§ 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.

(a) *Product identifying information* for the article that is being imported or offered for import. This consists of:

(1) *FDA Country of Production,* which is the country where the article was last manufactured, processed, or grown (including harvested, or collected and readied for shipment to the United States). The FDA Country of Production for an article that has undergone any manufacturing or processing is the country where that activity occurred provided that the manufacturing or processing had more than a minor, negligible, or insignificant effect on the article.

(2) *The Complete FDA Product Code,* which must be consistent with the invoice description of the product.

(3) *The Full Intended Use Code.*

(b) *Importer of record contact information,* which is the telephone and email address of the importer of record.

[81 FR 85870, Nov. 29, 2016, as amended at 87 FR 62984, Oct. 18, 2022]

§ 1.73 Food.

(a) *Food contact substances.* An ACE filer must submit the information specified in § 1.72 at the time of filing entry in ACE for food that is a food contact substance.

(b) *Low-acid canned food.* For an article of food that is a low-acid canned food, the ACE filer must submit at the time of filing entry the Food Canning Establishment Number and the Submission Identifier, and can dimensions or volume, except that the ACE filer does not need to submit this information in ACE at the time of entry if the article is being imported or offered for import for laboratory analysis only and will not be taste tested or otherwise ingested.

(c) *Acidified food.* For an article of food that is an acidified food, the ACE filer must submit at the time of filing entry the Food Canning Establishment Number and the Submission Identifier, and can dimensions or volume, except that the ACE filer does not need to submit this information in ACE at the time of entry if the article is being imported or offered for import for laboratory analysis only and will not be taste tested or otherwise ingested.

§ 1.74 Human 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 drugs, including biological products and eligible prescription drugs as defined in § 251.2 of this chapter that are imported or offered for import under section 804 of the Federal Food, Drug, and Cosmetic Act, intended for human use that are regulated by the FDA Center for Drug Evaluation and Research.

(a) For a drug intended for human use that is not an eligible prescription drug covered under paragraph (b) of this section:

(1) *Registration and listing.* The Drug Registration Number and the Drug Listing Number of the foreign establishment where the human 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 at the time of entry filing in ACE is the unique facility identifier of the foreign establishment where the human 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 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 human drug article being imported or offered for import.

(2) *Drug application number.* For a drug intended for human use that is the subject of an approved application

under section 505(b) or 505(j) of the Federal Food, Drug, and Cosmetic Act, the number of the new drug application or abbreviated new drug application. For a biological product regulated by the FDA Center for Drug Evaluation and Research that is required to have an approved biologics license application, the number of the applicable application.

(3) *Investigational new drug application number*. For a drug intended for human use that is the subject of an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act, the number of the investigational new drug application.

(b) For an eligible prescription drug as defined in §251.2 of this chapter that is imported or offered for import under section 804 of the Federal Food, Drug, and Cosmetic Act:

(1) *Registration and listing*. The Drug Registration Number and the Drug Listing Number. For the purposes of this section, the Drug Registration Number that must be submitted in ACE is the unique facility identifier submitted by the Foreign Seller registrant under §251.9 of this chapter in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act. For the purposes of this section, the Drug Listing Number is the National Drug Code number that the Importer will use when relabeling the eligible prescription drug as required in §251.13 of this chapter.

(2) *Drug application number*. The number of the new drug application or abbreviated new drug application for the counterpart FDA-approved drug.

(3) *Lot or control number*. The lot or control number assigned by the manufacturer of the eligible prescription drug.

(4) *FDA Quantity*. FDA Quantity, which is the quantity of each eligible prescription drug in an import line delineated by packaging level, including the type of package from the largest packaging unit to the smallest packaging unit; the quantity of each packaging unit; and the volume and/or weight of each of the smallest of the packaging units.

(5) *Pre-Import Request number*. The Pre-Import Request number assigned by FDA.

[85 FR 62125, Oct. 1, 2020, as mended at 86 FR 17060, Apr. 1, 2021]

§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