-2020-081 or SR-NASDAQ-2020-082 and should be submitted by April 6, 2021. Rebuttal comments should be submitted by April 20, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹²³

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-05343 Filed 3-15-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270-267, OMB Control No. 3235-0272]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Extension:

Rule 11a-2

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the "Commission") has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 11a-2 (17 CFR 270.11a-2) under the Investment Company Act of 1940 (15 U.S.C. 80a-1 *et seq.*) permits certain registered insurance company separate accounts, subject to certain conditions, to make exchange offers without prior approval by the Commission of the terms of those offers. Rule 11a-2 requires disclosure, in certain registration statements filed pursuant to the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) of any administrative fee or sales load imposed in connection with an exchange offer.

There are currently 676 registrants governed by Rule 11a-2. The Commission includes the estimated burden of complying with the information collection required by Rule

¹²³ 17 CFR 200.30-3(a)(12); 17 CFR 200.30-3(a)(57).

¹¹⁵ 15 U.S.C. 78f(b)(5).

¹¹⁶ 15 U.S.C. 78f(b)(8).

¹¹⁷ 15 U.S.C. 78f(b)(4).

¹¹⁸ *Id.*

¹¹⁹ 15 U.S.C. 78f(b)(5).

¹²⁰ 15 U.S.C. 78f(b)(8).

¹²¹ 17 CFR 240.19b-4.

11a-2 in the total number of burden hours estimated for completing the relevant registration statements and reports the burden of Rule 11a-2 in the separate Paperwork Reduction Act ("PRA") submissions for those registration statements (see the separate PRA submissions for Form N-3 (17 CFR 274.11b), Form N-4 (17 CFR 274.11c) and Form N-6 (17 CFR 274.11d). The Commission is requesting a burden of one hour for Rule 11a-2 for administrative purposes.

The estimate of average burden hours is made solely for the purposes of the PRA, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules or forms. With regard to Rule 11a-2, the Commission includes the estimate of burden hours in the total number of burden hours estimated for completing the relevant registration statements and reported on the separate PRA submissions for those statements (see the separate PRA submissions for Form N-3, Form N-4 and Form N-6).

The information collection requirements imposed by Rule 11a-2 are mandatory. Responses to the collection of information will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view background documentation for this information collection at the following website: www.reginfo.gov. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) www.reginfo.gov/public/do/PRAMain and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or by sending an email to: PRA_Mailbox@sec.gov.

Dated: March 11, 2021.

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-05378 Filed 3-15-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, March 18, 2021.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at <https://www.sec.gov>.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION:

For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551-5400.

Dated: March 11, 2021.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2021-05456 Filed 3-12-21; 11:15 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91288; File No. SR-CBOE-2021-015]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Update its Fees Schedule in Connection With the Exchange's Plans To List and Trade Options on the Mini-RUT Index ("MRUT" or "Mini-RUT")

March 10, 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 March 1, 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, II, and III 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

Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") proposes to update its Fees Schedule in connection with the Exchange's plans to list and trade options on the Mini-RUT Index ("MRUT" or "Mini-RUT"). 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, 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

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

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 its Fees Schedule in connection with its plans to list and trade MRUT options, effective March 1, 2021.

Background

MRUT options are options on the Mini-RUT Index, the value of which is 1/10th the value of the Russell 2000 ("RUT") Index. The Russell 2000 Index measures the performance of small-cap segment of the U.S. equity universe. It is a subset of the Russell 3000 Index and includes approximately 2,000 U.S.-based securities based on a combination of their market cap and current index membership. The Russell 2000 Index is constructed to provide a comprehensive and unbiased small-cap barometer and is completely reconstituted annually to ensure larger stocks do not distort the performance and characteristics of the true small-cap opportunity set. The Russell 2000 Index is a commonly used benchmark for mutual funds that identify themselves as "small-cap," and much like the S&P 500 Index ("SPX"), is used to benchmark large capitalization stocks. The Exchange understands that investors often use Russell 2000 Index-related products to diversify their portfolios and benefit from market trends. RUT options currently offer these benefits to investors but may be expensive given their larger notional value and are therefore primarily used by institutional market participants. By contrast, MRUT options are reduced-value options (1/10th) compared to RUT options that will offer individual investors lower cost options to obtain the potential benefits of options on the Russell 2000 Index.

The Exchange believes that investors will benefit from the availability of Mini-RUT option contracts by making options overlying the higher-valued RUT Index more readily available as an investing tool and at more affordable prices for investors. The Exchange also believes that the investor-base for MRUT options are likely to be the same investor-base for Mini-SPX options ("XSP"), which are also proprietary, reduced-value options on a broad-based index (SPX), as they are both designed to provide low-cost means to hedge investors' portfolios in connection with higher-value broad-based indexes (*i.e.*, the RUT and SPX Index) with a smaller

outlay of capital. As such, the Exchange will allow the same type of expirations, settlement and exercise style, minimum increments, strike price intervals and Market-Maker appointment weights for MRUT options as it currently does for XSP options and anticipates that MRUT options will have the same investor base as XSP options.³ The Exchange now proposes to amend its Fees Schedule to accommodate the planned listing and trading of MRUT options. The Exchange notes that because both MRUT and XSP are mini-index options intended for the same investor-base, the majority of the proposed changes amend the Fees Schedule in connection with trading in MRUT options in a manner that is generally consistent with the way in which existing transactions fees and programs currently apply to trading in XSP options.

Standard Transaction Rates and Surcharges

First, the Exchange proposes to adopt certain standard transaction fees in connection with MRUT options in a manner that closely aligns the fees assessed for MRUT options with that of the fees assessed for RUT options. As described above, MRUT options and RUT options track the same underlying index, yet MRUT options are 1/10th the size of standard RUT options contracts. As such, the proposed rule change adopts certain fees for MRUT options in the Rate Table for All Products Excluding Underlying Symbol A⁴ that are approximately 1/10th of the fees currently assessed for RUT options, as follows:

- Adopts fee code CQ, appended to all Customer (capacity "C") orders in MRUT options and assesses a fee of \$0.02 per contract. This proposed fee is approximately 1/10th of the fees assessed for Customer orders in RUT options (\$0.18).
- Adopts fee code FM, appended to all Clearing Trading Permit Holder ("TPHs") (capacity "F") and for Non-TPH Affiliate of a Clearing TPH (capacity "L") (collectively, "Firms") orders in MRUT options and assesses a fee of \$0.02 per contract. The proposed fee is approximately 1/10th of the fees assessed for Firm orders in RUT options (\$0.26);

³ See Securities Exchange Act Release Nos. 90748 (December 21, 2020), 85 FR 85759 (December 29, 2020) (SR-CBOE-2020-118); and 91067 (February 5, 2021), 86 FR 9108 (February 11, 2021) (SR-CBOE-2020-118) [sic].

⁴ Underlying Symbol List A includes OEX, XEO, RUT, RLG, RLV, RUI, UKXM, SPX (includes SPXW), SPESG and VIX. See Choe Options Fees Schedule, Footnote 34.

- Adopts fee code MM, which is appended to all Market-Maker (capacity "M") orders in MRUT options and assesses a fee of \$0.03 per contract. The proposed fee is approximately 1/10th of the fees assessed for Market-Maker orders in RUT options (\$0.30); and

- Adopts fee code BM, appended to all Broker-Dealer (capacity "B"), Joint Back-Office (capacity "J"), Non-TPH Market-Maker (capacity "N"), and Professional (capacity "U") (collectively, "Non-Customers") orders in MRUT options and assesses a fee of \$0.04 per contract. The proposed fee is approximately 1/10th of the difference between the two rates assessed for Non-Customer orders in RUT options (\$0.25 for manual and AIM transactions and \$0.65 for non-AIM electronic transactions).

The Exchange also proposes to waive the proposed MRUT transaction fees for Firms and Market-Makers through August 31, 2021. Specifically, proposed footnote 32 (appended to MRUT options for Market-Maker and Firm transaction fees in the Rate Table—All Products Excluding Underlying Symbol List A) provides that transaction fees for orders executed in MRUT options with a capacity code of "F", "L", or "M" will be waived through August 31, 2021. The proposed waiver is intended to encourage liquidity in a newly listed and traded product on the Exchange.

In addition to the above transaction fees, the proposed rule change also adopts certain surcharges to MRUT transactions within the Rate Table—All Products Excluding Underlying Symbol List A. The proposed rule change applies an Index License Surcharge Fee of \$0.02 to all Firm, Market-Maker and Non-Customer transactions in MRUT options. Currently, the Index License Surcharge Fee assesses a \$0.10 charge for transactions in DJX, MXEA and MXEF options. The proposed lower Index License Surcharge rate for MRUT options is intended to promote and encourage trading of MRUT options once listed. The Exchange notes that this is similar to lower (or waived) Index License fees for other options classes in order to similarly continue to promote their trading and growth.⁵

⁵ See *e.g.* Securities Exchange Act Release No. 90093 (October 5, 2020), 85 FR 64189 (October 9, 2020) (SR-CBOE-2020-088), which provides that "[t]he Exchange does not at this time propose to assess the Index License fee on transactions in SPESG in order to promote and encourage trading of SPESG once listed."; and Securities Exchange Act Release No. 87953 (January 13, 2020), 85 FR 3091 (January 17, 2020) (SR-CBOE-2020-001), which waived permanently the Index License fees for transactions in Sector Index options to continue to encourage their growth and trading.

The proposed rule change adds MRUT options to the list of options, which currently includes XSP, for which the FLEX Surcharge Fee of \$0.10 (capped at \$250 per trade) applies to electronic FLEX orders executed by all capacity codes.⁶ The proposed rule change adopts an Exotic Surcharge of \$0.03 for Customer transactions in MRUT, which is consistent with the Exotic Surcharge currently assessed for Customer transactions in XSP. Additionally, the Exchange proposes to exclude MRUT orders from the AIM Contra Fee by amending footnote 18 (appended to the AIM Contra Fee) to provide that the AIM Contra Execution Fee applies to all orders (excluding facilitation orders, per footnote 11) in all products, except MRUT, XSP,⁷ Sector Indexes and Underlying Symbol List A, executed in the Automated Improvement Mechanism (“AIM”), Solicitation Auction Mechanism (“SAM”), FLEX AIM and FLEX SAM auctions, that were initially entered as the contra party to an Agency/Primary Order. Applicable standard transaction fees will apply to AIM, SAM, FLEX AIM and FLEX SAM executions in MRUT, XSP, Sector Indexes and Underlying Symbol List A. The Exchange also proposes to exclude Firm, Market-Maker and Non-Customer complex orders in MRUT from the Complex Surcharge by amending footnote 35 (appended to the Complex Surcharge) to provide that the Complex Surcharge applies per contract per side surcharge for noncustomer complex order executions that remove liquidity from the COB and auction responses in the Complex Order Auction (“COA”) and AIM in all classes except MRUT, XSP, Sector Indexes and Underlying Symbol List A. The proposed FLEX and Exotic surcharges and exclusion from the AIM Contra Fee (and, instead, the application of the proposed standard transaction fees) and Complex Surcharge in connection with transactions in MRUT will provide consistency with the fees and exclusions currently applicable to transactions in XSP.

Fees Programs

The proposed rule change excludes MRUT volume from the Liquidity Provider Sliding Scale, which offers

credits on Market-Maker orders where a Market-Maker achieves certain volume thresholds based on total national Market-Maker volume in all underlying symbols, excluding Underlying Symbol List A and XSP, during the calendar month. Specifically, the proposed rule change updates the Liquidity Provider Sliding Scale table to provide that volume thresholds are based on total national Market-Maker volume in all underlying symbols excluding Underlying Symbol List A, MRUT and XSP during the calendar month, and that it applies in all underlying symbols excluding Underlying Symbol List A, MRUT and XSP. The proposed rule change also updates footnote 10 (appended to the Liquidity Provider Sliding Scale) to provide that the Liquidity Provider Sliding Scale applies to Liquidity Provider (Cboe Options Market-Maker, DPM and LMM) transaction fees in all products except (1) Underlying Symbol List A (34), MRUT and XSP,⁸ and (2) volume executed in open outcry.⁹

The proposed rule change updates the Volume Incentive Program (“VIP”) table to exclude MRUT volume from the VIP, which currently offers a per contract credit for certain percentage threshold levels of monthly Customer and Non-Customer volume in all underlying symbols, excluding Underlying Symbol List A, Sector Indexes, DJX, MXEA, MXEF and XSP. The proposed rule change also amends footnote 36 (appended to the VIP table) to reflect the proposed exclusion of MRUT from the VIP by providing (in relevant part) that: The Exchange shall credit each Trading Permit Holder the per contract amount resulting from each public customer (“C” capacity code) order transmitted by that Trading Permit Holder which is executed electronically on the Exchange in all underlying symbols excluding Underlying Symbol List A, Sector Indexes, DJX, MRUT, MXEA, MXEF, XSP, QCC trades, public customer to public customer electronic complex order executions, and executions related

to contracts that are routed to one or more exchanges in connection with the Options Order Protection and Locked/Crossed Market Plan referenced in Rule 5.67, provided the Trading Permit Holder meets certain percentage thresholds in a month as described in the Volume Incentive Program (VIP) table; the percentage thresholds are calculated based on the percentage of national customer volume in all underlying symbols excluding Underlying Symbol List A, Sector Indexes, MRUT, MXEA, MXEF, DJX and XSP entered and executed over the course of the month; and in the event of a Cboe Options System outage or other interruption of electronic trading on Cboe Options, the Exchange will adjust the national customer volume in all underlying symbols excluding Underlying Symbol List A, Sector Indexes, MRUT, MXEA, MXEF, DJX and XSP for the entire trading day.¹⁰

The proposed rule change excludes MRUT from the list of products eligible to receive Break-Up Credits in orders executed in AIM, SAM, FLEX AIM, and FLEX SAM, by amending the Break-Up Credits table to exclude MRUT along with the products currently excluded—Underlying Symbol List A, Sector Indexes, DJX, MXEA, MXEF and XSP.

The Exchange also proposes to exclude Firm transactions in MRUT from the Clearing TPH Fee Cap. Specifically, it amends footnote 22 (appended to the Clearing TPH Fee Cap table) to provide that all non-facilitation business executed in AIM or open outcry, or as a QCC or FLEX transaction, transaction fees for Clearing TPH Proprietary and/or their Non-TPH Affiliates in all products except MRUT, XSP, Sector Indexes and Underlying Symbol List A (which includes SPX), in the aggregate, are capped at \$55,000 per month per Clearing TPH. It additionally updates footnote 11 (which is also appended to the Clearing TPH Fee Cap table) to provide that the Clearing TPH Fee Cap in all products except MRUT, XSP, Underlying Symbol List A and Sector Indexes (the “Fee Cap”),¹¹ among other programs, apply to (i) Clearing TPH proprietary orders (“F” capacity code), and (ii) orders of Non-TPH Affiliates of a Clearing TPH.

The Exchange proposes to exclude MRUT from eligibility for the Order Router Subsidy (“ORS”) and Complex Order Router Subsidy (“CORS”) Programs, in which Participating TPHs

⁶ The FLEX Surcharge Fee will only be charged up to the first 2,500 contracts per trade. See Cboe Options Fees Schedule, Footnote 17.

⁷ The proposed rule change also makes clear in the first sentence of footnote 18 that the AIM Contra Execution Fee is not applicable to transaction in XSP. This is currently the case and is clear in the subsequent language within footnote 18 as well as the manner in which the fees are presented in Rate Table—All Products Excluding Underlying Symbol List A.

⁸ The proposed rule change corrects an inadvertent grammatical error in footnote 10 in connection with the exclusion of XSP from the Liquidity Provider Sliding Scale.

⁹ The proposed rule change also updates footnote 6, which is appended to the Liquidity Provider Sliding Scale Program, the VIP, and the ORS/CORS Programs to reflect the exclusion of MRUT options from these programs in the same manner as the options classes currently excluded from these programs. Specifically, amended footnote 6 provides that in the event of a Cboe Options System outage or other interruption of electronic trading on Cboe Options that lasts longer than 60 minutes, the Exchange will adjust the national volume in all underlying symbols excluding Underlying Symbol List A, Sector Indexes, MRUT, MXEA, MXEF, DJX and XSP for the entire trading day.

¹⁰ See *supra* note 8.

¹¹ The Exchange notes that it also corrects an error in footnote 11 by moving the abbreviated definition for the Clearing TPH Fee Cap (“Fee Cap”) [sic], to the end of the clause describing the cap.

or Participating Non-Cboe TPHs may receive a payment from the Exchange for every executed contract routed to the Exchange through their system in certain classes. Specifically, the proposed rule change updates the ORS/CORS Program tables to provide that ORS/CORS participants whose total aggregate non-customer ORS and CORS volume is greater than 0.25% of the total national volume (excluding volume in options classes included in Underlying Symbol List A, Sector Indexes, DJX, MRUT, MXEA, MXEF or XSP) will receive an additional payment for all executed contracts exceeding that threshold during a calendar month, and updates footnote 30 (appended to the ORS/CORS Program tables) to accordingly provide that Cboe Options does not make payments under the program with respect to executed contracts in options classes included in Underlying Symbols List A, Sector Indexes, DJX, MRUT, MXEA, MXEF or XSP.¹²

The Exchange notes that excluding MRUT transactions from the above-described programs is consistent with the manner in which XSP transactions are also excluded each of these programs today.

Additionally, the Exchange proposes to exclude MRUT from the Marketing Fee Program by updating the Marketing Fee table to provide that the marketing fee will be assessed on transactions of Market-Makers (including DPMs and LMMs), resulting from customer orders at the per contract rate provided above on all classes of equity options, options on ETFs, options on ETNs and index options, except that the marketing fee shall not apply to Sector Indexes, DJX, MXEA, MXEF or Underlying Symbol List A. The Exchange notes that, in this way, MRUT will be treated as most of the Exchange's other exclusively listed products that are currently excluded from the Marketing Fee Program. The Exchange does believe that it is necessary at the point of newly listing

and trading for MRUT options to be eligible for the Marketing Fee Program and may determine in the future to submit a fee filing to add MRUT to the Marketing Fee Program if the Exchange believes it would potentially generate more customer order flow in MRUT.

MRUT LMM Program

Finally, the Exchange proposes to adopt a financial program for LMMs appointed in MRUT options. As proposed, the MRUT LMM Incentive Program provides that if the appointed LMM in MRUT provides continuous electronic quotes during Regular Trading Hours that meet or exceed the proposed heightened quoting standards (below) in at least 99% of the series 90% of the time in a given month, the LMM will receive a payment for that month in the amount of \$20,000 (or pro-rated amount if an appointment begins after the first trading day of the month or ends prior to the last trading day of the month).

Premium level	Expiring		Near term		Mid term		Long term	
	14 days or less		15 days to 60 days		61 days to 270 days		271 days or greater	
	Width	Size	Width	Size	Width	Size	Width	Size
\$0.00–\$1.00	\$0.08	1	\$0.10	1	\$0.15	1	\$0.80	1
\$1.01–\$3.00	0.15	1	0.15	1	0.15	1	0.85	1
\$3.01–\$5.00	0.15	1	0.18	1	0.20	1	1.00	1
\$5.01–\$10.00	0.45	1	0.20	1	0.35	1	1.25	1
\$10.01–\$25.00	1.25	1	0.55	1	0.50	1	2.25	1
\$25.01–\$100.00	3.00	1	2.00	1	1.75	1	4.00	1
Greater than \$100.00	8.00	1	8.00	1	8.00	1	8.00	1

Meeting or exceeding the heightened quoting standards in MRUT, as proposed, to receive the proposed compensation payment is optional for an MRUT LMM. The Exchange may consider other exceptions to this quoting standard based on demonstrated legal or regulatory requirements or other mitigating circumstances. In calculating whether an LMM met the heightened quoting standard each month, the Exchange will exclude from the calculation in that month the business day in which the LMM missed meeting or exceeding the heightened quoting standard in the highest number of series. In addition to the above rebate, if the appointed LMM meets or exceeds the above heightened quoting standards in a given month and provides an average daily volume ("ADV") in MRUT that meets or exceeds 25,000 contracts in a given month, the LMM will receive the Monthly ADV Payment amount that corresponds to the level of ADV in

MRUT provided for that month per the MRUT Volume Incentive Pool program below:

MRUT ADV	Monthly ADV payment
0–24,999 contracts	\$0.00
25,000–49,999 contracts	25,000
50,000–100,000 contracts	35,000
Greater than 100,000 contracts	50,000

The heightened requirements and MRUT Volume Incentive Pool offered by the MRUT LMM Incentive Program are designed to incentivize LMMs to provide significant liquidity in MRUT options during the trading day upon their listing and trading on the Exchange, which, in turn, would provide greater trading opportunities, added market transparency and enhanced price discovery for all market participants in MRUT.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,¹³ in general, and furthers the objectives of Section 6(b)(4),¹⁴ in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with the objectives of Section 6(b)(5)¹⁵ 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

¹² See *supra* note 8.

¹³ 15 U.S.C. 78f.

¹⁴ 15 U.S.C. 78f(b)(4).

¹⁵ 15 U.S.C. 78f(b)(5).

open market and a national market system, and, in general, to protect investors and the public interest, and, particularly, is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Standard Transaction Rates and Surcharges

The Exchange believes that the proposed amendments to the Fees Schedule in connection with standard transaction rates and surcharges for MRUT transactions are reasonable, equitable and not unfairly discriminatory. Specifically, the Exchange believes that it is reasonable to assess fees for Customer, Market-Maker, Firm, and Non-Customer orders in MRUT that reflect approximately 1/10th of the transactions fees assessed for corresponding orders in RUT because of the relation between MRUT options and RUT options, wherein MRUT options overlie an index 1/10th the value of the index that underlies RUT options. Additionally, the Exchange believes it is reasonable to waive the transaction fees for Market-Maker and Firm orders in MRUT options through August 31, 2021 because the waiver is designed to encourage order flow from these market participants in a newly listed and traded options class on the Exchange. The Exchange recognizes that Market-Makers and Firms each provide important and distinct sources of liquidity to the Exchange and increased liquidity provides more trading opportunities, in turn, signaling additional corresponding increase in order flow from other market participants, and, as a result, contributing towards a robust, well-balanced market ecosystem. The Exchange also believes that it is reasonable to assess a lower Index License fee on transactions in MRUT because MRUT is a new product and the Exchange wishes to promote and encourage trading of MRUT once listed. The Exchange notes that, similar to assessing a lower Index License fee, the Index License fees for certain options in other classes are waived in order to continue to promote their trading and growth.¹⁶ Moreover, the Exchange believes it is reasonable to assess the same FLEX and Exotic surcharge rates to orders in MRUT as it does for XSP and to exclude MRUT from the Complex Surcharge and AIM Contra Fee (and to apply the standard transaction fees for MRUT orders in lieu of the AIM Contra Fee) because these proposed surcharges and surcharge exclusions will provide consistency between the fees assessed

for orders in MRUT and XSP, which are both mini-index options designed to offer investors lower cost options to obtain the potential benefits of options on a broad-based index options and intended for the same investor-base. Therefore, the Exchange believes it is appropriate to amend the Fees Schedule in a manner that similarly situates fees assessed for orders in MRUT options with those assessed for orders in XSP options.

The Exchange believes the proposed standard transaction rates and surcharges (or exclusions) are equitable and not unfairly discriminatory because they will apply automatically and uniformly to all Customer, Firm, Market-Maker and/or Non-Customer, orders, as applicable, in MRUT options. The Exchange also believes that it is equitable and not unfairly discriminatory to waive the transaction fees (through August 31, 2021) for Market-Maker and Firm orders in MRUT because, as stated above, the Exchange recognizes that these market participants can provide key and distinct sources of liquidity, which is particularly important for a newly listed and traded options class on the Exchange. An increase in general market-making activity facilitates tighter spreads, which tend to signal additional corresponding increase in order flow from other market participants, ultimately incentivizing more overall order flow and improving liquidity levels and price transparency on the Exchange to the benefit of all market participants. Similarly, the Exchange also recognizes that Firms can be an important source of liquidity when they facilitate their own customers' trading activity, thus, adding transparency and promoting price discovery to the benefit of all market participants. The Exchange notes too that Market-Makers and Firms take on a number of obligations that other market participants do not have. For example, unlike other market participants, Market-Makers take on quoting obligations and other market making requirements and Firms must have higher capital requirements, clear trades for other market participants, and must be members of OCC.

Fees Programs

The Exchange believes that the proposed updates to the Fees Schedule in connection with the application of certain fees programs to transactions in MRUT options are reasonable, equitable and not unfairly discriminatory. Particularly, the Exchange believes it is reasonable to exclude transactions in MRUT options from the Liquidity Provider Sliding Scale, the VIP, the

Break-Up Credits table, the Clearing TPH Fee cap, and the ORS/CORS programs in the same manner in which transactions in XSP options are currently excluded from the same programs today as the Exchange believes it is appropriate to update these fees programs in a manner that similarly situates transactions in MRUT with transactions in XSP, as both mini-index options are designed to offer investors lower cost options to obtain the potential benefits of options on a broad-based index options and are intended for the same investor base. Additionally, the Exchange believes that excluding MRUT from the Marketing Fee Program is reasonable most of the Exchange's other proprietary products are currently excluded from the Marketing Fee Program. The Exchange does believe that it is necessary at the point of newly listing and trading for MRUT transactions to be eligible for the Marketing Fee Program and may determine in the future to submit a fee filing to add MRUT to the Marketing Fee Program if the Exchange believes it would potentially generate more customer order flow in MRUT options.

The Exchange believes that excluding MRUT transactions from certain fees programs is equitable and not unfairly discriminatory because the programs will equally not apply to, or exclude in the same manner, all market participants' orders in MRUT options. The Exchange notes that the proposed rule change does not alter any of the existing program rates or volume calculations, but instead, merely proposes not to include transactions in MRUT in those programs and volume calculations in the same way that transactions in XSP options are not currently included, or, regarding the Marketing Fee Program, in the same way transactions in most of the Exchange's other exclusively listed products are not currently included.

MRUT LMM Program

The Exchange believes the proposed MRUT LMM Incentive Program is reasonable, equitable and not unfairly discriminatory. Particularly, the proposed MRUT LMM Incentive Program is a reasonable financial incentive program because the proposed heightened quoting standards and rebate amount for meeting the heightened quoting standards in MRUT series are reasonably designed to incentivize an appointed LMM to meet the proposed heightened quoting standards during RTH for MRUT, thereby providing liquid and active markets, which facilitates tighter spreads, increased trading opportunities, and overall

¹⁶ See *supra* note 5.

enhanced market quality to the benefit of all market participants, particularly in a newly listed and traded product on the Exchange during the trading day. The Exchange believes that the proposed heightened quoting standards are reasonable because they are similar to the detail and format (specific expiration categories and corresponding premiums, quote widths, and sizes) of the heightened quoting standards currently in place for MSCI LMMs, SPESG LMMs, GTH SPX/SPXW LMMs and GTH VIX LMMs.¹⁷ For example, the expiration categories are the same as those for the GTH VIX LMM heightened quoting standards. The Exchange believes the proposed smaller quote widths and sizes in the proposed heightened quoting standards for MRUT LMMs reasonably reflect what the Exchange believes will be typical market characteristics in MRUT options, given their smaller notional value and minimum increments and general retail base, thus smaller, retail-sized orders. Moreover, the Exchange believes that the proposed \$20,000 monthly rebate for an LMM that meets the proposed heightened quoting standards in MRUT in a month is reasonable and equitable as it equal or comparable to the rebates offered for other LMM incentive programs for other proprietary products.¹⁸ For example, the MSCI LMM Incentive Program also offers \$20,000 per month for each MSCI series in which the appointed LMM meets the given heighten quoting standards. The Exchange also believes it is reasonable to offer an additional payment that corresponds to an MRUT LMM's level of ADV in MRUT options, if it meets the heightened quoting standards, because the proposed MRUT Volume Incentive Pool is a volume-based incentive designed to further encourage LMMs to provide significant liquidity in MRUT options during the trading day, which is particularly important for a newly listed and traded options class on the Exchange. The Exchange also offers many other volume-based incentives in the Fees Schedule.¹⁹

Finally, the Exchange believes it is equitable and not unfairly discriminatory to offer the financial

incentive to MRUT LMMs pursuant to the proposed MRUT LMM Incentive Program, because it will benefit all market participants trading MRUT during RTH by encouraging the LMMs to satisfy the heightened quoting standard, which incentivizes continuous increased liquidity and thereby may provide more trading opportunities and tighter spreads. Indeed, the Exchange notes that its LMMs serve a crucial role in providing quotes and the opportunity for market participants to trade MRUT, which can lead to increased volume, providing for robust markets. The Exchange ultimately wishes to sufficiently incentivize LMMs to provide liquid and active markets in the newly listed and traded MRUT options during the trading day to encourage liquidity, thereby protecting investors and the public interest. The Exchange also notes that an LMM may have added costs each month that it needs to undertake in order to satisfy that heightened quoting standard (e.g., having to purchase additional logical connectivity). The Exchange believes the proposed program is equitable and not unfairly discriminatory because similar programs currently exist for LMMs in other proprietary products,²⁰ and the proposed program will equally apply to any TPH that is appointed as a MRUT LMM. Additionally, if an LMM does not satisfy the heightened quoting standard in MRUT for any given month, then it simply will not receive the offered payment for that month.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes the proposed amendments to its Fee Schedule will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that 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 proposed MRUT transactions fee and surcharge amounts for each separate type of market participant will be assessed automatically and uniformly to all such market participants, i.e., all qualifying Customer orders in MRUT will be assessed the same amount, all Market-Maker orders in MRUT will be assessed the same amount, and so on. Likewise, the proposed rule change will uniformly exclude all transactions in MRUT from certain programs and fees/surcharges (i.e., the AIM Contra Fee and Complex

Surcharge), as it currently does for XSP options or as it does for the Exchange's other proprietary products. The Exchange does not believe that waiving the MRUT transaction fees for Market-Makers and Firms in the first six months of MRUT options listing and trading on the Exchange will impose any burden on intramarket competition because these participants may, as discussed above, provide key and distinct sources of liquidity, which is particularly important for a newly listed and traded options class on the Exchange. Also, Market-Makers and Firms take on a number of obligations that other market participants do not have. Unlike other market participants, Market-Makers take on quoting obligations and other market making requirements and Firms must have higher capital requirements, clear trades for other market participants, and must be members of OCC. The Exchange also does not believe that the proposed LMM incentive program for MRUT options would impose any burden on intramarket competition because it applies to all LMMs appointed to MRUT in a uniform manner, in the same way similar programs apply to LMMs in other proprietary products today. To the extent these LMMs receive a benefit that other market participants do not, as stated, LMMs have different obligations and are held to different standards. For example, LMMs play a crucial role in providing active and liquid markets in their appointed products, especially in the newly developing MRUT market, thereby providing a robust market which benefits all market participants. Such Market-Makers also have obligations and regulatory requirements that other participants do not have.

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 purposes of the Act because the propose fees assessed and rebates offered apply to a product exclusively listed on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)

¹⁷ See Cboe Options Fees Schedule, "MSCI LMM Incentive Program", "GTH VIX/VIXW LMM Incentive Program", "GTH SPX/SPXW LMM Incentive Program", and "RTH SPESG LMM Incentive Program".

¹⁸ See *id.*

¹⁹ See e.g., Cboe Options Fees Schedule, Volume Incentive Program table, Liquidity Provider Sliding Scale table, Cboe Options Clearing Trading Permit Holder Proprietary Products Sliding Scale table, and Floor Broker ADV Discount table, each of which offers reduced transaction fees for meeting various levels of options volume.

²⁰ See *supra* note 17.

of the Act²¹ and paragraph (f) of Rule 19b-4²² 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 will 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-CBOE-2021-015 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-2021-015. 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-CBOE-2021-015 and should be submitted on or before April 6, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²³

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-05348 Filed 3-15-21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91291; File No. SR-DTC-2021-002]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing of a Proposed Rule Change To Revise the Clearing Agency Investment Policy

March 10, 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 March 8, 2021, The Depository Trust Company ("DTC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change would revise the Clearing Agency Investment Policy ("Investment Policy") of The Depository Trust Company ("DTC") and its affiliates, National Securities Clearing Corporation ("NSCC") and Fixed Income Clearing Corporation ("FICC," and together with DTC and NSCC, the "Clearing Agencies") in order to (1) enhance the methodology for determining investment limits for investments in bank deposits, and (2) clarify the description of certain

investable funds of the Government Securities Division of FICC ("GSD"), as described in greater detail below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Clearing Agencies are proposing to revise the Investment Policy, which was adopted for each clearing agency in December 2016³ and is maintained in compliance with Rule 17Ad-22(e)(16) under the Act,⁴ in order to (1) enhance the methodology for determining investment limits for investments in bank deposits, and (2) clarify the description of certain investable funds of GSD, as described in greater detail below.

Overview of the Investment Policy

The Investment Policy governs the management, custody and investment of cash deposited to the respective NSCC and FICC Clearing Funds, and the DTC Participants Fund,⁵ the proprietary liquid net assets (cash and cash equivalents) of the Clearing Agencies, and other funds held by the Clearing Agencies pursuant to their respective rules.

³ See Securities Exchange Act Release No. 79528 (December 12, 2016), 81 FR 91232 (December 16, 2016) (SR-DTC-2016-007, SR-FICC-2016-005, SR-NSCC-2016-003).

⁴ 17 CFR 240.17Ad-22(e)(16). As discussed in this filing, the Investment Policy also addresses compliance with the requirements of Rule 17Ad-22(e)(3). 17 CFR 240.17Ad-22(e)(3).

⁵ The respective Clearing Funds of NSCC and FICC, and the DTC Participants Fund are described further in the Rules & Procedures of NSCC ("NSCC Rules"), the DTC Rules, By-laws and Organization Certificate ("DTC Rules"), the Clearing Rules of the Mortgage-Backed Securities Division of FICC ("MBSD Rules") or the Rulebook of the Government Securities Division of FICC ("GSD Rules"), respectively, available at <http://dtcc.com/legal/rules-and-procedures>. See Rule 4 (Clearing Fund) of the NSCC Rules, Rule 4 (Participants Fund and Participants Investment) of the DTC Rules, Rule 4 (Clearing Fund and Loss Allocation) of the GSD Rules and Rule 4 (Clearing Fund and Loss Allocation) of the MBSD Rules.

²¹ 15 U.S.C. 78s(b)(3)(A).

²² 17 CFR 240.19b-4(f).

²³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

The Investment Policy identifies the guiding principles for investments and defines the roles and responsibilities of DTCC staff in administering the Investment Policy pursuant to those principles. The Investment Policy is co-owned by DTCC's Treasury group ("Treasury")⁶ and the Counterparty Credit Risk team ("CCR") within DTCC's Group Chief Risk Office ("GCRO").⁷ Treasury is responsible for identifying potential counterparties to investment transactions, establishing and managing investment relationships with approved investment counterparties, and making and monitoring all investment transactions with respect to the Clearing Agencies. CCR is responsible for conducting a credit review of any potential counterparty, updating those reviews on a quarterly basis, and establishing an investment limit for each counterparty. CCR is also responsible for ongoing monitoring of counterparties and recommending changes to investment limits when appropriate.

The Investment Policy also identifies sources of funds that may be invested, and the permitted investments of those funds, including the authority required to make such investments and the parameters of, and limitations on, each type of investment. Allowable investments include bank deposits, reverse repurchase agreements, direct obligations of the U.S. government, money market mutual funds, high-grade corporate debt, and hedge transactions. Finally, the Investment Policy defines the approval authority required to exceed established investment limits.

The Investment Policy is reviewed and approved by the Boards annually. In connection with a recent annual review of the Investment Policy, the Clearing Agencies have decided to propose revisions to the Investment Policy in order to (1) enhance the methodology for determining investment limits for investments in bank deposits, and (2) clarify the description of certain investable funds of GSD, as described in greater detail below.

Proposed Enhancement to the Formula for Setting Bank Deposit Investment Limits

Section 6.2.1 of the Investment Policy sets forth the investment limits applicable to bank deposit investments. Currently, bank deposit investment limits are determined based on the bank counterparty's external credit rating. For example, investments in a bank deposits with a bank counterparty with an external credit rating of AAA or Aaa are limited to no more than \$750 million, and an investment with a bank counterparty with an external credit rating of BBB+ or Baa1 are limited to no more than \$100 million.

The Clearing Agencies are proposing to enhance the methodology for setting investment limits and investment caps on bank deposits with a particular counterparty by including a consideration of the size of the bank counterparty, measured as the total shareholders' equity capital, in this calculation. Under the proposed methodology, an investment limit for a bank deposit counterparty would continue to be based on the counterparty's credit rating, but would be the lower of (1) a percentage of its total shareholders' equity capital, and (2) the applicable dollar value that is currently in Section 6.2.1 of the Investment Policy. For example, investments in a bank deposits with a bank counterparty with an external credit rating of AAA or Aaa and total shareholders' equity capital of \$9 billion would be limited to no more than \$750 million, however, investments with a bank counterparty with the same external credit rating and total shareholders' equity capital of \$2 billion would be limited to no more than \$300 million.

The proposed approach would permit the Clearing Agencies to take into account the size of a counterparty in setting investment limits rather than apply the same investment limits to each counterparty with the same credit rating without regard to the entity's size. The proposal is designed to mitigate the Clearing Agencies' risk exposure to smaller bank counterparties.

Proposed Revisions to the Description of Investable Funds of GSD

The Clearing Agencies are also proposing to amend Section 5 of the Investment Policy to revise the description of investable funds of GSD, which are currently described as "GSD Forward Margin." The proposed changes would refer to these funds as "GSD Forward Mark Adjustment Payment," which is the term used in the

GSD Rules to refer to these funds.⁸ The proposed change to clarify the term used to describe these funds would prevent any confusion about which funds are included in Section 5 and invested pursuant to the Policy.

2. Statutory Basis

The Clearing Agencies believe that the proposed rule changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, the Clearing Agencies believe that the proposed modifications to the Investment Policy are consistent with Section 17A(b)(3)(F) of the Act⁹ and Rule 17Ad-22(e)(16) under the Act,¹⁰ for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of each of the Clearing Agencies be designed to assure the safeguarding of securities and funds that are in the custody or control of each of the Clearing Agencies or for which they are responsible.¹¹ The investment guidelines and governance procedures set forth in the Investment Policy are designed to safeguard funds that are in the custody or control of the Clearing Agencies or for which they are responsible. Such protections include, for example, following a prudent and conservative investment philosophy that places the highest priority on maximizing liquidity and risk avoidance. The Clearing Agencies believe the proposed change to consider the size of a bank counterparty in setting its bank deposit investment limits would allow it to adhere to these guidelines by minimizing the risk posed by smaller counterparties, measured by their shareholders' equity capital. Therefore, the Clearing Agencies believe the proposed change would allow the Clearing Agencies to continue to operate the Investment Policy pursuant to a prudent and conservative investment philosophy that assures the safeguarding of securities and funds that are in their custody and control, or for which they are responsible.

Additionally, the proposed change to align the description of investable funds of GSD with the description of these funds in the GSD Rules would clarify the funds that are subject to the Policy and, thereby, improve the effectiveness of the Investment Policy and allow the Investment Policy to continue to be administered in alignment with the

⁶ Treasury is a part of the DTCC Finance Department and is responsible for the safeguarding, investment and disbursement of funds on behalf of the Clearing Agencies and in accordance with the principles outlined in the Investment Policy.

⁷ Among other responsibilities, GCRO is generally responsible for the systems and processes designed to identify and manage credit, market and liquidity risks to the Clearing Agencies.

⁸ See Rule 1 (Definitions) of the GSD Rules. *Supra* note 5.

⁹ 15 U.S.C. 78q-1(b)(3)(F).

¹⁰ 17 CFR 240.17Ad-22(e)(16).

¹¹ 15 U.S.C. 78q-1(b)(3)(F).

investment guidelines and governance procedures set forth therein. Given that such guidelines and governance procedures are designed to safeguard funds that are in the custody or control of the Clearing Agencies or for which they are responsible, the Clearing Agencies believe the proposed changes are consistent with the requirements of Section 17A(b)(3)(F) of the Act.¹²

Rule 17Ad-22(e)(16) under the Act requires the Clearing Agencies to establish, implement, maintain and enforce written policies and procedures reasonably designed to safeguard the Clearing Agencies' own and their participants' assets, minimize the risk of loss and delay in access to these assets, and invest such assets in instruments with minimal credit, market, and liquidity risks.¹³ The Clearing Agencies believe that the Investment Policy follows a prudent and conservative investment philosophy, placing the highest priority on maximizing liquidity and avoiding risk of loss, by setting appropriate investment limits and creating clear guidelines. As originally implemented, the Investment Policy was designed to meet the requirements of Rule 17Ad-22(e)(16) under the Act.¹⁴

For the reasons stated above, the Clearing Agencies believe that the proposed revisions would both strengthen the risk management objectives of the Investment Policy and improve the clarity of the Policy and, therefore, make the Investment Policy more effective in governing the management, custody, and investment of funds of and held by the Clearing Agencies. In this way, the proposed changes would better allow the Clearing Agencies to maintain this document in a way that is designed to meet the requirements of Rule 17Ad-22(e)(16). Therefore, the Clearing Agencies believe the proposed revisions would be consistent with the requirements of Rule 17Ad-22(e)(16) under the Act.¹⁵

(B) Clearing Agency's Statement on Burden on Competition

Each of the Clearing Agencies believes that none of the proposed revisions to the Investment Policy would have any

impact, or impose any burden, on competition. The Investment Policy applies equally to allowable investments of Clearing Fund and Participants Fund deposits, as applicable, of each member of the Clearing Agencies, and establishes a uniform policy at the Clearing Agencies. The proposed changes to the Investment Policy would not affect any changes on the fundamental purpose or operation of this document and, as such, would also not have any impact, or impose any burden, on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Clearing Agencies have not solicited or received any written comments relating to this proposal. The Clearing Agencies will notify the Commission of any written comments received by the Clearing Agencies.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove such proposed rule change, or
- (B) institute proceedings to determine whether the proposed rule change should be 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-DTC-2021-002 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549. All submissions should refer to File Number SR-DTC-2021-002. 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 DTC and on DTCC's website (<http://dtcc.com/legal/sec-rule-filings.aspx>). 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-DTC-2021-002 and should be submitted on or before April 6, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁶

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-05344 Filed 3-15-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270-574, OMB Control No. 3235-0648]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Extension:
Rule 498

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) ("Paperwork

¹² *Id.*

¹³ When the Investment Policy was implemented, the Clearing Agencies were subject to the requirements of subsection (d) of Rule 17Ad-22 and the Investment Policy was designed to meet the requirements of Rule 17Ad-22(d)(3). See *supra* note 3; 17 CFR 240.17Ad-22(d). The Commission subsequently adopted Rule 17Ad-22(e) and amended Rule 17Ad-22(d) such that the Clearing Agencies became subject to the new requirements of Rule 17Ad-22(e) and are no longer subject to the requirements of Rule 17Ad-22(d). *Id.*

¹⁴ 17 CFR 240.17Ad-22(e)(16).

¹⁵ *Id.*

¹⁶ 17 CFR 200.30-3(a)(12).

Reduction Act”), the Securities and Exchange Commission (“the Commission”) has submitted to the Office of Management and Budget (“OMB”) a request for extension of the previously approved collection of information discussed below.

Rule 498 (17 CFR 230.498) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) (“Securities Act”) permits open-end management investment companies (“funds”) to satisfy their prospectus delivery obligations under the Securities Act by sending or giving key information directly to investors in the form of a summary prospectus (“Summary Prospectus”) and providing the statutory prospectus on a website. Upon an investor’s request, funds are also required to send the statutory prospectus to the investor. In addition, under rule 498, a fund that relies on the rule to meet its statutory prospectus delivery obligations must make available, free of charge, the fund’s current Summary Prospectus, statutory prospectus, statement of additional information, and most recent annual and semi-annual reports to shareholders at the website address specified in the required Summary Prospectus legend (17 CFR 270.498(e)(1)). A Summary Prospectus that complies with rule 498 is deemed to be a prospectus that is authorized under Section 10(b) of the Securities Act and Section 24(g) of the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*).

The purpose of rule 498 is to enable a fund to provide investors with a Summary Prospectus containing key information necessary to evaluate an investment in the fund. Unlike many other federal information collections, which are primarily for the use and benefit of the collecting agency, this information collection is primarily for the use and benefit of investors. The information filed with the Commission also permits the verification of compliance with securities law requirements and assures the public availability and dissemination of the information.

Based on an analysis of fund filings, the Commission estimates that approximately 10,536 funds are using a Summary Prospectus. The Commission estimates that the annual hourly burden per fund associated with the compilation of the information required on the cover page or the beginning of the Summary Prospectus is 0.5 hours, and estimates that the annual hourly burden per fund to comply with the website posting requirement is approximately 1 hour, requiring a total

of 1.5 hours per fund per year.¹ Thus the total annual hour burden associated with these requirements of the rule is approximately 15,804.² The Commission estimates that the annual cost burden is approximately \$18,105 per fund, for a total annual cost burden of approximately \$190,754,280.³

Estimates of the average burden hours are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms. Under rule 498, use of the Summary Prospectus is voluntary, but the rule’s requirements regarding provision of the statutory prospectus upon investor request are mandatory for funds that elect to send or give a Summary Prospectus in reliance upon rule 498. The information provided under rule 498 will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: www.reginfo.gov. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) www.reginfo.gov/public/do/PRAMain and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or by sending an email to: PRA_Mailbox@sec.gov.

Dated: March 11, 2021.

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021–05376 Filed 3–15–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91292; File No. SR–FICC–2021–001]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of a Proposed Rule Change To Revise the Clearing Agency Investment Policy

March 10, 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 March 8, 2021, Fixed Income Clearing Corporation (“FICC”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency’s Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change would revise the Clearing Agency Investment Policy (“Investment Policy”) of Fixed Income Clearing Corporation (“FICC”) and its affiliates, The Depository Trust Company (“DTC”) and National Securities Clearing Corporation (“NSCC,” and, together with DTC and FICC, the “Clearing Agencies”) in order to (1) enhance the methodology for determining investment limits for investments in bank deposits, and (2) clarify the description of certain investable funds of the Government Securities Division of FICC (“GSD”), as described in greater detail below.

II. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

¹ 0.5 hours per fund + 1 hour per fund = 1.5 hours per fund.

² 1.5 hours per fund × 10,536 fund = 15,804 hours.

³ \$18,105 per fund × 10,536 fund = \$190,754,280.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Clearing Agencies are proposing to revise the Investment Policy, which was adopted for each clearing agency in December 2016³ and is maintained in compliance with Rule 17Ad-22(e)(16) under the Act,⁴ in order to (1) enhance the methodology for determining investment limits for investments in bank deposits, and (2) clarify the description of certain investable funds of GSD, as described in greater detail below.

Overview of the Investment Policy

The Investment Policy governs the management, custody and investment of cash deposited to the respective NSCC and FICC Clearing Funds, and the DTC Participants Fund,⁵ the proprietary liquid net assets (cash and cash equivalents) of the Clearing Agencies, and other funds held by the Clearing Agencies pursuant to their respective rules.

The Investment Policy identifies the guiding principles for investments and defines the roles and responsibilities of DTCC staff in administering the Investment Policy pursuant to those principles. The Investment Policy is co-owned by DTCC's Treasury group ("Treasury")⁶ and the Counterparty Credit Risk team ("CCR") within DTCC's Group Chief Risk Office ("GCRO").⁷ Treasury is responsible for identifying potential counterparties to investment transactions, establishing

and managing investment relationships with approved investment counterparties, and making and monitoring all investment transactions with respect to the Clearing Agencies. CCR is responsible for conducting a credit review of any potential counterparty, updating those reviews on a quarterly basis, and establishing an investment limit for each counterparty. CCR is also responsible for ongoing monitoring of counterparties and recommending changes to investment limits when appropriate.

The Investment Policy also identifies sources of funds that may be invested, and the permitted investments of those funds, including the authority required to make such investments and the parameters of, and limitations on, each type of investment. Allowable investments include bank deposits, reverse repurchase agreements, direct obligations of the U.S. government, money market mutual funds, high-grade corporate debt, and hedge transactions. Finally, the Investment Policy defines the approval authority required to exceed established investment limits.

The Investment Policy is reviewed and approved by the Boards annually. In connection with a recent annual review of the Investment Policy, the Clearing Agencies have decided to propose revisions to the Investment Policy in order to (1) enhance the methodology for determining investment limits for investments in bank deposits, and (2) clarify the description of certain investable funds of GSD, as described in greater detail below.

Proposed Enhancement to the Formula for Setting Bank Deposit Investment Limits

Section 6.2.1 of the Investment Policy sets forth the investment limits applicable to bank deposit investments. Currently, bank deposit investment limits are determined based on the bank counterparty's external credit rating. For example, investments in a bank deposits with a bank counterparty with an external credit rating of AAA or Aaa are limited to no more than \$750 million, and an investment with a bank counterparty with an external credit rating of BBB+ or Baa1 are limited to no more than \$100 million.

The Clearing Agencies are proposing to enhance the methodology for setting investment limits and investment caps on bank deposits with a particular counterparty by including a consideration of the size of the bank counterparty, measured as the total shareholders' equity capital, in this calculation. Under the proposed

methodology, an investment limit for a bank deposit counterparty would continue to be based on the counterparty's credit rating, but would be the lower of (1) a percentage of its total shareholders' equity capital, and (2) the applicable dollar value that is currently in Section 6.2.1 of the Investment Policy. For example, investments in a bank deposits with a bank counterparty with an external credit rating of AAA or Aaa and total shareholders' equity capital of \$9 billion would be limited to no more than \$750 million, however, investments with a bank counterparty with the same external credit rating and total shareholders' equity capital of \$2 billion would be limited to no more than \$300 million.

The proposed approach would permit the Clearing Agencies to take into account the size of a counterparty in setting investment limits rather than apply the same investment limits to each counterparty with the same credit rating without regard to the entity's size. The proposal is designed to mitigate the Clearing Agencies' risk exposure to smaller bank counterparties.

Proposed Revisions to the Description of Investable Funds of GSD

The Clearing Agencies are also proposing to amend Section 5 of the Investment Policy to revise the description of investable funds of GSD, which are currently described as "GSD Forward Margin." The proposed changes would refer to these funds as "GSD Forward Mark Adjustment Payment," which is the term used in the GSD Rules to refer to these funds.⁸ The proposed change to clarify the term used to describe these funds would prevent any confusion about which funds are included in Section 5 and invested pursuant to the Policy.

2. Statutory Basis

The Clearing Agencies believe that the proposed rule changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, the Clearing Agencies believe that the proposed modifications to the Investment Policy are consistent with Section 17A(b)(3)(F) of the Act⁹ and Rule 17Ad-22(e)(16) under the Act,¹⁰ for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of each

³ See Securities Exchange Act Release No. 79528 (December 12, 2016), 81 FR 91232 (December 16, 2016) (SR-DTC-2016-007, SR-FICC-2016-005, SR-NSCC-2016-003).

⁴ 17 CFR 240.17Ad-22(e)(16). As discussed in this filing, the Investment Policy also addresses compliance with the requirements of Rule 17Ad-22(e)(3). 17 CFR 240.17Ad-22(e)(3).

⁵ The respective Clearing Funds of NSCC and FICC, and the DTC Participants Fund are described further in the Rules & Procedures of NSCC ("NSCC Rules"), the DTC Rules, By-laws and Organization Certificate ("DTC Rules"), the Clearing Rules of the Mortgage-Backed Securities Division of FICC ("MBSD Rules") or the Rulebook of the Government Securities Division of FICC ("GSD Rules"), respectively, available at <http://dtcc.com/legal/rules-and-procedures>. See Rule 4 (Clearing Fund) of the NSCC Rules, Rule 4 (Participants Fund and Participants Investment) of the DTC Rules, Rule 4 (Clearing Fund and Loss Allocation) of the GSD Rules and Rule 4 (Clearing Fund and Loss Allocation) of the MBSD Rules.

⁶ Treasury is a part of the DTCC Finance Department and is responsible for the safeguarding, investment and disbursement of funds on behalf of the Clearing Agencies and in accordance with the principles outlined in the Investment Policy.

⁷ Among other responsibilities, GCRO is generally responsible for the systems and processes designed to identify and manage credit, market and liquidity risks to the Clearing Agencies.

⁸ See Rule 1 (Definitions) of the GSD Rules. *Supra* note 5.

⁹ 15 U.S.C. 78q-1(b)(3)(F).

¹⁰ 17 CFR 240.17Ad-22(e)(16).

of the Clearing Agencies be designed to assure the safeguarding of securities and funds that are in the custody or control of each of the Clearing Agencies or for which they are responsible.¹¹ The investment guidelines and governance procedures set forth in the Investment Policy are designed to safeguard funds that are in the custody or control of the Clearing Agencies or for which they are responsible. Such protections include, for example, following a prudent and conservative investment philosophy that places the highest priority on maximizing liquidity and risk avoidance. The Clearing Agencies believe the proposed change to consider the size of a bank counterparty in setting its bank deposit investment limits would allow it to adhere to these guidelines by minimizing the risk posed by smaller counterparties, measured by their shareholders' equity capital. Therefore, the Clearing Agencies believe the proposed change would allow the Clearing Agencies to continue to operate the Investment Policy pursuant to a prudent and conservative investment philosophy that assures the safeguarding of securities and funds that are in their custody and control, or for which they are responsible.

Additionally, the proposed change to align the description of investable funds of GSD with the description of these funds in the GSD Rules would clarify the funds that are subject to the Policy and, thereby, improve the effectiveness of the Investment Policy and allow the Investment Policy to continue to be administered in alignment with the investment guidelines and governance procedures set forth therein. Given that such guidelines and governance procedures are designed to safeguard funds that are in the custody or control of the Clearing Agencies or for which they are responsible, the Clearing Agencies believe the proposed changes are consistent with the requirements of Section 17A(b)(3)(F) of the Act.¹²

Rule 17Ad-22(e)(16) under the Act requires the Clearing Agencies to establish, implement, maintain and enforce written policies and procedures reasonably designed to safeguard the Clearing Agencies' own and their participants' assets, minimize the risk of loss and delay in access to these assets, and invest such assets in instruments with minimal credit, market, and liquidity risks.¹³ The Clearing Agencies

believe that the Investment Policy follows a prudent and conservative investment philosophy, placing the highest priority on maximizing liquidity and avoiding risk of loss, by setting appropriate investment limits and creating clear guidelines. As originally implemented, the Investment Policy was designed to meet the requirements of Rule 17Ad-22(e)(16) under the Act.¹⁴

For the reasons stated above, the Clearing Agencies believe that the proposed revisions would both strengthen the risk management objectives of the Investment Policy and improve the clarity of the Policy and, therefore, make the Investment Policy more effective in governing the management, custody, and investment of funds of and held by the Clearing Agencies. In this way, the proposed changes would better allow the Clearing Agencies to maintain this document in a way that is designed to meet the requirements of Rule 17Ad-22(e)(16). Therefore, the Clearing Agencies believe the proposed revisions would be consistent with the requirements of Rule 17Ad-22(e)(16) under the Act.¹⁵

(B) Clearing Agency's Statement on Burden on Competition

Each of the Clearing Agencies believes that none of the proposed revisions to the Investment Policy would have any impact, or impose any burden, on competition. The Investment Policy applies equally to allowable investments of Clearing Fund and Participants Fund deposits, as applicable, of each member of the Clearing Agencies, and establishes a uniform policy at the Clearing Agencies. The proposed changes to the Investment Policy would not affect any changes on the fundamental purpose or operation of this document and, as such, would also not have any impact, or impose any burden, on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Clearing Agencies have not solicited or received any written comments relating to this proposal. The Clearing Agencies will notify the Commission of any written comments received by the Clearing Agencies.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be 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-FICC-2021-001 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR-FICC-2021-001. 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

¹¹ 15 U.S.C. 78q-1(b)(3)(F).

¹² *Id.*

¹³ When the Investment Policy was implemented, the Clearing Agencies were subject to the requirements of subsection (d) of Rule 17Ad-22 and the Investment Policy was designed to meet the requirements of Rule 17Ad-22(d)(3). See *supra* note

3; 17 CFR 240.17Ad-22(d). The Commission subsequently adopted Rule 17Ad-22(e) and amended Rule 17Ad-22(d) such that the Clearing Agencies became subject to the new requirements of Rule 17Ad-22(e) and are no longer subject to the requirements of Rule 17Ad-22(d). *Id.*

¹⁴ 17 CFR 240.17Ad-22(e)(16).

¹⁵ *Id.*

inspection and copying at the principal office of FICC and on DTCC's website (<http://dtcc.com/legal/sec-rule-filings.aspx>). 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-FICC-2021-001 and should be submitted on or before April 6, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁶

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-05341 Filed 3-15-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91293; File No. SR-NSCC-2021-003]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing of a Proposed Rule Change To Revise the Clearing Agency Investment Policy

March 10, 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 March 8, 2021, National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change would revise the Clearing Agency Investment Policy ("Investment Policy") of National Securities Clearing Corporation ("NSCC") and its affiliates, The Depository Trust Company ("DTC") and Fixed Income Clearing Corporation ("FICC," and together with DTC and NSCC, the "Clearing Agencies") in order to (1) enhance the methodology for determining investment limits for investments in bank deposits, and (2)

clarify the description of certain investable funds of the Government Securities Division of FICC ("GSD"), as described in greater detail below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Clearing Agencies are proposing to revise the Investment Policy, which was adopted for each clearing agency in December 2016³ and is maintained in compliance with Rule 17Ad-22(e)(16) under the Act,⁴ in order to (1) enhance the methodology for determining investment limits for investments in bank deposits, and (2) clarify the description of certain investable funds of GSD, as described in greater detail below.

Overview of the Investment Policy

The Investment Policy governs the management, custody and investment of cash deposited to the respective NSCC and FICC Clearing Funds, and the DTC Participants Fund,⁵ the proprietary liquid net assets (cash and cash equivalents) of the Clearing Agencies, and other funds held by the Clearing

Agencies pursuant to their respective rules.

The Investment Policy identifies the guiding principles for investments and defines the roles and responsibilities of DTCC staff in administering the Investment Policy pursuant to those principles. The Investment Policy is co-owned by DTCC's Treasury group ("Treasury")⁶ and the Counterparty Credit Risk team ("CCR") within DTCC's Group Chief Risk Office ("GCRO").⁷ Treasury is responsible for identifying potential counterparties to investment transactions, establishing and managing investment relationships with approved investment counterparties, and making and monitoring all investment transactions with respect to the Clearing Agencies. CCR is responsible for conducting a credit review of any potential counterparty, updating those reviews on a quarterly basis, and establishing an investment limit for each counterparty. CCR is also responsible for ongoing monitoring of counterparties and recommending changes to investment limits when appropriate.

The Investment Policy also identifies sources of funds that may be invested, and the permitted investments of those funds, including the authority required to make such investments and the parameters of, and limitations on, each type of investment. Allowable investments include bank deposits, reverse repurchase agreements, direct obligations of the U.S. government, money market mutual funds, high-grade corporate debt, and hedge transactions. Finally, the Investment Policy defines the approval authority required to exceed established investment limits.

The Investment Policy is reviewed and approved by the Boards annually. In connection with a recent annual review of the Investment Policy, the Clearing Agencies have decided to propose revisions to the Investment Policy in order to (1) enhance the methodology for determining investment limits for investments in bank deposits, and (2) clarify the description of certain investable funds of GSD, as described in greater detail below.

⁶ Treasury is a part of the DTCC Finance Department and is responsible for the safeguarding, investment and disbursement of funds on behalf of the Clearing Agencies and in accordance with the principles outlined in the Investment Policy.

⁷ Among other responsibilities, GCRO is generally responsible for the systems and processes designed to identify and manage credit, market and liquidity risks to the Clearing Agencies.

³ See Securities Exchange Act Release No. 79528 (December 12, 2016), 81 FR 91232 (December 16, 2016) (SR-DTC-2016-007, SR-FICC-2016-005, SR-NSCC-2016-003).

⁴ 17 CFR 240.17Ad-22(e)(16). As discussed in this filing, the Investment Policy also addresses compliance with the requirements of Rule 17Ad-22(e)(3). 17 CFR 240.17Ad-22(e)(3).

⁵ The respective Clearing Funds of NSCC and FICC, and the DTC Participants Fund are described further in the Rules & Procedures of NSCC ("NSCC Rules"), the DTC Rules, By-laws and Organization Certificate ("DTC Rules"), the Clearing Rules of the Mortgage-Backed Securities Division of FICC ("MBSD Rules") or the Rulebook of the Government Securities Division of FICC ("GSD Rules"), respectively, available at <http://dtcc.com/legal/rules-and-procedures>. See Rule 4 (Clearing Fund) of the NSCC Rules, Rule 4 (Participants Fund and Participants Investment) of the DTC Rules, Rule 4 (Clearing Fund and Loss Allocation) of the GSD Rules and Rule 4 (Clearing Fund and Loss Allocation) of the MBSD Rules.

¹⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

Proposed Enhancement to the Formula for Setting Bank Deposit Investment Limits

Section 6.2.1 of the Investment Policy sets forth the investment limits applicable to bank deposit investments. Currently, bank deposit investment limits are determined based on the bank counterparty's external credit rating. For example, investments in a bank deposits with a bank counterparty with an external credit rating of AAA or Aaa are limited to no more than \$750 million, and an investment with a bank counterparty with an external credit rating of BBB+ or Baa1 are limited to no more than \$100 million.

The Clearing Agencies are proposing to enhance the methodology for setting investment limits and investment caps on bank deposits with a particular counterparty by including a consideration of the size of the bank counterparty, measured as the total shareholders' equity capital, in this calculation. Under the proposed methodology, an investment limit for a bank deposit counterparty would continue to be based on the counterparty's credit rating, but would be the lower of (1) a percentage of its total shareholders' equity capital, and (2) the applicable dollar value that is currently in Section 6.2.1 of the Investment Policy. For example, investments in a bank deposits with a bank counterparty with an external credit rating of AAA or Aaa and total shareholders' equity capital of \$9 billion would be limited to no more than \$750 million, however, investments with a bank counterparty with the same external credit rating and total shareholders' equity capital of \$2 billion would be limited to no more than \$300 million.

The proposed approach would permit the Clearing Agencies to take into account the size of a counterparty in setting investment limits rather than apply the same investment limits to each counterparty with the same credit rating without regard to the entity's size. The proposal is designed to mitigate the Clearing Agencies' risk exposure to smaller bank counterparties.

Proposed Revisions to the Description of Investable Funds of GSD

The Clearing Agencies are also proposing to amend Section 5 of the Investment Policy to revise the description of investable funds of GSD, which are currently described as "GSD Forward Margin." The proposed changes would refer to these funds as "GSD Forward Mark Adjustment Payment," which is the term used in the

GSD Rules to refer to these funds.⁸ The proposed change to clarify the term used to describe these funds would prevent any confusion about which funds are included in Section 5 and invested pursuant to the Policy.

2. Statutory Basis

The Clearing Agencies believe that the proposed rule changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, the Clearing Agencies believe that the proposed modifications to the Investment Policy are consistent with Section 17A(b)(3)(F) of the Act⁹ and Rule 17Ad-22(e)(16) under the Act,¹⁰ for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of each of the Clearing Agencies be designed to assure the safeguarding of securities and funds that are in the custody or control of each of the Clearing Agencies or for which they are responsible.¹¹ The investment guidelines and governance procedures set forth in the Investment Policy are designed to safeguard funds that are in the custody or control of the Clearing Agencies or for which they are responsible. Such protections include, for example, following a prudent and conservative investment philosophy that places the highest priority on maximizing liquidity and risk avoidance. The Clearing Agencies believe the proposed change to consider the size of a bank counterparty in setting its bank deposit investment limits would allow it to adhere to these guidelines by minimizing the risk posed by smaller counterparties, measured by their shareholders' equity capital. Therefore, the Clearing Agencies believe the proposed change would allow the Clearing Agencies to continue to operate the Investment Policy pursuant to a prudent and conservative investment philosophy that assures the safeguarding of securities and funds that are in their custody and control, or for which they are responsible.

Additionally, the proposed change to align the description of investable funds of GSD with the description of these funds in the GSD Rules would clarify the funds that are subject to the Policy and, thereby, improve the effectiveness of the Investment Policy and allow the Investment Policy to continue to be administered in alignment with the

investment guidelines and governance procedures set forth therein. Given that such guidelines and governance procedures are designed to safeguard funds that are in the custody or control of the Clearing Agencies or for which they are responsible, the Clearing Agencies believe the proposed changes are consistent with the requirements of Section 17A(b)(3)(F) of the Act.¹²

Rule 17Ad-22(e)(16) under the Act requires the Clearing Agencies to establish, implement, maintain and enforce written policies and procedures reasonably designed to safeguard the Clearing Agencies' own and their participants' assets, minimize the risk of loss and delay in access to these assets, and invest such assets in instruments with minimal credit, market, and liquidity risks.¹³ The Clearing Agencies believe that the Investment Policy follows a prudent and conservative investment philosophy, placing the highest priority on maximizing liquidity and avoiding risk of loss, by setting appropriate investment limits and creating clear guidelines. As originally implemented, the Investment Policy was designed to meet the requirements of Rule 17Ad-22(e)(16) under the Act.¹⁴

For the reasons stated above, the Clearing Agencies believe that the proposed revisions would both strengthen the risk management objectives of the Investment Policy and improve the clarity of the Policy and, therefore, make the Investment Policy more effective in governing the management, custody, and investment of funds of and held by the Clearing Agencies. In this way, the proposed changes would better allow the Clearing Agencies to maintain this document in a way that is designed to meet the requirements of Rule 17Ad-22(e)(16). Therefore, the Clearing Agencies believe the proposed revisions would be consistent with the requirements of Rule 17Ad-22(e)(16) under the Act.¹⁵

(B) Clearing Agency's Statement on Burden on Competition

Each of the Clearing Agencies believes that none of the proposed revisions to the Investment Policy would have any

¹² *Id.*

¹³ When the Investment Policy was implemented, the Clearing Agencies were subject to the requirements of subsection (d) of Rule 17Ad-22 and the Investment Policy was designed to meet the requirements of Rule 17Ad-22(d)(3). See *supra* note 3; 17 CFR 240.17Ad-22(d). The Commission subsequently adopted Rule 17Ad-22(e) and amended Rule 17Ad-22(d) such that the Clearing Agencies became subject to the new requirements of Rule 17Ad-22(e) and are no longer subject to the requirements of Rule 17Ad-22(d). *Id.*

¹⁴ 17 CFR 240.17Ad-22(e)(16).

¹⁵ *Id.*

⁸ See Rule 1 (Definitions) of the GSD Rules. *Supra* note 5.

⁹ 15 U.S.C. 78q-1(b)(3)(F).

¹⁰ 17 CFR 240.17Ad-22(e)(16).

¹¹ 15 U.S.C. 78q-1(b)(3)(F).

impact, or impose any burden, on competition. The Investment Policy applies equally to allowable investments of Clearing Fund and Participants Fund deposits, as applicable, of each member of the Clearing Agencies, and establishes a uniform policy at the Clearing Agencies. The proposed changes to the Investment Policy would not affect any changes on the fundamental purpose or operation of this document and, as such, would also not have any impact, or impose any burden, on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Clearing Agencies have not solicited or received any written comments relating to this proposal. The Clearing Agencies will notify the Commission of any written comments received by the Clearing Agencies.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove such proposed rule change, or
- (B) institute proceedings to determine whether the proposed rule change should be 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–NSCC–2021–003 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549. All submissions should refer to File Number SR–NSCC–2021–003. 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 NSCC and on DTCC's website (<http://dtcc.com/legal/sec-rule-filings.aspx>). 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–NSCC–2021–003 and should be submitted on or before April 6, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁶

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021–05347 Filed 3–15–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91294; File No. SR–NASDAQ–2020–062]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Proposed Rule Change, as Modified by Amendment, No. 1, To Amend Listing Rules Applicable to Special Purpose Acquisition Companies Whose Business Plan is To Complete One or More Business Combinations

March 10, 2021.

On September 3, 2020, The Nasdaq Stock Market LLC (“Nasdaq” or

“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 amend its listing rules to permit companies whose business plan is to complete one or more business combinations (“SPACs” or “Acquisition Companies”) 15 calendar days following the closing of a business combination to demonstrate that the SPAC has satisfied the applicable round lot shareholder requirement. The proposed rule change was published for comment in the **Federal Register** on September 22, 2020. ³ On November 4, 2020, pursuant to Section 19(b)(2) of the Exchange Act, ⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change. ⁵ On December 16, 2020, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act ⁶ to determine whether to approve or disapprove the proposed rule change. ⁷ On February 25, 2021, the Exchange filed Amendment No. 1 to the proposed rule change, which superseded the proposed rule change as originally filed, and is 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, as modified by Amendment No. 1, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend listing rules applicable to companies whose business plan is to complete one or more business combinations (the “Original Proposal”). The Exchange is filing this proposal (“Amendment No. 1”) to amend the Original Proposal. Amendment No. 1 supersedes the

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 89897 (September 16, 2020), 85 FR 59574. Comments received on the proposal are available on the Commission's website at: <https://www.sec.gov/comments/sr-nasdaq-2020-062/srnasdaq2020062.htm>.

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 90340, 85 FR 71704 (November 10, 2020). The Commission designated December 21, 2020, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ See Securities Exchange Act Release No. 90682, 85 FR 83113 (December 16, 2020).

¹⁶ 17 CFR 200.30–3(a)(12).

Original Proposal in its entirety to add an additional disclosure requirement.

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

Nasdaq is filing this amendment to SR-NASDAQ-2020-062, which was published for comment by the Commission on September 16, 2020.⁸ The original proposal would allow certain acquisition companies listed under IM-5101-2 with a 15-day period after closing a business combination to provide evidence that the combined company satisfied the round lot shareholder requirement for initial listing at the time of the business combination. This Amendment No. 1 would require a company relying on this 15-day period to file a Form 8-K, were required by SEC rules, or issue a press release noting that the company is relying upon the additional 15 calendar days available under Nasdaq rules to demonstrate compliance.

In 2009, Nasdaq adopted additional listing requirements for a company whose business plan is to complete an initial public offering and engage in a merger or acquisition with one or more unidentified companies within a specific period of time ("Acquisition Companies").⁹ Such a company is required to keep at least 90% of the proceeds from its initial public offering in an escrow account and, until the company has completed one or more business combinations having an aggregate fair market value of at least 80% of the value of the escrow account, must meet the requirements for initial listing following each business

combination.¹⁰ If a shareholder vote on the business combination is held, public shareholders voting against a business combination must have the right to convert their shares of common stock into a pro rata share of the aggregate amount then in the escrow account (net of taxes payable and amounts distributed to management for working capital purposes) if the business combination is approved and consummated.¹¹ If the combined company does not meet the initial listing requirements following a business combination, Nasdaq Staff will issue a Staff Delisting Determination under Nasdaq Rule 5810.

Under the existing rules, "following each business combination" with an Acquisition Company, the resulting company must satisfy all initial listing requirements. The rule does not provide a timetable for the company to demonstrate that it satisfies those requirements, however. Accordingly, Nasdaq proposes to modify the rule to specify if the Acquisition Company demonstrates that it will satisfy all requirements except the applicable round lot shareholder requirement, then the company will receive 15 calendar days following the closing to demonstrate that it satisfied the applicable round lot shareholder requirement immediately following the transaction's closing.

Ordinarily, in determining compliance with the round lot shareholder requirement at the time of a business combination, Nasdaq will review a company's public disclosures and information provided by the company about the transaction. For example, the merger agreement may result in the Acquisition Company issuing a round lot of shares to more than 300 holders of the target of the business combination at closing. If public information is not available that enables Nasdaq to determine compliance, Nasdaq will typically request that the company provide additional information such as registered shareholder lists from the company's transfer agent, data from Cede & Co. about shares held in street name, or data from broker-dealers and from third parties that distribute information such as proxy materials for

the broker-dealers.¹² If the company can provide information demonstrating compliance before the business combination closes, no further information would be required.

However, Nasdaq has observed that in some cases it can be difficult for a company to obtain evidence demonstrating the number of shareholders that it has or will have following a business combination. As noted above, shareholders of an Acquisition Company may redeem or tender their shares until just before the time of the business combination, and the company may not know how many shareholders will choose to redeem until very close to the consummation of the business combination. In cases where the number of round lot shareholders is close to the applicable requirement, this could affect the ability for Nasdaq to determine compliance before the business combination closes. Accordingly, for a company that has demonstrated that it will satisfy all initial listing requirements except for the round lot shareholder requirement before consummating the business combination, Nasdaq will allow the company 15 calendar days after the closing of the business combination, if necessary, to demonstrate that it also complied with the round lot requirement at the time of the business combination. To be clear, the company must still demonstrate that it satisfied the round lot shareholder requirement immediately following the business combination; the proposal is merely giving the company 15 calendar days to provide evidence that it did.

Providing Acquisition Companies with an additional 15 days to demonstrate compliance with the round lot rule as of the date of the business combination will result in the continuation of the listing of companies that have completed a business combination but not yet demonstrated that they satisfied all initial listing requirements. For this reason, the Exchange proposes that each Acquisition Company that has not demonstrated compliance with the applicable round lot shareholder requirement on the date of the business combination's closing will be required to issue a press release or file a Form 8-K, if required, prior to closing of the business combination, stating that the company is relying upon the additional 15 calendar days available under Nasdaq rules to demonstrate

¹⁰ See Nasdaq Rule IM-5101-2(d) and (e).

¹¹ See Nasdaq Rule IM-5101-2(d). If a shareholder vote on the business combination is not held, the company must provide all shareholders with the opportunity to redeem their shares for cash equal to their pro rata share of the aggregate amount then in the deposit account (net of taxes payable and amounts distributed to management for working capital purposes). Nasdaq Rule IM-5101-2(e).

¹² Companies must seek this information from third parties because many accounts are held in street name and shareholders may object to being identified to the company.

⁸ Securities Exchange Act Release No. 99897 (September 22, 2020), 85 FR 59574 (September 16, 2020).

⁹ Securities Exchange Act Release No. 58228 (July 25, 2008), 73 FR 44794 (July 31, 2008) (adopting the predecessor to IM-5101-2).

compliance. The company also will be required to note that in the event it is unable to demonstrate compliance, the company will be subject to delisting. In the event the Acquisition Company does not make the required public disclosure prior to the closing of the business combination, Nasdaq will halt trading in the company's securities until such time as the required announcement is made public.

Nasdaq believes that this proposal balances the burden placed on the Acquisition Company to obtain accurate shareholder information for the new entity and the need to ensure that a company that does not satisfy the initial listing requirements following a business combination enters the delisting process promptly. If the company does not evidence compliance within the proposed time period, Nasdaq staff would issue a delisting determination, which the company could appeal to an independent Hearings Panel as described in the 5800 Series of the Nasdaq Rules. Nasdaq also believes that the disclosure requirement will help provide transparency to investors about the status of the company during this time.

Finally, Nasdaq proposes a non-substantive change to eliminate a duplicate paragraph in paragraphs (d) and (e) of IM-5101-2 and to add a new paragraph designation.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,¹³ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁴ in particular, in that it is designed to promote just and equitable principles of trade, 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, by imposing a specific timeline for Acquisition Companies to demonstrate that they will comply with the initial listing requirements following a business combination and allowing a reasonable period of time for the company to provide evidence that it complied with the round lot shareholder requirement at the time of the business combination.

The proposed rule would specify the time when an Acquisition Company must demonstrate compliance with the initial listing standards following the completion of a business combination, thereby enhancing investor protection. Specifically, it would require an

Acquisition Company to provide evidence *before* completing the business combination that it will satisfy all requirements for initial listing, except for the round lot shareholder requirement. While the proposed rule would allow Acquisition Companies 15 calendar days, if needed, to provide evidence that they also complied with the round lot shareholder requirement at the time of the business combination, that additional time is a reasonable accommodation given both the difficulty companies face in identifying their shareholders and the ability for the Acquisition Company's shareholders to redeem their shares when the business combination is consummated. In that regard, Acquisition Companies are unlike other newly listing companies, which do not face redemptions and are not already listed and trading at the time they must demonstrate compliance. Importantly, the company must still demonstrate that it satisfied the round lot shareholder requirement immediately following the business combination. The proposed rule also requires an Acquisition Company utilizing the additional 15 day period after closing of the business combination to file a Form 8-K, were required by SEC rules, or issue a press release, prior to the closing of the business combination, noting that the company is relying upon the additional 15 calendar days available under Nasdaq rules to demonstrate compliance. The company must also note that in the event it is unable to demonstrate compliance, the company will be subject to delisting. In the event the Acquisition Company does not make the required disclosure prior to the listing of the combined company, Nasdaq will halt trading in the company's securities until such time as the required announcement is made public. The Exchange believes this disclosure requirement will ensure that prospective investors are aware that the company has not yet demonstrated that it meets the shareholder requirement and therefore may be delisted. In light of these requirements, Nasdaq believes that the proposed rule change appropriately balances the protection of prospective investors with the protection of shareholders of the Acquisition Company, the latter of whom would be harmed if Nasdaq issued a delisting determination at a time when the company did, in fact, satisfy all initial listing requirements but could not yet provide proof.

The proposed rule change is also consistent with Section 6(b)(7) of the Act in that it provides a fair procedure

for the prohibition or limitation by the Exchange of any person with respect to access to services offered. The proposed rule change accounts for the particular difficulties encountered by Acquisition Companies when attempting to determine their total number of shareholders due to the ability of shareholders to redeem their shares. Acquisition Companies will still be required to demonstrate compliance with all initial listing standards immediately following the business combination, which is the initial listing of the combined company. This is no different from the requirements imposed on other newly listing companies.

The non-substantive changes to eliminate a duplicate paragraph in paragraphs (d) and (e) of IM-5101-2 and to add a new paragraph designation will improve the rule's readability and thereby remove an impediment to a free and open market and a national market system and help to better protect investors, which Nasdaq believes is consistent with the requirements of Section 6(b)(5) of the Act.¹⁵

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 not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule would clarify that a company listing in connection with a merger with an Acquisition Company must provide evidence before completing the business combination that it will satisfy all requirements for initial listing, although a reasonable accommodation would be made to allow the company to demonstrate compliance with the round lot shareholder requirement before issuing a delisting letter if that is the only requirement that the company cannot demonstrate compliance with before completing the business combination. This change is not expected to have any impact on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

On December 21, 2020, the Commission issued an Order Instituting Proceedings¹⁶ ("OIP") pursuant to Section 19(b)(2)(B) of the Act to determine whether to approve or disapprove the Original Proposal

¹³ 15 U.S.C. 78f(b).

¹⁶ Securities Exchange Act Release No. 90682 (December 21, 2020), 85 FR 83113 (December 16, 2020).

¹³ 15 U.S.C. 78f(b).

¹⁴ 15 U.S.C. 78f(b)(5).

superseded by this Amendment No. 1. In response to the OIP, the Council of Institutional Investors (“CII”) submitted a comment letter dated January 7, 2021.¹⁷ Simultaneous to the submission of this Amendment No. 1, the Exchange is submitting a comment letter in response to the Commission’s OIP. That comment letter addresses the issues raised in the CII comment letter.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as modified by Amendment No. 1, 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–NASDAQ–2020–062 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–NASDAQ–2020–062. 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–NASDAQ–2020–062, and should be submitted on or before April 6, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–05345 Filed 3–15–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91287; File No. SR–LTSE–2021–01]

Self-Regulatory Organizations; Long-Term Stock Exchange, Inc.; Order Approving Proposed Rule Change To Amend LTSE Rule 14.501 To Specify the Process for Enforcing Compliance With LTSE Rule 14.425 for Listed Companies

March 10, 2021.

I. Introduction

On January 19, 2021, Long-Term Stock Exchange, Inc. (“LTSE” or “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 amend Rule 14.501(d)(2)(A)(iii) to specify the process for enforcing compliance with LTSE Rule 14.425, which requires each listed company of the Exchange to adopt and publish “Long-Term Policies” as set forth in the rule. The proposed rule change was published for comment in the **Federal Register** on February 4, 2021. ³ No comment letters were received in response to the Notice. This order approves the proposed rule change.

II. Description of the Proposed Rule Change

The Exchange proposes to amend Rule 14.501(d)(2)(A)(iii) to specify the process under LTSE Rule Series 14.500

for enforcing compliance with LTSE Rule 14.425, which requires listed Companies ⁴ to adopt and publish Long-Term Policies consistent with a defined set of principles (the “Principles”) articulated in LTSE Rule 14.425(b). ⁵ As the Exchange states, LTSE Rule 14.425(a) requires Companies to adopt and publish the following policies: A Long-Term Stakeholder Policy; a Long-Term Strategy Policy; a Long-Term Compensation Policy; a Long-Term Board Policy; and a Long-Term Investor Policy (collectively, the “Policies”). ⁶ LTSE Rule 14.425(b) establishes that Companies have flexibility in developing what they believe to be appropriate policies for their businesses on condition that each of the Policies must be consistent with the Principles. ⁷ Under LTSE Rule 14.425(c), Companies also are required to review their Policies at least annually, make them publicly available free of charge on or through their websites, and provide related disclosures in certain filings with the Commission. ⁸ In addition, the Exchange has represented to the Commission that it will enforce the provisions of LTSE Rule 14.425 by ensuring that each Company has addressed all of the requirements enumerated for each of the prescribed Policies, consistent with the Principles, and that each Company has made the Policies publicly available without cost. ⁹

Currently, LTSE states that it enforces the provisions of LTSE Rule 14.425 through a number of rules in the LTSE Rulebook. ¹⁰ The Exchange notes that, under LTSE Rule 14.101, the Exchange may at all times exercise its broad discretionary authority to suspend or delist Companies based on any event, condition, or circumstance that exists or

⁴ “Company” means the issuer of a security listed or applying to list on the Exchange. For purposes of Chapter 14 of the LTSE Rules, the term “Company” includes an issuer that is not incorporated, such as, for example, a limited partnership. See LTSE Rule 14.002(a)(5).

⁵ See Notice, *supra* note 3, at 8244. LTSE Rule Series 14.500 sets forth the procedures of the Exchange relating to a Company’s failure to meet the listing standards in Chapter 14 of the Exchange’s rules, which comprises the corporate governance standards set forth in Rule Series 14.400, including Rule 14.425 regarding Long-Term Policies.

⁶ See *id.* See also Securities Exchange Act Release No. 86722 (August 21, 2019), 84 FR 44952 (August 27, 2019) (SR–LTSE–2019–01) (“Long-Term Policies Approval Order”) (Order Approving Proposed Rule Change To Adopt Rule 14.425, Which Would Require Companies Listed on the Exchange To Develop and Publish Certain Long-Term Policies).

⁷ See Notice, *supra* note 3, at 8244.

⁸ See *id.*

⁹ See *id.* See also Long-Term Policies Approval Order, *supra* note 6, at 44954.

¹⁰ See Notice, *supra* note 3, at 8244.

¹⁷ See Letter from Jeffrey P. Mahoney, Council of Institutional Investors Letter to Secretary, Securities and Exchange Commission (January 7, 2021). CII also raised concerns with the SPAC structure that are outside the scope of Nasdaq’s proposal.

¹⁸ 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. 91019 (January 29, 2021), 86 FR 8243 (February 4, 2021) (“Notice”).

occurs that makes initial or continued listing of the securities on the Exchange inadvisable or unwarranted in the opinion of the Exchange to protect investors and the public interest, among other objectives.¹¹ Under LTSE Rule 14.500(a), LTSE staff is responsible for identifying deficiencies that may lead to delisting.¹² Under LTSE Rule 14.410, a Company is required to provide the Exchange with prompt notification after an Executive Officer of the Company becomes aware of any noncompliance by the Company with the LTSE Rule Series 14.400, which includes Rule 14.425.¹³ Under LTSE Rule 14.207(a)(1), the Exchange may request any additional information or documentation, public or non-public, deemed necessary to make a determination regarding a Company's continued listing, and a Company may be denied continued listing if it fails to provide such information within a reasonable period of time.¹⁴ In addition, the Exchange states that it plans to monitor Company compliance with Rule 14.425 annually and on an ad hoc basis.¹⁵

Finally, LTSE Rule 14.501 sets forth the provisions regarding the Exchange's process for notifying Companies regarding different types of deficiencies and their corresponding consequences.¹⁶ The Exchange states that there are four types of Company deficiency notifications that the Exchange may issue pursuant to LTSE Rule 14.501(a): (i) Staff Delisting Determinations, which are notifications of deficiencies that, unless appealed, subject the Company to immediate suspension and delisting; (ii) notifications of deficiencies for which the Company may submit a plan of compliance ("Plan of Compliance") for staff review; (iii) notifications of deficiencies for which a Company is entitled to an automatic cure or compliance period; and (iv) Public Reprimand Letters.¹⁷ LTSE Rule 14.501(d) identifies the deficiencies that fall within each of these four categories,¹⁸ and provides that in the case of a deficiency not specified in LTSE Rule 14.501(d)(1)–(4), LTSE staff will issue either a Staff Delisting Determination or a Public Reprimand Letter.¹⁹

The Exchange proposes to amend LTSE Rule 14.501(d)(2)(A)(iii) to specify that deficiencies relating to LTSE Rule 14.425 would be included among those for which a Company may submit a Plan of Compliance for staff review.²⁰ The Exchange states that this would be similar to how other corporate governance rules are handled generally in LTSE Rule 14.501(d)(2)(A)(iii).²¹

Under LTSE Rule 14.501(d)(2)(C), a Company has 45 calendar days to submit a plan to regain compliance.²² According to the Exchange, LTSE staff may extend this deadline for up to an additional five calendar days upon good cause shown and may request such additional information from the Company as is necessary to make a determination regarding whether to grant such an extension.²³ The Exchange asserts that this time period appropriately balances the interests of the Exchange in ensuring compliance with its listing standards with the application of principles-based listing standards by the Company.²⁴

According to the Exchange, the process for reviewing such a Plan of Compliance is set forth in LTSE Rule 14.501(d)(2)(B) and would be unchanged by this proposal.²⁵ Under that provision, the Exchange may provide the Company with up to 180 days to regain compliance (with certain exceptions), issue a Staff Delisting Determination letter, or issue a Public

Reprimand Letter in accordance with LTSE Rule 14.501(d)(4).²⁶ Under LTSE Rule 14.500(a), a Public Reprimand Letter or Staff Delisting Determination, upon timely request by a Company, is subject to review by a Listings Review Committee, which will adjudicate the request in accordance with the procedures and timelines set forth in LTSE Rules 14.502, 14.504, and 14.505.²⁷

The Exchange asserts that providing an opportunity for remediation to Companies that face a deficiency with respect to LTSE Rule 14.425 will allow Companies to formulate effective Policies tailored to Company-specific needs.²⁸ The Exchange argues that the ability to tailor Policies, if necessary, to changing circumstances, while remaining anchored to the Principles, is essential for ensuring that the Policies are effective and meaningful tools for supporting long-term value creation for Companies and their investors.²⁹ To that end, the Exchange maintains that, in case of a deficiency, Companies will be able to achieve compliance by changing Policies or practices related to the deficiency, amending the applicable Policies, or some combination of both, provided that the changes are consistent with the Principles.³⁰

III. Discussion and Commission Findings

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of Section 6 of the Act.³¹ In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,³² which requires, among other things, that rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, 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 that those rules are not designed to

²⁰ See *id.* at 8244. The proposed rule change would also remove two erroneous "or"s in LTSE Rule 14.501(d)(2)(A)(iii). See *id.* at 8244 n.8.

²¹ See *id.* (citing LTSE Rules 14.408(a) (Meetings of Shareholders), 14.408(c) (Quorum), 14.411 (Review of Related Party Transactions), 14.412 (Shareholder Approval), 14.406 (Code of Conduct), 14.407(a)(4)(D) (Partner Meetings of Limited Partners), 14.407(a)(4)(E) (Quorum of Limited Partnerships), 14.407(a)(4)(G) (Related Party Transactions of Limited Partnerships), 14.413 (Voting Rights), and 14.414 (Internal Audit Function)).

²² See *id.* at 8244.

²³ See *id.*

²⁴ See *id.* The Exchange also states that, notwithstanding the mandated period to submit a Plan of Compliance and regain compliance under LTSE Rule 14.501(d)(2), as set forth in LTSE Rule 14.501(c) and repeated in LTSE Rule 14.207(b)(2), "a listed Company that receives a notification of deficiency from the Exchange is required to make a public announcement by filing a Form 8-K, where required by [Commission] rules, or by issuing a press release disclosing receipt of the notification and the Rule(s) upon which the deficiency is based, and describing each specific basis and concern identified by the Exchange in reaching its determination that the Company does not meet the listing standard." For avoidance of doubt, the Exchange further states that a request for information by LTSE staff pursuant to LTSE Rule 14.207(a)(1), absent a notification of deficiency, will not require a public announcement by the subject Company pursuant to LTSE Rules 14.501(c) or 14.207(b)(2). See *id.* at 8244 n.9.

²⁵ See *id.* at 8244.

²⁶ See *id.*

²⁷ See *id.*

²⁸ See *id.* at 8245.

²⁹ See *id.*

³⁰ See *id.* For the avoidance of doubt, the Exchange states that each Company shall be solely responsible for ensuring any changes in its practices to conform to its Policies do not violate any legal, regulatory, contractual, or other requirements applicable to the Company. See *id.* at 8245 n.11.

³¹ 15 U.S.C. 78f. In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

³² 15 U.S.C. 78f(b)(5).

¹¹ See *id.* at 8245.

¹² See *id.* at 8244.

¹³ See *id.*

¹⁴ See *id.*

¹⁵ See *id.* at 8244 n.6.

¹⁶ See *id.* at 8244.

¹⁷ See *id.*

¹⁸ See *id.*

¹⁹ See *id.* at 8244 n.7.

permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission notes that the proposed rule change will bring the Exchange's handling of deficiencies in a Company's compliance with LTSE Rule 14.425 into alignment with its handling of deficiencies in a Company's compliance with other LTSE Rules pertaining to corporate governance,³³ as detailed in the adjudicatory process set forth in LTSE Rule Series 14.500. The Commission further notes that any Company listed on LTSE would already have had to adopt and publish Long-Term Policies prior to being accepted for listing. The Commission therefore believes it is reasonable to afford a Company the opportunity to submit a Plan of Compliance should a deficiency subsequently arise in this area. The Commission notes in this regard that, in addition to submitting a Plan of Compliance, a listed Company that receives a deficiency notification from the Exchange is required to make a public announcement that discloses its receipt of the notification and the basis for it, and that such announcement must be made as promptly as possible but not more than four business days following receipt of the notification.³⁴ Based on the foregoing, the Commission finds that the proposed rule change is consistent with the Act.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,³⁵ that the proposed rule change (SR-LTSE-2021-01), be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁶

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-05340 Filed 3-15-21; 8:45 am]

BILLING CODE 8011-01-P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Modification of Section 301 Action: Enforcement of U.S. WTO Rights in the Large Civil Aircraft Dispute

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice.

SUMMARY: The U.S. Trade Representative has determined to

modify the action being taken in the investigation by suspending the additional tariffs on goods of the European Union for a period of four months. The suspension is in accord with a joint U.S.-EU statement that promotes a resolution of the large civil aircraft dispute.

DATES: As of 12:01 a.m. eastern standard time on March 11, 2021, the additional duties on products of the European Union covered by the action taken in this investigation are suspended for a period of four months.

FOR FURTHER INFORMATION CONTACT: For questions about the investigation or this notice, contact Associate General Counsel Megan Grimball, at (202) 395-5725, or Director for Europe Michael Rogers, at (202) 395-3320.

SUPPLEMENTARY INFORMATION:

A. Proceedings in the Investigation

For background on the proceedings in this investigation, please see prior notices, including: Notice of initiation, 84 FR 15028 (April 12, 2019); notice of determination and action, 84 FR 54245 (October 9, 2019); and notices concerning revisions or modifications of action, 85 FR 10204 (February 21, 2020), 85 FR 50866 (August 18, 2020), 86 FR 674 (January 6, 2021), 86 FR 9420 (February 12, 2021), and FR Doc. 2021-05035 (March 11, 2021).

B. Modification of Action

Section 307(a) of the Trade Act of 1974, as amended, (Trade Act) provides that the U.S. Trade Representative may modify or terminate any action subject to the specific direction, if any, of the President with respect to such action, that is being taken under section 301 if any of the conditions described in section 301(a)(2) exist. Section 301(a)(2)(B)(iv) of the Trade Act provides that the U.S. Trade Representative is not required to take action under section 301(a)(1) "in extraordinary cases, where the taking of action . . . would have an adverse impact on the United States economy substantially out of proportion to the benefits of such action, taking into account the impact of not taking such action on the credibility of [actions taken under section 301]."

On March 5, 2021, the United States and the European Union issued a Joint Statement promoting a resolution of the large civil aircraft dispute:

The European Union and the United States today agreed on the mutual suspension for four months of the tariffs related to the World Trade Organization (WTO) Aircraft disputes. The suspension will cover all tariffs both on aircraft as well as on non-aircraft products,

and will become effective as soon as the internal procedures on both sides are completed.

This will allow the EU and the US to ease the burden on their industries and workers and focus efforts towards resolving these long running disputes at the WTO.

The EU and the US are committed to reach a comprehensive and durable negotiated solution to the Aircraft disputes. Key elements of a negotiated solution will include disciplines on future support in this sector, outstanding support measures, monitoring and enforcement, and addressing the trade distortive practices of and challenges posed by new entrants to the sector from non-market economies, such as China.

These steps signal the determination of both sides to embark on a fresh start in the relationship.

Promoting a successful resolution of the dispute by suspending the additional duties provides benefits to the U.S. economy that outweigh any adverse impacts on the U.S. economy, and the suspension maintains the credibility of the section 301 action. Accordingly, the U.S. Trade Representative has determined, in accordance with sections 307(a) and 301(a)(2)(B)(iv) of the Trade Act, to modify the action by suspending the additional duties on products of the European Union for four months. The decision to modify the action takes into account the public comments received in response to prior notices issued in the investigation as well as the advice of the interagency Section 301 Committee.

To give effect to the U.S. Trade Representative's determination, as specified in the Annex to this notice, the additional duties imposed by subheadings 9903.89.05, 9903.89.07, 9903.89.10, 9903.89.13, 9903.89.16, 9903.89.19, 9903.89.22, 9903.89.25, 9903.89.28, 9903.89.31, 9903.89.34, 9903.89.37, 9903.89.40, 9903.89.43, 9903.89.46, 9903.89.52, 9903.89.55, 9903.89.57, 9903.89.59, 9903.89.61, and 9903.89.63, and as provided by their associated subchapter notes, will not apply to products of Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden, that are entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern standard time on March 11, 2021, and before 12:01 a.m. eastern daylight time on July 11, 2021.

Any product of Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus,

³³ See *supra* note 21 and accompanying text.

³⁴ See LTSE Rule 14.501(c); *supra* note 24.

³⁵ 15 U.S.C. 78s(b)(2).

³⁶ 17 CFR 200.30-3(a)(12).

Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden, that was admitted into a U.S. foreign trade zone in 'privileged foreign status' as defined in 19 CFR 146.41, before 12:01 a.m. eastern standard time on March 11, 2021, will remain subject to the applicable duties in subheadings 9903.89.05, 9903.89.07, 9903.89.10, 9903.89.13, 9903.89.16, 9903.89.19, 9903.89.22, 9903.89.25, 9903.89.28, 9903.89.31, 9903.89.34, 9903.89.37, 9903.89.40, 9903.89.43, 9903.89.46, 9903.89.52, 9903.89.55, 9903.89.57, 9903.89.59, 9903.89.61, and 9903.89.63 upon entry for consumption.

Any product of Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden covered by subparagraph 2 of the Annex to this notice, that is admitted into a U.S. foreign trade zone on or after 12:01 a.m. eastern standard time on March 11, 2021, and before 12:01 a.m. eastern daylight time on July 11, 2021, may be admitted in any status, as applicable, as defined in 19 CFR 146, Subpart D.

The U.S. Trade Representative will continue to consider the action taken in this investigation.

Annex

Effective with respect to articles the product of Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden that are entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern standard time on March 11, 2021, and entered for consumption, or withdrawn from warehouse for consumption, before 12:01 a.m. eastern daylight time on July 11, 2021:

1. Note 21(a) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting "Except as provided in note 21(u) of this subdivision," and by inserting "Except as provided in notes 21(u) and 21(v) of this subdivision," in lieu thereof.

2. Note 21 to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by inserting in alphabetical order:

"(v) The U.S. Trade Representative has determined that additional duties imposed by subheadings 9903.89.05, 9903.89.07, 9903.89.10, 9903.89.13, 9903.89.16, 9903.89.19, 9903.89.22, 9903.89.25,

9903.89.28, 9903.89.31, 9903.89.34, 9903.89.37, 9903.89.40, 9903.89.43, 9903.89.46, 9903.89.52, 9903.89.55, 9903.89.57, 9903.89.59, 9903.89.61, and 9903.89.63 and as provided by their associated subchapter notes, shall not apply to articles the product of Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden that are entered on or after 12:01 a.m. eastern standard time on March 11, 2021 and before 12:01 a.m. eastern daylight time on July 11, 2021."

Greta M. Peisch,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2021-05354 Filed 3-15-21; 8:45 am]

BILLING CODE 3290-F1-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2021-2060]

Petition for Exemption; Summary of Petition Received; Airlines for America

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief 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 April 5, 2021.

ADDRESSES: Send comments identified by docket number FAA-2021-0079 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, 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 20590-0001, 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 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nia Daniels, (202) 267-7626, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Timothy R. Adams,

Deputy Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2021-0079.

Petitioner: Airlines for America.

Section of 14 CFR Affected: 121.463(c).

Description of Relief Sought: Airlines for America (A4A), on behalf of its member airlines, petitions for relief from § 121.463(c). The relief, if granted, would suspend the requirement for aircraft dispatcher operating familiarization flights until March 31, 2022. The petition seeks to allow dispatchers who have completed operating familiarization flights in previous years to remain qualified without exposing them and flight crew members to an increased risk for exposure to COVID-19.

[FR Doc. 2021-05432 Filed 3-15-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2021–0067]

Agency Information Collection

Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: High Density Traffic Airports; Slot Allocation and Transfer Methods**AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request approval from the Office of Management and Budget (OMB) to renew a currently approved information collection. The FAA collects information from U.S. and foreign air carriers holding a slot at Ronald Reagan Washington National Airport (DCA), John F. Kennedy International Airport (JFK), and LaGuardia Airport (LGA); operating scheduled flights at Newark Liberty International Airport (EWR), Los Angeles International Airport (LAX), O'Hare International Airport (ORD), and San Francisco International Airport (SFO); and conducting unscheduled operations at DCA and LGA. The information collected is necessary to support the advance management of air traffic demand by the FAA Slot Administration in an effort to reduce potential delays. The FAA proposes renaming this information collection to "FAA Runway Slot Administration and Schedule Analysis" to more accurately reflect the collection of information related to multiple airports subject to different FAA regulatory and voluntary processes under this program.

DATES: Written comments should be submitted by May 17, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; telephone: (800) 647–5527, or (202) 366–9826. You must identify FAA Docket Number FAA–2021–0067 at the beginning of your comments. You may also submit comments through the internet at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Matthew Gonabe, FAA Slot Administration, by email at: matthew.gonabe@faa.gov; phone: (609) 485–9554.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: Public comment is invited on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0524.

Title: High Density Traffic Airports; Slot Allocation and Transfer Methods.

Form Numbers: There are no FAA forms associated with this collection.

Type of Review: Renewal of an information collection.

Background: The FAA has implemented several initiatives to address air traffic congestion and delay at certain airports within the National Airspace System (NAS). DCA slot rules are established under 14 CFR part 93, subparts K and S. The FAA has issued Orders limiting operations at JFK and LGA.¹ These Orders resulted from increasing congestion and delays at the airports requiring the FAA to allocate arrival and departure slots at JFK and LGA. In addition, the FAA has designated EWR, ORD, SFO, and LAX as Level 2 schedule-facilitated airports under the IATA Worldwide Slot Guidelines (WSG) now known as the Worldwide Airport Slot Guidelines (WASG).² At Level 2 airports, the FAA seeks the cooperation of all carriers planning operations, on a voluntary basis, to maintain close communications on runway schedules and facilitate adjustments, as needed.

¹ Operating Limitations at John F. Kennedy International Airport, 73 FR 3510 (Jan. 18, 2008), as most recently amended 85 FR 58258 (Sep. 18, 2020); Operating Limitations at New York LaGuardia Airport, 71 FR 77854 (Dec. 27, 2006), as most recently amended 85 FR 58255 (Sep. 18, 2020).

² Notice of Submission Deadline for Schedule Information for O'Hare International, John F. Kennedy International, and Newark Liberty International Airports for the Summer 2009 Scheduling Season, 73 FR 54659 (Sept. 22, 2008); Notice of Submission Deadline for Schedule Information for San Francisco International Airport for the Summer 2012 Scheduling Season, 76 FR 64163 (Oct. 17, 2011); Notice of Submission Deadline for Schedule Information for Los Angeles International Airport for the Summer 2015 Scheduling Season 80 FR 12253 (Mar. 6, 2015); Notice of Change of Newark Liberty International Airport Designation, 81 FR 19861 (Apr. 6, 2016). The FAA reaffirmed the Level 2 designations by 85 FR 65134 (Oct. 14, 2020). These designations remain effective until the FAA announces a change in the **Federal Register**.

At DCA, U.S. and foreign air carriers, including commuter operators, must notify the FAA of: (1) Written consent and requests for confirmation of slot transfers; (2) slots required to be returned and slots voluntarily returned; (3) requests to be included in a lottery for the permanent allocation of available slots; (4) reports on usage of slots on a bi-monthly basis; and (5) requests for slots in low-demand hours or other temporary allocations. Operators must obtain a reservation from the FAA prior to conducting an unscheduled operation. At LGA, U.S. and foreign air carriers must notify the FAA of: (1) Written consent and requests for confirmation of slot transfers; (2) slots required to be returned and slots voluntarily returned; (3) requests to be included in a lottery for the permanent allocation of available slots; and (4) reports usage of slots on a bi-monthly basis. Carriers must also request and obtain a reservation from the FAA prior to conducting an unscheduled operation. At JFK, U.S. and foreign air carriers must notify the FAA of: (1) Written consent and requests for confirmation of slot transfers; (2) requests for seasonal allocation of historic and additional available slots; (3) reports on usage of slots on a seasonal basis; (4) the return of slots; and (5) changes to allocated slots. At EWR, LAX, ORD, and SFO, all carriers are asked to notify the FAA of their intended operating schedules during designated hours on a semiannual basis (for each winter and summer scheduling season) based on the IATA WASG Calendar of Coordination Activities and provide updates throughout the year when there are significant schedule changes.

The FAA estimates that all information from carriers is submitted electronically from data stored in carrier scheduling databases. Requests for unscheduled flight reservations are submitted electronically via the internet. The FAA also proposes to rename the collection to "FAA Runway Slot Administration and Schedule Analysis" to more accurately reflect the collection of information related to multiple airports subject to different FAA regulatory and voluntary processes.

Respondents: 119 unique carriers; unknown number of carriers conducting unscheduled operations at LGA and DCA.

Frequency: Information is collected as needed; some reporting on bimonthly or semiannual basis.

Estimated Average Burden per Response: 6 minutes per slot transaction per respondent (*i.e.*, transferor and

transferee); 6 minutes per slot return; 6 minutes per schedule update; 6 minutes per request for inclusion in a lottery; 2 minutes per unscheduled slot request; 1.5 hours per schedule submission; and 1 hour per slot usage report.

Estimated Total Annual Burden:
5602.6 hours.

Issued in Washington, DC, on March 10, 2021.

Matthew S. Gonabe,

Program Specialist, FAA Slot Administration.

[FR Doc. 2021-05334 Filed 3-15-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2021-2062]

Petition for Exemption; Summary of Petition Received; Airlines for America

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief 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 March 22, 2021.

ADDRESSES: Send comments identified by docket number FAA-2020-0307 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, 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 20590-0001, 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 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nia Daniels, (202) 267-9677, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Timothy R. Adams,

Deputy Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2020-0307.

Petitioner: Airlines for America.

Section(s) of 14 CFR Affected:

121.407(c)(2), 121.409(b)(2)(i), 121.417(c)(2)(i)(C)-(D) and (E)(4), 121.424(a)(1), 121.427(b)(2)(i)-(iii), (e)(1)(ii) and (e)(2), 121.441(b)(1), and 121.805(b)(5)(iii)

Description of Relief Sought: The petitioner requests an extension and amendment of Exemption No. 18512C to allow certificate holders to use alternative methods to conduct certain required crewmember emergency procedures during recurrent, conversion, and upgrade training, checking, and evaluation until September 30, 2021. The petitioner seeks an amendment to the Conditions and Limitations of Exemption No. 18512C, which require a crewmember using alternative methods to complete the drills using the normal procedures during the person's next regularly scheduled recurrent ground training or within 12 calendar months (plus grace month) of the training using the alternative methods, whichever is earlier. The petitioner seeks an amendment to allow up to 24 calendar months after use of the alternative methods for crewmembers to complete

the emergency drills or performance drills using the normal procedures.

[FR Doc. 2021-05431 Filed 3-15-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2020-0224]

Controlled Substances and Alcohol Use and Testing: FirstGroup plc. Application for Exemption From the Drug and Alcohol Clearinghouse Pre-Employment Full Query

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that FirstGroup plc (FirstGroup) has applied for an exemption on behalf of three of its subsidiaries, First Student, Inc., First Transit, Inc., and First Mile Square, which employ commercial driver's license (CDL) holders subject to drug and alcohol testing. FirstGroup requests an exemption from the requirement that an employer must conduct a full query of FMCSA's Drug and Alcohol Clearinghouse (Clearinghouse) before employing a CDL holder to perform safety-sensitive functions. Under the requested exemption, in lieu of a full query, FirstGroup would conduct a limited pre-employment query of the Clearinghouse. If the limited query indicated that information about the driver existed in the Clearinghouse, FirstGroup would then conduct a full query of the Clearinghouse, with the driver-applicant providing consent in the Clearinghouse as required. In addition, FirstGroup would conduct a second limited query within 30 to 35 days of the initial limited query and conduct multiple limited queries on all its CDL drivers each year thereafter.

DATES: Comments must be received on or before April 15, 2021.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number FMCSA-2020-0224 by any of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. See the *Public Participation and Request for Comments* section below for further information.

- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.

- *Fax:* (202) 493–2251.

Each submission must include the Agency name and the docket number for this notice (FMCSA–2020–0224). Note that DOT posts all comments received without change to www.regulations.gov, including any personal information included in a comment. Please see the *Privacy Act* heading below.

Docket: For access to the docket to read background documents or comments, go to www.regulations.gov at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its regulatory exemptions process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.dot.gov/privacy.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Clemente, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; (202) 366–2722; MCPSD@dot.gov. If you have questions on viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2020–0224), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the

body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to www.regulations.gov and put the docket number, “FMCSA–2020–0224” in the “Keyword” box, and click “Search.” When the new screen appears, click on “Comment Now!” button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved absent the exemption (49 U.S.C 31315(b)(1)). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must specify the effective period (up to 5 years) and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Background

Current Regulation Requirements

Under 49 CFR 382.701(a)(2) employers of CDL holders must not employ a driver subject to the testing requirements of 49 CFR part 382 without first conducting a pre-employment full query of the

Clearinghouse. A full query allows the employer to see any information that exists about a driver in the Clearinghouse. An employer must obtain the driver’s specific consent, provided electronically through the Clearinghouse, prior to the release of detailed information provided in response to the full query.

A limited query is permitted to satisfy the annual query requirement in 49 CFR 382.701(b)(1), which pertains to currently employed drivers. The limited query, conducted after obtaining the driver’s general consent, will tell the employer whether information about the individual driver exists in the Clearinghouse but will not release that information to the employer. General consent is obtained and retained outside the Clearinghouse and may be in written or electronic form. If the response to a limited query indicates there is information about the driver in the Clearinghouse, the employer must conduct a full query, after obtaining the driver’s specific consent, within 24 hours, as required by 49 CFR 382.701(b)(3).

Applicant’s Request

FirstGroup requests an exemption from the rule prohibiting an employer from employing a driver subject to drug and alcohol testing requirements to perform safety-sensitive functions without first conducting a full query of the Clearinghouse. Under the requested exemption, FirstGroup would, in lieu of a full query, conduct a limited pre-employment query of the Clearinghouse before one of its members employed a driver. If the limited query indicated that information about the driver exists in the Clearinghouse, FirstGroup would then conduct a full query of the Clearinghouse, with the driver applicant providing consent in the Clearinghouse as required. In addition, FirstGroup would conduct a second limited query within 30 to 35 days of the initial query, would conduct quarterly limited queries on all its CDL drivers for the first year of the exemption, and for years 2 through 5, would conduct semi-annual limited queries on all its CDL drivers.

FirstGroup believes the requirements of 49 CFR 382.701(a)(2) is hindering its ability to hire at the speed and level needed to keep pace with the demands of the contracted school and transit transportation industry. FirstGroup also believes the exemption is needed since the delays and administrative costs related to conducting a full query during FirstGroup’s driver hiring process is resulting in hundreds of thousands of dollars of increased costs.

A copy of FirstGroup's exemption application is included in the docket referenced above.

IV. Request for Comments

In accordance with 49 U.S.C. 31315(b), FMCSA requests public comment from all interested persons on FirstGroup's application for an exemption from § 382.701(a)(2). All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2021-05328 Filed 3-15-21; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA—FMCSA—2000–7006; FMCSA—2000–7165; FMCSA—2001–11426; FMCSA—2002–12294; FMCSA—2004–18885; FMCSA—2004–19477; FMCSA—2005–21711; FMCSA—2006–24783; FMCSA—2006–26066; FMCSA—2007–0071; FMCSA—2008–0021; FMCSA—2008–0106; FMCSA—2008–0174; FMCSA—2008–0266; FMCSA—2008–0292; FMCSA—2008–0340; FMCSA—2010–0161; FMCSA—2010–0187; FMCSA—2010–0201; FMCSA—2010–0287; FMCSA—2010–0354; FMCSA—2010–0385; FMCSA—2012–0039; FMCSA—2012–0161; FMCSA—2012–0215; FMCSA—2012–0216; FMCSA—2012–0279; FMCSA—2013–0168; FMCSA—2013–0170; FMCSA—2014–0002; FMCSA—2014–0006; FMCSA—2014–0007; FMCSA—2014–0010; FMCSA—2014–0011; FMCSA—2014–0296; FMCSA—2014–0299; FMCSA—2014–0300; FMCSA—2016–0028; FMCSA—2016–0030; FMCSA—2016–0207; FMCSA—2016–0208; FMCSA—2016–0209; FMCSA—2016–0210; FMCSA—2018–0010; FMCSA—2018–0207]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions for 66

individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these individuals to continue to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates provided below.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, fmcamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Comments

To view comments go to www.regulations.gov. Insert the docket number, FMCSA–2000–7006, FMCSA–2000–7165, FMCSA–2001–11426, FMCSA–2002–12294, FMCSA–2004–18885, FMCSA–2004–19477, FMCSA–2005–21711, FMCSA–2006–24783, FMCSA–2006–26066, FMCSA–2007–0071, FMCSA–2008–0021, FMCSA–2008–0106, FMCSA–2008–0174, FMCSA–2008–0266, FMCSA–2008–0292, FMCSA–2008–0340, FMCSA–2010–0161, FMCSA–2010–0187, FMCSA–2010–0201, FMCSA–2010–0287, FMCSA–2010–0354, FMCSA–2010–0385, FMCSA–2012–0039, FMCSA–2012–0161, FMCSA–2012–0215, FMCSA–2012–0216, FMCSA–2012–0279, FMCSA–2013–0168, FMCSA–2013–0170, FMCSA–2014–0002, FMCSA–2014–0006, FMCSA–2014–0007, FMCSA–2014–0010, FMCSA–2014–0011, FMCSA–2014–0296, FMCSA–2014–0299, FMCSA–2014–0300, FMCSA–2016–0028, FMCSA–2016–0030, FMCSA–2016–0207, FMCSA–2016–0208, FMCSA–2016–0209, FMCSA–2016–0210, FMCSA–2018–0010, or FMCSA–2018–0207 in the keyword box, and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, and click “Browse Comments.” If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of

the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

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 www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.transportation.gov/privacy.

II. Background

On January 7, 2021, FMCSA published a notice announcing its decision to renew exemptions for 66 individuals from the vision requirement in 49 CFR 391.41(b)(10) to operate a CMV in interstate commerce and requested comments from the public (86 FR 697). The public comment period ended on February 5, 2021, and one comment was received.

FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would achieve a level of safety equivalent to, or greater than, the level that would be achieved by complying with the current regulation § 391.41(b)(10).

The physical qualification standard for drivers regarding vision found in § 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of at least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

III. Discussion of Comments

FMCSA received one comment in this proceeding and it was unrelated to the scope of this notice.

IV. Conclusion

Based on its evaluation of the 66 renewal exemption applications and comments received, FMCSA confirms its decision to exempt the following drivers from the vision requirement in § 391.41(b)(10).

In accordance with 49 U.S.C. 31136(e) and 31315(b), the following groups of drivers received renewed exemptions in the month of February and are discussed below. As of February 5, 2021, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 63 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (65 FR 20245; 65 FR 33406; 65 FR 57230; 65 FR 57234; 67 FR 10471; 67 FR 19798; 67 FR 46016; 67 FR 57266; 67 FR 57627; 69 FR 19611; 69 FR 51346; 69 FR 52741; 69 FR 53493; 69 FR 62742; 69 FR 64806; 70 FR 2705; 70 FR 48797; 70 FR 61493; 71 FR 26602; 71 FR 32183; 71 FR 41310; 71 FR 50970; 71 FR 53489; 71 FR 62147; 71 FR 62148; 71 FR 63379; 72 FR 1050; 72 FR 1051; 72 FR 1056; 72 FR 64273; 73 FR 6242; 73 FR 6244; 73 FR 15567; 73 FR 16950; 73 FR 16952; 73 FR 27015; 73 FR 27018; 73 FR 35197; 73 FR 35198; 73 FR 36955; 73 FR 38498; 73 FR 38499; 73 FR 48273; 73 FR 48275; 73 FR 51336; 73 FR 51689; 73 FR 61922; ; 73 FR 61925; 73 FR 61925; 73 FR 63047; 73 FR 74565; 73 FR 75803; 73 FR 75807; 73 FR 76439; 73 FR 78421; 73 FR 78423; 74 FR 6209; 74 FR 62632; 75 FR 9477; 75 FR 19674; 75 FR 22179; 75 FR 36778; 75 FR 36779; 75 FR 39725; 75 FR 44051; 75 FR 47883; 75 FR 50799; 75 FR 52062; 75 FR 54958; ; 75 FR 59327; 75 FR 59327; 75 FR 61833; 75 FR 63257; 75 FR 64396; 75 FR 69737; 75 FR 70078; 75 FR 72863; 75 FR 77591; 75 FR 77942; 75 FR 77949; 75 FR 79079; 75 FR 79083; 75 FR 79084; 76 FR 1499; 76 FR 2190; 76 FR 4413; 76 FR 5425; 76 FR 70215; 77 FR 13689; 77 FR 20879; 77 FR 23797; 77 FR 31427; 77 FR 36338; 77 FR 38384; 77 FR 41879; 77 FR 46153; 77 FR 48590; 77 FR 52381; 77 FR 52389; 77 FR 52391; 77 FR 56261; 77 FR 60008; 77 FR 60010; 77 FR 64582; 77 FR 64583; 77 FR 64583; 77 FR 64841; 77 FR 65933; 77 FR 68200; 77 FR 68202; 77 FR 71671; 77 FR 74273; 77 FR 74730; 77 FR 74733; 77 FR 74734; 77 FR 75496; 77 FR 76166; 78 FR 797; 78 FR 63302; 78 FR 64280; 78 FR 67454; 78 FR 77780; 79 FR 4803; 79 FR 10606; 79 FR 10609; 79 FR 14331; 79 FR 22003; 79 FR 23797; 79 FR 35212; 79 FR 35218; 79 FR 35220; 79 FR 37843; 79 FR 38659; 79 FR 38661; 79 FR 41735; 79 FR 45868; 79 FR 46153; 79 FR 47175; 79 FR 51643; 79 FR 53514; 79 FR 56097; 79 FR 56099; 79 FR 56104; 79 FR 56117; 79 FR 58856; 79 FR 59348; 79 FR 59357; 79 FR 64001; 79 FR 65759; 79 FR 65760; 79 FR 70928; 79 FR 72754; 79 FR 72756; 79 FR 73397; 79 FR 73686; 79 FR 73687; 79 FR 73689; 79 FR 74169; 80 FR 3305; 80 FR 9304; 80 FR 63869; 80 FR 80443; 81 FR 20435; 81 FR 28138; 81 FR 39320; 81 FR 45214; 81 FR 66720; 81 FR 66726; 81 FR 70248; 81 FR 70251;

81 FR 70253; 81 FR 71173; 81 FR 72664; 81 FR 80161; 81 FR 81230; 81 FR 90046; 81 FR 90050; 81 FR 91239; 81 FR 94013; 81 FR 96165; 81 FR 96178; 81 FR 96180; 81 FR 96191; 81 FR 96196; 82 FR 13048; 83 FR 3861; 83 FR 6925; 83 FR 18633; 83 FR 28325; 83 FR 28342; 83 FR 34661; 83 FR 53724; 83 FR 56140; 83 FR 56902; 84 FR 2309; 84 FR 2311; 84 FR 2314); Lennie D. Baker, Jr. (NC) Donald L. Blakeley II (NV) Timothy Bradford (TN) Scott Brady (FL) Marty R. Brewster (KS) David S. Brumfield (KY) Todd A. Carlson (MN) Dionicio Carrera (TX) Juan Castanon (NM) Scott F. Chalfant (DE) Derrick L. Cowan (NC) Dorothy J. Crum (OH) Louis J. Cullen (NJ) Larry G. Davis (TN) Christopher L. Depuy (OH) Craig E. Dorrance (MT) Lucious J. Erwin (TX) James H. Facemyre (WV) Hector O. Flores (MD) Larry J. Folkerts (IA) Christopher K. Foot (NV) Kelvin Frandin Bombu (KY) Stanley W. Goble (IA) John P. Grum (PA) William R. Guida (PA) Walter D. Hague, Jr. (VA) Eric C. Hammer (MO) Billy R. Hampton (NC) Clifford J. Harris (VA) Nylo K. Helberg (ND) Robert K. Ipock (NC) Jesse P. Jamison (TN) Perry D. Jensen (WI) Robert E. Kelley (WA) Lewis A. Kielhack (IL) Gregory L. Kockelman (MN) Matthew B. Lairamore (OK) Bradley W. Lovelace (NC) Duane R. Martin (PA) John C. McLaughlin (SD) Rodney M. Pegg (PA) Chad M. Quarles (AL) Joseph L. Rigsby (AL) Joe A. Root (MN) Preston S. Salisbury (MT) Benny L. Sanchez (CA) Randal C. Schmude (WI) James C. Sharp (PA) Joseph B. Shaw, Jr. (VA) Sylvester Silver (VA) Kenneth D. Sisk (NC) Loren Smith (SD) Paul W. Sorenson (UT) David C. Stitt (KS) Gary R. Thomas (OH) Richard T. Traigle (LA) David J. Triplett (KY) Melvin V. Van Meter (PA) Nicholas J. Vance (OH)

Michael J. Welle (MN)
Carl V. Wheeler (NC)
Earl L. White, Jr. (NH)
Joseph F. Wood (MS)

The drivers were included in docket numbers FMCSA–2000–7006; FMCSA–2000–7165; FMCSA–2001–11426; FMCSA–2002–12294; FMCSA–2004–18885; FMCSA–2004–18885; FMCSA–2004–19477; FMCSA–2005–21711; FMCSA–2006–24783; FMCSA–2006–26066; FMCSA–2007–0071; FMCSA–2008–0021; FMCSA–2008–0106; FMCSA–2008–0174; FMCSA–2008–0266; FMCSA–2008–0292; FMCSA–2008–0340; FMCSA–2010–0161; FMCSA–2010–0187; FMCSA–2010–0201; FMCSA–2010–0287; FMCSA–2010–0354; FMCSA–2010–0385; FMCSA–2012–0039; FMCSA–2012–0161; FMCSA–2012–0215; FMCSA–2012–0216; FMCSA–2012–0279; FMCSA–2013–0168; FMCSA–2013–0170; FMCSA–2014–0002; FMCSA–2014–0006; FMCSA–2014–0007; FMCSA–2014–0010; FMCSA–2014–0011; FMCSA–2014–0296; FMCSA–2014–0299; FMCSA–2016–0028; FMCSA–2016–0030; FMCSA–2016–0207; FMCSA–2016–0208; FMCSA–2016–0209; FMCSA–2016–0210; FMCSA–2018–0010; FMCSA–2018–0207. Their exemptions were applicable as of February 5, 2021, and will expire on February 5, 2023.

As of February 18, 2021, and in accordance with 49 U.S.C. 31136(e) and 31315, the following two individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (80 FR 2473; 80 FR 18693; 82 FR 13048; 84 FR 2314): Keith A. Looney (AR) and Van C. Mac (IL)

The drivers were included in docket number FMCSA–2014–0030. Their exemptions were applicable as of February 18, 2021, and will expire on February 18, 2023.

As of February 25, 2021, and in accordance with 49 U.S.C. 31136(e) and 31315, the following individual has satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (69 FR 64806; 70 FR 2705; 72 FR 1056; 73 FR 76439; 75 FR 79084; 77 FR 75496; 80 FR 3723; 82 FR 13048; 84 FR 2314): Lester W. Carter (CA)

The driver was included in docket number FMCSA–2004–19477. The exemption was applicable as of February 25, 2021, and will expire on February 25, 2023.

In accordance with 49 U.S.C. 31315(b), each exemption will be valid

for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2021-05364 Filed 3-15-21; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2020-0015]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt seven individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. They are unable to meet the vision requirement in one eye for various reasons. The exemptions enable these individuals to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

DATES: The exemptions were applicable on February 5, 2021. The exemptions expire on February 5, 2023.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as

being available in the docket, go to www.regulations.gov/docket?D=FMCSA-2020-0015 and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366-9317 or (202) 366-9826 before visiting Dockets Operations.

B. Privacy Act

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 www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.transportation.gov/privacy.

II. Background

On January 7, 2021, FMCSA published a notice announcing receipt of applications from seven individuals requesting an exemption from vision requirement in 49 CFR 391.41(b)(10) and requested comments from the public (86 FR 695). The public comment period ended on February 5, 2021, and one comment was received.

FMCSA has evaluated the eligibility of these applicants and determined that granting the exemptions to these individuals would achieve a level of safety equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(10).

The physical qualification standard for drivers regarding vision found in § 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of at least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

III. Discussion of Comments

FMCSA received one comment in this proceeding. Tracy Ibinger submitted a comment stating that the Minnesota Department of Public Safety has no objections to the decision to grant an exemption to Burl V. Ingebretsen.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The Agency's decision regarding these exemption applications is based on medical reports about the applicants' vision, as well as their driving records and experience driving with the vision deficiency. The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the January 7, 2021, **Federal Register** notice (86 FR 695) and will not be repeated here.

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their limitation and demonstrated their ability to drive safely. The seven exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including amblyopia, corneal scarring, ectopia lentis, optic nerve hypoplasia, and retinal detachment. In most cases, their eye conditions did not develop recently. Five of the applicants were either born with their vision impairments or have had them since childhood. The two individuals that developed their vision conditions as adults have had them for a range of 3 to 4 years. Although each applicant has one eye that does not meet the vision requirement in § 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and, in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV.

Doctors' opinions are supported by the applicants' possession of a valid license to operate a CMV. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV with their limited vision in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves

substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions.

The applicants in this notice have driven CMVs with their limited vision in careers ranging for 3 to 92 years. In the past 3 years, no drivers were involved in crashes, and no drivers were convicted of moving violations in CMVs. All the applicants achieved a record of safety while driving with their vision impairment that demonstrates the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

Consequently, FMCSA finds that in each case exempting these applicants from the vision requirement in § 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption.

V. Conditions and Requirements

The terms and conditions of the exemption are provided to the applicants in the exemption document and includes the following: (1) Each driver must be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the standard in § 391.41(b)(10) and (b) by a certified medical examiner (ME) who attests that the individual is otherwise physically qualified under § 391.41; (2) each driver must provide a copy of the ophthalmologist's or optometrist's report to the ME at the time of the annual medical examination; and (3) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this

exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the seven exemption applications, FMCSA exempts the following drivers from the vision requirement, § 391.41(b)(10), subject to the requirements cited above:

Johnny J. Brown (MS)
Gordon L. Hendricks (TX)
Justin T. Hoben (IL)
Burl V. Ingebretsen (MN)
Weldon D. Rudder (OK)
Patrick W. Sargent (MT)
John F. Skrobarczyk (TX)

In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2021-05366 Filed 3-15-21; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA-2008-0135]

Petition for Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that on February 22, 2021, the Port Authority Trans-Hudson Corporation (PATH) petitioned the Federal Railroad Administration (FRA) for an extension of a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 229, Railroad Locomotive Safety Standards. FRA assigned the petition Docket Number FRA-2008-0135.

Specifically, PATH requests continued relief from 49 CFR 229.123, *Pilots, snowplows, end plates*, which requires lead locomotives to be equipped with a pilot, snowplow, or end plate that extends across both rails. PATH further requests that the relief be effective for the life of the current PATH PA-5 fleet, noting that a waiver of this same regulation covering the prior fleet of PATH cars, as well as the current PA-5 fleet, has been in effect for over 31

years. PATH states the installation of such a device to deflect foreign objects from the running rail could possibly cause such an object to be deflected into the power rail, potentially causing power outages or damage due to electrical arcing. PATH also explains the addition of a pilot would interfere with the transponder interrogator antennas that are currently installed as part of the Communications Based Train Control system.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- **Website:** <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- **Fax:** 202-493-2251.
- **Mail:** Docket Operations Facility, U.S. Department of Transportation (DOT), 1200 New Jersey Ave. SE, W12-140, Washington, DC 20590.
- **Hand Delivery:** 1200 New Jersey Ave. SE, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by April 30, 2021 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <https://www.transportation.gov/privacy>. See

also <https://www.regulations.gov/privacyNotice> for the privacy notice of [regulations.gov](https://www.regulations.gov).

Issued in Washington, DC.

John Karl Alexy,

*Associate Administrator for Railroad Safety,
Chief Safety Officer.*

[FR Doc. 2021-05373 Filed 3-15-21; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA-2021-0028]

Petition for Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that on February 16, 2021, the Walkersville Southern Railroad (WSRR) petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 215, Freight Car Safety Standards, and part 224, Reflectorization. FRA assigned the petition Docket Number FRA-2021-0028

Specifically, WSRR seeks a special approval pursuant to 49 CFR 215.203, *Restricted cars*, for one class N5 caboose, #477532, built in 1927. WSRR also seeks a waiver of compliance from the requirements of 49 CFR 215.303, *Stenciling of restricted cars*, and 49 CFR part 224, Reflectorization, to maintain the historic nature of the car. WSRR states it will maintain, service, and operate this caboose in excursion service in Walkersville, Maryland, on other-than-main track, at speeds not exceeding 10 miles per hour.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- **Website:** <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- **Fax:** 202-493-2251.

- **Mail:** Docket Operations Facility, U.S. Department of Transportation (DOT), 1200 New Jersey Ave. SE, W12-140, Washington, DC 20590.

- **Hand Delivery:** 1200 New Jersey Ave. SE, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by April 30, 2021 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacyNotice> for the privacy notice of [regulations.gov](https://www.regulations.gov).

Issued in Washington, DC.

John Karl Alexy,

*Associate Administrator for Railroad Safety,
Chief Safety Officer.*

[FR Doc. 2021-05375 Filed 3-15-21; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA-2021-0008]

Petition for Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that on January 1, 2021, The Everett Railroad Company (EV) petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 230, Steam Locomotive Inspection and Maintenance Standards. FRA assigned the petition Docket Number FRA-2021-0008.

Specifically, EV requests relief from 49 CFR 230.16(a), *Annual inspection*, to extend the annual inspection interval on

locomotive EV 11 until March 2022, and 49 CFR 230.17(a), *One thousand four hundred seventy-two (1472) service day inspection*, to extend the 1472-day inspection to a 16-year interval. EV states that the COVID-19 public health emergency has caused EV to halt excursion service, which resulted in EV 11 only accumulating one service day since its 2020 annual inspection. EV anticipates operating EV 11 for about 40 service days in 2021.

EV 11 is currently stored inside a shop building, and EV does not anticipate operating the locomotive until May 2021 or later.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- **Website:** <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- **Fax:** 202-493-2251.

- **Mail:** Docket Operations Facility, U.S. Department of Transportation (DOT), 1200 New Jersey Ave. SE, W12-140, Washington, DC 20590.

- **Hand Delivery:** 1200 New Jersey Ave. SE, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by April 30, 2021 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in

the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacyNotice> for the privacy notice of [regulations.gov](https://www.regulations.gov).

Issued in Washington, DC.

John Karl Alexy,

*Associate Administrator for Railroad Safety,
Chief Safety Officer.*

[FR Doc. 2021-05374 Filed 3-15-21; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Homeless Veterans; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App.2, that virtual meetings of the Advisory Committee on Homeless

Veterans will be held April 6-7, 2021 from 12:00 p.m. to 4:00 p.m. (Eastern Standard Time). The virtual meetings are open to the public.

The purpose of the Committee is to provide the Secretary of Veterans Affairs with an on-going assessment of the effectiveness of the policies, organizational structures, and services of VA in assisting Veterans at-risk and experiencing homelessness. The Committee shall assemble, and review information related to the needs of homeless Veterans and provide advice on the most appropriate means of providing assistance to that subset of the Veteran population. The Committee will make recommendations to the Secretary of Veterans Affairs regarding such activities.

The agenda will include briefings from officials at VA and other Federal, state, and local agencies regarding services for homeless Veterans.

No time will be allocated at this virtual meeting for receiving oral

presentations from the public. Interested parties should provide written comments on issues affecting homeless Veterans for review by the Committee to Mr. Adam M. Ruege at Adam.Ruege2@va.gov and/or Ms. Leisa Davis at Leisa.Davis@va.gov.

Members of the public who wish to virtually attend should contact Leisa Davis (Leisa.Davis@va.gov) of the Veterans Health Administration, Homeless Programs Office no later than March 26, 2021, to provide their name, professional affiliation, email address, and phone number. There will also be a call-in number at 1-800-767-1750; access code: 53757.

Dated: March 10, 2021.

Jelessa M. Burney,

*Federal Advisory Committee Management
Officer.*

[FR Doc. 2021-05326 Filed 3-15-21; 8:45 am]

BILLING CODE 8320-01-P

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Federal Register

Vol. 86, No. 49

Tuesday, March 16, 2021

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Presidential Documents

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FEDERAL REGISTER PAGES AND DATE, MARCH

11847-12078.....	1
12079-12256.....	2
12257-12514.....	3
12515-12798.....	4
12799-13148.....	5
13149-13442.....	8
13443-13622.....	9
13623-13796.....	10
13797-13970.....	11
13971-14220.....	12
14221-14362.....	15
14363-14524.....	16

CFR PARTS AFFECTED DURING MARCH

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR	362.....	12122
Proclamations:	381.....	12122
10149.....	533.....	12122
10150.....	590.....	12122
10151.....	592.....	12122
10152.....		
10153.....	12 CFR	
10154.....	228.....	13805
10155.....	302.....	12079
Executive Orders:	1002.....	14363
14017.....	Proposed Rules:	
14018.....	700.....	13494
14019.....	701.....	13494
14020.....	702.....	13498
14021.....	703.....	13494, 13498
Administrative Orders:	704.....	13494
Memorandums:	713.....	13494
NSPM-16 of February	1026.....	12839
7, 2019 (amended		
by EO 14020).....	13 CFR	
13797	120.....	13149
Notices:		
Notice of March 2,	14 CFR	
2021.....	1.....	13629
12793	11.....	13629, 13630
Notice of March 2,	21.....	13630
2021.....	25.....	14229, 14231, 14233,
12795		14234, 14237
Notice of March 2,	39.....	12086, 12802, 12804,
2021.....		12807, 12809, 13157, 13159,
12797		13162, 13165, 13443, 13445,
Notice of March 5,		13631, 13633, 13637, 13640,
2021.....		13805, 13807, 13809, 13811,
13621		13814, 13972, 13975, 13982,
		13985, 13987, 13989, 14238,
5 CFR		14241, 14366
532.....		13630
11857, 12799		13629
Proposed Rules:		13629
849.....		11859, 11860, 13168,
13217		13169, 13171, 13172, 13447,
		13448, 13642, 13644, 13992
6 CFR		13629
43.....		13629
47.....		13629
48.....		13629
71.....		11859, 11860, 13168,
13169, 13171, 13172, 13447,		
13448, 13642, 13644, 13992		
89.....		13629
91.....		13629
97.....		12812, 12815, 12816,
12819		
107.....		13629, 13630
401.....		13448
404.....		13448
413.....		13448
414.....		13448
415.....		13448
417.....		13448
420.....		13448
431.....		13448
433.....		13448
435.....		13448
437.....		13448
440.....		13448
450.....		13448
460.....		13448
1264.....		14244
1271.....		14244
9 CFR		
Proposed Rules:		
Ch. I.....	13221	
Ch. III.....	13221	
149.....	12293	
307.....	12122	
350.....	12122	
352.....	12122	
354.....	12122	

Proposed Rules:	556.....13181	37 CFR	115.....11913
25.....14387	558.....13181	210.....12822	176.....11913
39.....12127, 12294, 12550,	1308.....11862, 12257		
12857, 12862, 13222, 13225,	Proposed Rules:	40 CFR	
13228, 13229, 13232, 13234,	1308.....12296	49.....12260	47 CFR
13237, 13239, 13502, 13505,	22 CFR	52.....11867, 11870, 11872,	0.....12545
13665, 13828, 13830, 13833,	Proposed Rules:	11873, 11875, 11878, 12092,	1.....12545
13836, 13838, 13841, 14017,	213.....11905	12095, 12107, 12263, 12265,	25.....11880
14020, 14023, 14281, 14283,	24 CFR	12270, 12827, 13191, 13655,	27.....13659
14285, 14289, 14290, 14293	28.....14370	13658, 13816, 13819, 14000,	74.....13660
71.....12129, 12865, 12866,	30.....14370	14007	Proposed Rules:
12868, 13242, 13244, 13246,	87.....14370	62.....12109, 13459	1.....12146, 12312, 12556,
13247, 13249, 13668, 13670,	180.....14370	63.....13819	12898
14026, 14293, 14295	3280.....13645	81.....12107	2.....13266
73.....12552	3282.....13645, 14370	141.....12272, 14003	9.....12399
15 CFR	3285.....13645	180.....12829, 13196, 13459	15.....13266
740.....13173	26 CFR	271.....12834	25.....13266
742.....13173	1.....12821, 13191, 13647,	282.....12110	27.....12146, 13266
744.....12529, 13173, 13179	13648	Proposed Rules:	63.....12312
16 CFR	Proposed Rules:	49.....14392	73.....12161, 12162, 12163,
317.....12091	1.....12886, 13250	52.....11913, 11915, 12143,	12556, 12898, 13278, 13516,
17 CFR	29 CFR	12305, 12310, 12554, 12889,	13684, 14401
201.....13645	780.....12535	13254, 13256, 13260, 13264,	101.....13266
275.....13024	788.....12535	13511, 13514, 13671, 13679,	
279.....13024	795.....12535	13843, 14055, 14061, 14297,	48 CFR
18 CFR	4044.....14280	14299, 14392, 14396	Ch. 1.....13794
157.....12257	Proposed Rules:	62.....11916	4.....13794
Proposed Rules:	103.....14297	81.....12892	52.....13794
4.....13506	780.....14027	141.....13846, 14063	
5.....13506	788.....14027	257.....14066	49 CFR
35.....12132	791.....14038	271.....12895	191.....12834
284.....12132, 12879	795.....14027	282.....12145	192.....12834, 12835
19 CFR	2204.....13251	751.....14398	209.....11888
4.....14245	31 CFR	42 CFR	211.....11888
12.....13993	16.....12537	Proposed Rules:	389.....11891
Ch. I.....12534	27.....12537	51c.....13872	Ch. XII.....13971
122.....14245	35.....13449	43 CFR	Proposed Rules:
123.....14245	50.....12537	8365.....14009	571.....13684
145.....14245	33 CFR	44 CFR	
149.....14245	100.....13998	64.....12117	50 CFR
20 CFR	117.....12821	Proposed Rules:	17.....11892, 13200, 13465
655.....13995	165.....12539, 12541, 12543,	206.....14067	300.....13475
656.....13995	13649, 13651, 13653	45 CFR	635.....12291, 12548, 13491
21 CFR	Proposed Rules:	1230.....13822	648.....13823, 14012
510.....13181	96.....11913	2554.....13822	660.....13824, 14379
516.....13181	165.....12887, 14389	Proposed Rules:	679.....11895, 13215, 13493,
520.....13181	34 CFR	160.....13683	14013, 14014, 14015
522.....13181	Proposed Rules:	164.....13683	680.....11895
524.....13181	Ch. III.....12136, 14048, 14374	46 CFR	Proposed Rules:
526.....13181	361.....13511	401.....14184	17.....12563
529.....13181		404.....14184	223.....13517, 13518
		Proposed Rules:	226.....13517, 13518
		71.....11913	622.....12163, 12166
			648.....12591
			660.....14401

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List March 15, 2021

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