the total for each type of transaction in which they engaged.

(i) *Voluntary reporting of insurance transactions.* If, during calendar year 2018, total transactions were $2 million or less in each of the insurance categories covered by the survey, on an accrual basis, the U.S. insurance company may, in addition to providing the required total for each type of transaction, voluntarily report transactions at a country and affiliation level of detail on the applicable mandatory schedule(s).

(ii) [Reserved]

(3) *Exemption claims.* Any U.S. person that receives the BE–140 survey form from BEA, but is not subject to the reporting requirements, must file an exemption claim by completing the determination of reporting status section of the BE–140 survey and returning it to BEA by the due date of the survey. The requirement in this paragrpah (b)(3) is necessary to ensure compliance with reporting requirements and efficient administration of the Act by eliminating unnecessary follow-up contact.

(d) *Covered types of insurance services.* Insurance services covered by the BE–140 survey consist of transactions between U.S. insurance companies and foreign persons for:

(1) Premiums earned on reinsurance assumed from companies resident abroad;

(2) Losses incurred on reinsurance assumed from companies resident abroad;

(3) Premiums paid for reinsurance ceded to companies resident abroad;

(4) Losses recovered on reinsurance ceded to companies resident abroad;

(5) Premiums earned from direct insurance sold to foreign persons;

(6) Losses incurred on direct insurance sold to foreign persons;

(7) Receipts for auxiliary insurance services provided to foreign persons; and

(8) Payments for auxiliary insurance services provided by foreign persons.

(e) *Types of transactions excluded from the scope of this survey.* Premiums paid to, or losses received from, foreign insurance companies on direct insurance.

(f) *Due date.* A fully completed and certified BE–140 report, or qualifying exemption claim with the determination of reporting status section completed, is due to be filed with BEA not later than September 30, 2019.

[FR Doc. 2019–12373 Filed 6–11–19; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA–2015–D–2496]

Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry entitled ''Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Guidance for Industry.'' Given the relatively new presence of electronic nicotine delivery systems (ENDS) on the U.S. market and FDA's final rule deeming these products to be subject to the tobacco product authorities in the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA expects to receive premarket tobacco product application (PMTA) submissions from manufacturers of ENDS. This guidance is intended to assist applicants to prepare PMTAs for ENDS products.

DATES: The announcement of the guidance is published in the **Federal Register** on June 12, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2015–D–2496 for ''Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Guidance for Industry.'' 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.

- 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.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]

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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