the information at: *https://www.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Paul Hart, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–CTP–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems.''

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the FD&C Act and granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Under section 901(b) of the FD&C Act (21 U.S.C. 387a(b)), FDA's tobacco product authorities in chapter IX of the FD&C Act apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary of Health and Human Services by regulation deems to be subject to chapter IX. On May 10, 2016, in the **Federal Register**, FDA published its final rule, ''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products'' (Deeming rule) extending FDA's tobacco product authority to ENDS, among other products (81 FR 28973). In the same issue of the **Federal Register**, FDA concurrently announced the availability of the draft guidance, ''Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request'' (81 FR 28781). FDA received comments on the draft guidance and those comments were considered as the guidance was finalized. Changes made as a result of public comments include recommendations for constituent testing, single applications for new tobacco products that an applicant intends to market as a modified risk tobacco product, and the number batches and replicates related to product testing.

Under section 910 of the FD&C Act (21 U.S.C. 387j), persons seeking to market a new tobacco product (as defined in section 910(a)(1) of the FD&C Act) must first submit a PMTA to FDA and obtain a marketing authorization order, unless FDA has issued an order that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, or the new tobacco product is exempt from demonstrating substantial equivalence pursuant to the reasons outlined in section 905(j)(3) of the FD&C Act (21 U.S.C. 387e(j)(3)). ENDS products, the subject of this guidance, likely would be considered new tobacco products. Given the relatively new presence of ENDS on the U.S. market, FDA anticipates that many manufacturers of these new tobacco products will seek a marketing authorization order by filing a PMTA. This guidance explains, among other things, when a PMTA is required, general procedures for review of an ENDS PMTA, what information the FD&C Act requires applicants to submit in a PMTA, and what information FDA recommends applicants submit in an ENDS PMTA to show whether permitting such new tobacco product to be marketed is appropriate for the protection of the public health.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on PMTAs for ENDS. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 1107.1 have been approved under OMB control number 0910–0768.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at either *https://www.regulations.gov* or *https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance.*

Dated: June 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12389 Filed 6–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 171

[Docket ID: DOD–2018–OS–0051]

RIN 0790–AK42

Wildfire Suppression Aircraft Transfer Act of 1996

AGENCY: Office of the Assistant Secretary of Defense for Sustainment, DoD.

ACTION: Final rule.

SUMMARY: This final rule removes the DoD regulation which implemented law authorizing the sale of aircraft and aircraft parts to entities that contract with the Federal government for the delivery of fire retardant by air in order to suppress wildfire. This authorization has since expired. Existing statutory authorities allow the sale or transfer of aircraft and aircraft parts to Fire Fighter

Agencies, rendering this part obsolete and unnecessary.

DATES: This rule is effective on June 12, 2019.

FOR FURTHER INFORMATION CONTACT: Lt. Col. Shonry Webb at 571–372–5217.

SUPPLEMENTARY INFORMATION: It has been determined that publication of this CFR part removal for public comment is impracticable, unnecessary, and contrary to public interest since it is removing obsolete information. This rule implemented the Wildfire Suppression Aircraft Transfer Act of 1996. The law authorized DoD, during the period October 1996 through September 2005, to sell aircraft and aircraft parts to entities that contract with the Federal government for the delivery of fire retardant by air in order to suppress wildfire. This authorization was extended from October 2012 through September 2017, but it has since expired. Existing authorities in 10 U.S. Code 2576—Surplus military equipment: Sale to state and local law enforcement, firefighting, homeland security, and emergency management agencies, allow the sale or transfer of aircraft and aircraft parts to Fire Fighter Agencies. This part is obsolete and unnecessary.

This rule is not significant under Executive Order (E.O.) 12866, ''Regulatory Planning and Review,'' therefore, the requirements of E.O. 13771, ''Reducing Regulation and Controlling Regulatory Costs'' do not apply.

List of Subjects in 32 CFR Part 171

Fire prevention.

PART 171—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 171 is removed.

Dated: June 7, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–12354 Filed 6–11–19; 8:45 am]

BILLING CODE 5001–06–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2018–0371; FRL–9995–06–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; District of Columbia; Administrative Corrections and Emissions Statements Certification for the 2008 Ozone National Ambient Air Quality Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving two state implementation plan (SIP) revisions submitted by the District of Columbia (the District). Under the Clean Air Act (CAA), states' SIPs must require stationary sources in ozone nonattainment areas to report annual emissions of nitrogen oxides (NO_X) and volatile organic compounds (VOC). The District formally submitted, as a SIP revision, a statement certifying that the District's existing SIP-approved emissions statements program satisfies these CAA requirements for the 2008 ozone National Ambient Air Quality Standards (NAAQS). Upon review of the District's submittal, EPA noted minor discrepancies between the District's SIP-approved provisions, including the provision containing the District's emissions statements requirements, and the current edition of the District of Columbia Municipal Regulations (DCMR) referenced in the District's submittal. Therefore, to correct these minor discrepancies and update the District's SIP, the District also formally submitted a revised edition of the sections of the DCMR which addresses the discrepancies. EPA is proposing to approve the District's SIP with the current edition of these SIP-approved provisions. EPA is also proposing to approve the District's emissions statements program certification for the 2008 ozone NAAQS. EPA is proposing to approve these SIP revisions in accordance with the requirements of the CAA.

DATES: This final rule is effective on July 12, 2019.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2018–0371. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Sara Calcinore, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2043. Ms. Calcinore can also be reached via electronic mail at *calcinore.sara@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under the CAA, EPA establishes NAAQS for criteria pollutants in order to protect human health and the environment. In response to scientific evidence linking ozone exposure to adverse health effects, EPA promulgated the first ozone NAAQS, the 0.12 parts per million (ppm) 1-hour ozone NAAQS, in 1979. See 44 FR 8202 (February 8, 1979). The CAA requires EPA to review and reevaluate the NAAQS every five years in order to consider updated information regarding the effects of the criteria pollutants on human health and the environment. On July 18, 1997, EPA promulgated a revised ozone NAAQS, referred to as the 1997 ozone NAAQS, of 0.08 ppm averaged over eight hours. See 62 FR 38855. This 8-hour ozone NAAQS was determined to be more protective of public health than the previous 1979 1-hour ozone NAAQS. In 2008, EPA strengthened the 8-hour ozone NAAQS from 0.08 to 0.075 ppm. The 0.075 ppm standard is referred to as the 2008 ozone NAAQS. See 73 FR 16436 (March 27, 2008).

On May 21, 2012 and June 11, 2012, EPA designated nonattainment areas for the 2008 ozone NAAQS. 77 FR 30088 and 77 FR 34221. Effective July 20, 2012, the Washington, DC–MD–VA area was designated as marginal nonattainment for the 2008 ozone NAAQS. The Washington, DC–MD–VA marginal nonattainment area includes the District of Columbia. 40 CFR 81.309.

Section 182 of the CAA identifies additional plan submissions and requirements for ozone nonattainment areas. Specifically, section 182(a)(3)(B) of the CAA requires that states develop and submit, as a revision to their SIP,