Chaplain tools;
Fishing supplies (lead sinkers, hooks, barrels, try works);
Cooper's tools; and
Blacksmith's tools.

E. Ship's Cargo:
Raw metal (iron, copper, bronze, lead);
Wood;
Ceramics;
Glassware (fine glass decanters);
Trade beads;
Containers (casks, baskets); and
Stone (for building or ballast).

F. Personal Goods Found on Ships:
Jewelry (gold, silver, stone);
Coins;
Gaming pieces (dice);
Buckles and buttons;
Chests;
Combs;
Pipes;
Religious items;
Timepieces;
Bedding, clothing and other textiles; and
Shoes.

Inapplicability of Notice and Delayed Effective Date

Because this amendment is being made in response to a bilateral agreement entered into in furtherance of the foreign affairs interests of the United States, pursuant to § 553(a)(1) of the Administrative Procedure Act, no notice of proposed rulemaking or public procedure is necessary. For the same reason, a delayed effective date is both impracticable and contrary to the public interest.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. Accordingly, this final rule is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Executive Order 12866

This amendment does not meet the criteria of a ''significant regulatory action'' as described in E.O. 12866.

Drafting Information

The principal author of this document was Peter T. Lynch, Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 12

Customs duties and inspections, Imports, Cultural property.

Amendment to the Regulations

Accordingly, Part 12 of the Customs Regulations (19 CFR Part 12) is amended as set forth below:

PART 12—[AMENDED]

1. The general authority and specific authority citation for Part 12, in part, continue to read as follows:

Sections 12.104—12.104i also issued under 19 U.S.C. 2612.

Authority: 5 U.S.C. 301, 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624.

* * * * *

§ 12.104g [Amended]

2. In § 12.104g, paragraph (a), the listing of agreements imposing import restrictions on described articles of cultural property of State Parties is amended by adding ''Canada'' in appropriate alphabetical order under the column headed ''State Party'', and adding adjacent to the listing of ''Canada'' the description ''Archaeological Artifacts and Ethnological Material Culture of Canadian Origin'' under the column headed ''Cultural Property'' and the reference ''T.D. 97–31'' under the column headed ''T.D. No.''

George J. Weise,

Commissioner of Customs.

Approved: April 9, 1997.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 97–10504 Filed 4–21–97; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 133

[T.D. 97–30]

RIN 1515–AC09

Disposition of Excluded Articles Pursuant to the Anticounterfeiting Consumer Protection Act

AGENCY: Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations to implement section 8 of the Anticounterfeiting Consumer Protection Act of 1996 (ACPA), which was enacted by Congress to protect consumers and American businesses from counterfeit copyrighted and trademarked products. Section 8 of the ACPA concerns the disposition of excluded articles and eliminates a statutory provision that allowed infringing imported goods to be returned to the country of export whenever it is shown that the importer had no reasonable grounds for believing his or her acts constituted a violation of law. The statutory amendment now requires government officials to destroy such goods. The regulatory change reflects the statutory amendment and is designed to help Customs fight counterfeiting more effectively.

EFFECTIVE DATE: May 22, 1997.

FOR FURTHER INFORMATION CONTACT: John Atwood, Intellectual Property Rights Branch, Office of Regulations and Rulings, (202) 482–6960.

SUPPLEMENTARY INFORMATION:

Background

Finding that counterfeit products cost American businesses an estimated $200 billion each year worldwide, Congress enacted the Anticounterfeiting Consumer Protection Act of 1996 (ACPA) to make sure that Federal law adequately addresses the scope and sophistication of modern counterfeiting. The provisions of the ACPA are designed to provide important weapons in the fight against counterfeiters. On July 2, 1996, the President signed the ACPA into law (Pub.L. 104–153, 110 Stat. 1386).

The ACPA contains 13 substantive sections, which will be implemented in several **Federal Register** documents. This document concerns section 8 of the ACPA, which amends title 17 of the United States Code (17 U.S.C. 603(c)), which concerns the enforcement of anti-counterfeiting laws and disposition of excluded articles. The amendment of section 603(c) removes a provision that allowed infringing imported goods to be returned to the country of export whenever it is shown that the importer had no reasonable grounds for believing his or her acts constituted a violation of law. By eliminating this provision in section 603(c), government officials are now required to destroy such goods.

The provisions of section 603(c) are provided for at §§ 133.42(c), 133.44(a), and 133.47 of the Customs Regulations (19 CFR 133.42(c), 133.44(a), and 133.47). Accordingly, these regulatory provisions are amended by removing the language which allows for the return of seized infringing merchandise to the importer or country of export.

Inapplicability of the Regulatory Flexibility Act, And Executive Order 12866

Inasmuch as these amendments merely conform the Customs Regulations to existing law as discussed

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.

[FR Doc. 97–10272 Filed 4–21–97; 8:45 am]

BILLING CODE 4820–02–P

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.

[FR Doc. 97–10340 Filed 4–21–97; 8:45 am]

BILLING CODE 4160–01–F

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.