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1. FDA. Submission of Food and Drug Administration Import Data in the Automated Commercial Environment. **Federal Register** (Docket No. FDA-2016-N-1487). Online November 29, 2016. Cited: January 31, 2017. <https://www.federalregister.gov/documents/2016/11/29/2016-28582/submission-of-food-and-drug-administration-import-data-in-the-automated-commercial-environment>.
2. FDA. Submission of Food and Drug Administration Import Data in the Automated Commercial Environment (Final Rule) Regulatory Impact Analysis. Economic Impact Analyses of FDA Regulations. Online November 29, 2016. Cited: January 31, 2017. <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm530862.htm>.
3. FDA. Office of Regulatory Affairs Reporting, Analysis, and Decision Support System (ORADSS). 2015-2017 data.

#### List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 1 be amended as follows:

#### PART 1—GENERAL ENFORCEMENT REGULATIONS

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

**Authority:** 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 373, 374, 379j-31, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107-188, 116 Stat. 594, 668-69; Pub. L. 111-353, 124 Stat. 3885, 3889.

- 2. Amend § 1.71 by adding in alphabetical order the definition for “Veterinary device” to read as follows:

#### § 1.71 Definitions.

\* \* \* \* \*

*Veterinary device* means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, that is intended for use in animals.

\* \* \* \* \*

- 3. Revise § 1.72 introductory text to read as follows:

#### § 1.72 Data elements that must be submitted in ACE for articles regulated by FDA.

*General.* When filing an entry in ACE, the ACE filer shall submit the following information for food contact substances, drugs, biological products, HCT/Ps, medical devices, veterinary devices, radiation-emitting electronic products, cosmetics, and tobacco products.

\* \* \* \* \*

- 4. Revise § 1.75 to read as follows:

#### § 1.75 Animal drugs and veterinary devices.

(a) *Animal drugs.* In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE for animal drugs:

(1) *Registration and listing.* For a drug intended for animal use, the Drug Registration Number and the Drug Listing Number if the foreign establishment where the drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States is required to register and list the drug under part 207 of this chapter. For the purposes of this section, the Drug Registration Number that must be submitted in ACE at the time of entry is the Unique Facility Identifier of the foreign establishment where the animal drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The Unique Facility Identifier is the identifier submitted by a registrant in accordance with the system specified under section 510(b) of the Federal Food, Drug, and Cosmetic Act. For the purposes of this section, the Drug Listing Number is the National Drug Code number of the animal drug article being imported or offered for import.

(2) *New animal drug application number.* For a drug intended for animal use that is the subject of an approved application under section 512 of the Federal Food, Drug, and Cosmetic Act, the number of the new animal drug application or abbreviated new animal drug application. For a drug intended for animal use that is the subject of a conditionally approved application under section 571 of the Federal Food, Drug, and Cosmetic Act, the application number for the conditionally approved new animal drug.

(3) *Veterinary minor species index file number.* For a drug intended for use in animals that is the subject of an Index

listing under section 572 of the Federal Food, Drug, and Cosmetic Act, the Minor Species Index File number of the new animal drug on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.

(4) *Investigational new animal drug file number.* For a drug intended for animal use that is the subject of an investigational new animal drug or generic investigational new animal drug file under part 511 of this chapter, the number of the investigational new animal drug or generic investigational new animal drug file.

(b) *Veterinary devices.* An ACE filer must submit the data specified in § 1.72 at the time of filing entry in ACE for veterinary devices.

Dated: July 2, 2020.

**Stephen M. Hahn,**

*Commissioner of Food and Drugs.*

In concurrence with FDA:

Dated: July 2, 2020.

**Timothy E. Skud,**

*Deputy Assistant Secretary (Tax, Trade, and Tariff Policy), Department of the Treasury.*

[FR Doc. 2020-15571 Filed 7-31-20; 8:45 am]

**BILLING CODE 4164-01-P**

## POSTAL SERVICE

### 39 CFR Part 113

#### New Mailing Standards for the Separation of Hazardous Materials

**AGENCY:** Postal Service™.

**ACTION:** Proposed revision; request for comment.

**SUMMARY:** The Postal Service proposes to amend Publication 52, *Hazardous, Restricted, and Perishable Mail* (Pub 52), to incorporate requirements for mailers to separate all air-eligible hazardous material (HAZMAT) from surface only transportation HAZMAT shipments and other non-HAZMAT items when tendering mail to the Postal Service in the domestic mail. Air eligible products, services or classes include Priority Mail Express®, Priority Mail®, First-Class Package Service®, Priority Mail Return Service® or First-Class Package Return Service® and surface only transportation are mail using Parcel Select®, Parcel Select Lightweight®, USPS Retail Ground®, or USPS Ground Return Service®. Additionally, the Postal Service for consistency will incorporate the current standard operating procedures for separation as it pertains to acceptance and dispatch personnel.

**DATES:** We must receive your comments on or before September 2, 2020.

**ADDRESSES:** Mail or deliver written comments to the Manager, Product Classification, U.S. Postal Service, 475 L'Enfant Plaza SW, Room 4446, Washington, DC 20260-5015. If sending comments by email, include the name and address of the commenter and send to [PCFederalRegister@usps.gov](mailto:PCFederalRegister@usps.gov), with a subject line of "HAZMAT Separation". Faxed comments will not be accepted. All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

You may inspect and photocopy all written comments, by appointment only, at USPS® Headquarters Library, 475 L'Enfant Plaza SW, 11th Floor North, Washington, DC 20260. These records are available for review Monday through Friday, 9 a.m. to 4 p.m. by calling 202-268-2906.

**FOR FURTHER INFORMATION CONTACT:** Dale Kennedy (202) 268-6592 or Mary Collins (202) 268-5551.

**SUPPLEMENTARY INFORMATION:** The Postal Service is proposing to amend PUB 52 with the provisions described below and, once adopted, will incorporate the revised PUB 52 by reference into part 113. You may view the text of the proposed edits to PUB 52 at: <https://pe.usps.com/>.

Air carriers are required to review HAZMAT shipments and complete HAZMAT checklists at the time of acceptance to mitigate risk to aviation. The Postal Service tenders mail, including packages containing both non-hazardous and hazardous materials to its contracted air carriers in sealed containers. Due to the sealed nature of the containers, air carriers are often unaware of the specific hazardous materials they are accepting and transporting. In order to facilitate the review of tendered items, certain air carriers require the Postal Service to separate HAZMAT mail from non-HAZMAT mail and tender the items at a specific time of day.

The Postal Service HAZMAT standard operating procedures state air-eligible HAZMAT must be separated with appropriate documentation from other non-HAZMAT mail for air transportation. The proposed change will require mailers to separate all air-eligible HAZMAT prior to acceptance to allow these pieces to flow in a more efficient manner and prevent co-mingled packages of surface only transportation HAZMAT and non-

HAZMAT mail when tendered to air carriers.

**Brittany Johnson,**

*Attorney, Federal Compliance.*

[FR Doc. 2020-15774 Filed 7-31-20; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R03-OAR-2020-0268; FRL-10011-85-Region 3]

### Air Plan Approval; Pennsylvania; 1997 8-Hour Ozone NAAQS Second Maintenance Plan for the Franklin County Area

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the Commonwealth of Pennsylvania. This revision pertains to the Commonwealth's plan, submitted by the Pennsylvania Department of Environmental Protection (DEP), for maintaining the 1997 8-hour ozone national ambient air quality standard (NAAQS) (referred to as the "1997 ozone NAAQS") in the Franklin County, Pennsylvania area (Franklin County Area). This action is being taken under the Clean Air Act (CAA).

**DATES:** Written comments must be received on or before September 2, 2020.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R03-OAR-2020-0268 at <https://www.regulations.gov>, or via email to [spielberger.susan@epa.gov](mailto:spielberger.susan@epa.gov). For comments submitted at [Regulations.gov](https://www.regulations.gov), follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [Regulations.gov](https://www.regulations.gov). For either manner of submission, 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. 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 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:

David Talley, 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) 814-2117. Mr. Talley can also be reached via electronic mail at [talley.david@epa.gov](mailto:talley.david@epa.gov).

**SUPPLEMENTARY INFORMATION:** On March 10, 2020, DEP submitted a revision to the Pennsylvania SIP to incorporate a plan for maintaining the 1997 ozone NAAQS in the Franklin County Area through July 25, 2027, in accordance with CAA section 175A.

## I. Background

In 1979, under section 109 of the CAA, EPA established primary and secondary NAAQS for ozone at 0.12 parts per million (ppm), averaged over a 1-hour period. 44 FR 8202 (February 8, 1979). On July 18, 1997 (62 FR 38856),<sup>1</sup> EPA revised the primary and secondary NAAQS for ozone to set the acceptable level of ozone in the ambient air at 0.08 ppm, averaged over an 8-hour period. EPA set the 1997 ozone NAAQS based on scientific evidence demonstrating that ozone causes adverse health effects at lower concentrations and over longer periods of time than was understood when the pre-existing 1-hour ozone NAAQS was set.

Following promulgation of a new or revised NAAQS, EPA is required by the CAA to designate areas throughout the nation as attaining or not attaining the NAAQS. On April 30, 2004 (69 FR 23858), EPA designated Franklin County as nonattainment for the 1997 ozone NAAQS.

Once a nonattainment area has three years of complete and certified air quality data that has been determined to attain the NAAQS, and the area has met

<sup>1</sup>In March 2008, EPA completed another review of the primary and secondary ozone standards and tightened them further by lowering the level for both to 0.075 ppm. 73 FR 16436 (March 27, 2008). Additionally, in October 2015, EPA completed a review of the primary and secondary ozone standards and tightened them by lowering the level for both to 0.70 ppm. 80 FR 65292 (October 26, 2015).