

above, pursuant to 5 U.S.C. 553(b)(B), notice and public procedure are unnecessary. Since this document is not subject to the notice and public procedure requirements of 5 U.S.C. 553, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Further, this document does not meet the criteria for a "significant regulatory action" as specified in Executive Order 12866.

#### List of Subjects in 19 CFR Part 133

Copyrights, Counterfeit goods, Customs duties and inspection, Imports, Penalties, Prohibited merchandise, Reporting and recordkeeping requirements, Restricted merchandise, Seizures and forfeitures, Trademarks, Trade names, Unfair competition.

#### Amendment to the Regulations

For the reasons stated above, part 133 of the Customs Regulations (19 CFR part 133) is amended as set forth below:

#### PART 133—TRADEMARKS, TRADE NAMES, AND COPYRIGHTS

1. The general authority citation for part 133 continues to read as follows:

**Authority:** 17 U.S.C. 101, 601, 602, 603; 19 U.S.C. 66, 1624; 31 U.S.C. 9701.

\* \* \* \* \*

#### § 133.42 [Amended]

2. In § 133.42, the third sentence of paragraph (c) is amended by removing the words " , unless the article may be returned to the country of export as provided in § 133.47".

#### § 133.44 [Amended]

3. In § 133.44, the first sentence of paragraph (a) is amended by removing the word "either" and the words "or, if the conditions prescribed by § 133.47 are met, permit the importer to return the article to the country of export". In the last sentence, the words "In either event, the" are removed and the word "The" is added in their place.

#### § 133.47 [Removed]

4. Section 133.47 is removed.

**Samuel H. Banks,**

*Acting Commissioner of Customs.*

Approved: March 24, 1997.

**John P. Simpson,**

*Deputy Assistant Secretary of the Treasury.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 5

#### Delegations of Authority and Organization

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending regulations for delegations of authority to allow the Director of the Center for Drug Evaluation and Research (CDER) and the Director of the Office of Compliance, CDER, to grant or deny a request, submitted in the form of a citizen petition under its pertinent regulations, for an exception or alternative to applicable current good manufacturing practice (CGMP) requirements for positron emission tomography (PET) drug products. This action is necessary to allow CDER to be able to grant an exception or alternative to applicable CGMP requirements for PET drug products when the request is made in a citizen petition.

**EFFECTIVE DATE:** April 28, 1997.

#### FOR FURTHER INFORMATION CONTACT:

Robert K. Leedham, Center for Drug Evaluation and Research (HFD-343), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1026, or

Donna G. Page, Division of Management Systems and Policy (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301-827-4816.

**SUPPLEMENTARY INFORMATION:** A final rule providing the Director and the Director of the Office of Compliance, CDER, with the authority to grant requested exceptions and alternatives to requirements in 21 CFR part 211 pertaining to CGMP's for PET radiopharmaceutical drug products is published elsewhere in this issue of the **Federal Register**. This delegation allows these two agency officials to grant or deny such requests when submitted in the form of a citizen petition under 21 CFR 10.30.

Further redelegation of the authorities delegated is authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

#### List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority of the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

#### PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

**Authority:** 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261-1282, 3701-3711a; secs. 2-12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); 21 U.S.C. 41-50, 61-63, 141-149, 467f, 679(b), 801-886, 1031-1309; secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701-1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u-300u-5, 300aa-1); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007-10008; E.O. 11490, 11921, and 12591.

2. Section 5.31 is amended by adding new paragraph (h) to read as follows:

#### § 5.31 Petitions under part 10.

\* \* \* \* \*

(h) The Director and the Director of the Office of Compliance, CDER, are each authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter requesting an exception or alternative to any requirement in part 211 of this chapter pertaining to current good manufacturing practice for positron emission tomography radiopharmaceutical drug products.

Dated: April 15, 1997.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 211

[Docket No. 94N-0421]

RIN 0910-AA45

#### Current Good Manufacturing Practice for Finished Pharmaceuticals; Positron Emission Tomography

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.