

§ 1.90 Notice of sampling.

When a sample of an article offered for import has been requested by the district director, FDA shall provide to the owner or consignee prompt notice of delivery of, or intention to deliver, such sample. Upon receipt of the notice, the owner or consignee shall hold such article and not distribute it until further notice from the district director or U.S. Customs and Border Protection of the results of examination of the sample.

■ 5. In § 1.94, revise the first sentence of paragraphs (a) and (c) to read as follows:

§ 1.94 Hearing on refusal of admission or destruction.

(a) If it appears that the article may be subject to refusal of admission, or that the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the district director shall give the owner or consignee a written or electronic notice to that effect, stating the reasons therefor. * * *

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(c) If the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the district director may give the owner or consignee a single written or electronic notice that provides the notice of refusal of admission and the notice of destruction of an article described in paragraph (a) of this section. * * *

PART 1005—IMPORTATION OF ELECTRONIC PRODUCTS

■ 6. The authority citation for part 1005 continues to read as follows:

Authority: 21 U.S.C. 360ii, 360mm.

■ 7. Revise § 1005.2 to read as follows:

§ 1005.2 Definitions.

As used in this part:

The term *owner* or *consignee* means the person who makes entry under the provisions of section 484 of the Tariff Act of 1930, as amended (19 U.S.C. 1484), namely, the “importer of record.”

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

■ 8. The authority citation for part 1271 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 263a, 264, 271.

■ 9. In § 1271.420, revise paragraph (a) to read as follows:

§ 1271.420 HCT/Ps offered for import.

(a) Except as provided in paragraphs (c) and (d) of this section, when an

HCT/P is offered for import, the importer of record must notify, either before or at the time of importation, the director of the district of the Food and Drug Administration (FDA) having jurisdiction over the port of entry through which the HCT/P is imported or offered for import, or such officer of the district as the director may designate to act in his or her behalf in administering and enforcing this part, and must provide sufficient information, including information submitted in the Automated Commercial Environment (ACE) system or any other electronic data interchange system authorized by the U.S. Customs and Border Protection Agency as required in part 1, subpart D of this chapter, for FDA to make an admissibility decision.

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Dated: November 21, 2016.

Leslie Kux,

Associate Commissioner for Policy, Food and Drug Administration.

In concurrence with FDA:

Dated: November 21, 2016.

Timothy E. Skud,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 558**

[Docket No. FDA–2016–N–1896]

New Animal Drugs for Use in Animal Feed; Category Definitions; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of December 1, 2016, for the final rule that appeared in the *Federal Register* of August 24, 2016. The direct final rule amends the animal drug regulations by revising the definitions of the two categories of new animal drugs used in medicated feeds to base category assignment only on approved uses in major animal species. This document confirms the effective date of the direct final rule.

DATES: Effective date of final rule published in the *Federal Register* of August 24, 2016 (81 FR 57796) confirmed: December 1, 2016.

FOR FURTHER INFORMATION CONTACT:

David Edwards, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6205.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of August 24, 2016 (81 FR 57796), FDA solicited comments concerning the direct final rule for a 75-day period ending November 7, 2016. FDA stated that the effective date of the direct final rule would be on December 1, 2016, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Authority: Therefore, under the animal drug provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 354, 360b, 360ccc, 360ccc–1, and 371), and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 558 is amended. Accordingly, the amendments issued thereby are effective.

Dated: November 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF JUSTICE**Drug Enforcement Administration****21 CFR Part 1308**

[Docket No. DEA–448]

Schedules of Controlled Substances: Temporary Placement of Furanyl Fentanyl Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this final order to temporarily schedule the synthetic opioid, *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-2-carboxamide (furanyl fentanyl), and its isomers, esters, ethers, salts and salts of isomers, esters and ethers, into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of furanyl fentanyl into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed