CAUTION: Do not interrupt the automatic sequence of operation of the leading edge de-ice boots once it is turned ON. The system should be turned OFF only after leaving the icing conditions and after the protected surfaces of the wing are free of ice.

(b) Within 10 months after the effective date of this AD, install an ice detector in accordance with EMBRAER Service Bulletin No.: 120–30–0027, dated May 9, 1997.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Atlanta ACO. Operators shall submit their requests through an appropriate FAA Principal Operations Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Atlanta ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) The installation of the ice detector shall be done in accordance with EMBRAER Service Bulletin No. 120–30–0027, dated May 9, 1997. This incorporation by reference was approved by the Director of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from EMBRAER, Empresa Brasileira De Aeronautica S/A, Sao Jose Dos Campos, Brazil. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the **Federal Register**, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on January 23, 1998.

Issued in Renton, Washington, on December 11, 1997.

Gilbert L. Thompson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–33000 Filed 12–18–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 4

[T.D. 98–3]

RIN 1515—AC27

Addition of Hong Kong to the List of Nations Entitled to Special Tonnage Tax Exemption

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: Pursuant to information provided by the Department of State, the United States Customs Service has found that Hong Kong does not impose or levy any discriminating duties of tonnage or imposts upon vessels wholly belonging to citizens of the United States, or upon the produce, manufactures, or merchandise imported in these vessels from the United States or any foreign country and that, accordingly, vessels of Hong Kong are exempt from the payment of special tonnage taxes and light money in ports of the United States. This document amends the Customs Regulations by adding Hong Kong to the list of nations whose vessels are exempt from the payment of any higher tonnage duties than are applicable to vessels of the United States and from the payment of light money.

EFFECTIVE DATE: The amendment to the 19 CFR 4.22 is effective on December 19, 1997. The exemption from special tonnage tax and light money for vessels registered in Hong Kong became effective on July 1, 1997.

FOR FURTHER INFORMATION CONTACT: Craig Clark, Entry and Carrier Rulings Branch (202) 927–2320.

SUPPLEMENTARY INFORMATION:

Background

Generally, the United States imposes regular and special tonnage taxes, and a duty of a specified amount per ton denominated ''light money'', on all foreign vessels which enter United States ports (46 U.S.C. App. 121 and 128). Vessels of a foreign nation, however, may be exempted from the payment of such special tonnage taxes and light money upon presentation of satisfactory proof that no discriminatory duties of tonnage or impost are imposed by that foreign nation on United States vessels or their cargoes (46 U.S.C. App. 141). The list of nations whose vessels have been found to be reciprocally exempt from the payment of any higher tonnage duties than are applicable to vessels of the United States and from the payment of light money is found at § 4.22, Customs Regulations (19 CFR 4.22). Nations granted these commercial privileges that subsequently impose discriminatory duties are subject to retaliatory suspension of the commercial privileges (46 U.S.C. App. 141 and 142).

Treatment of Hong Kong

On July 1, 1997, Hong Kong became a Special Administrative Region of the People's Republic of China. Before that date, vessels from Hong Kong had an exemption from special tonnage tax by virtue of Hong Kong's status as a British colony.

The Department of State has requested that Customs add Hong Kong to the list of nations under § 4.22 in order that vessels from Hong Kong receive the same treatment as they did prior to July 1, 1997. In addition, the Department of State has submitted information regarding the absence of discriminatory duties of tonnage or impost imposed on U.S. vessels in the ports of Hong Kong.

The Department of State's request is consistent with the terms of section 2 of the Act of October 5, 1992, referred to as the United States-Hong Kong Policy Act (Pub. L. 102–383, 106 Stat. 1448) codified in title 22, United States Code, section 5701, *et seq.*, which embodies the policy of the United States applicable to dealing with Hong Kong following reversion, including trade and commerce matters. That law demonstrates that dealings with Hong Kong after June 30, 1997, are to be conducted without change until and unless the Administration (the President) makes a determination that different treatment is warranted.

Finding

Based on the request and information submitted by the Department of State, and based on 22 U.S.C. 5701, *et seq.*, in order that vessels from Hong Kong remain exempt from the payment of special tonnage tax following reversion, the Customs Service has determined that Hong Kong should be added to the list of nations contained in 19 CFR 4.22, effective July 1, 1997. The Customs Regulations are amended accordingly.

Inapplicability of Public Notice and Delayed Effective Date Requirements, the Regulatory Flexibility Act, and Executive Order 12866

Because this amendment merely implements a statutory requirement and confers a benefit upon the public, pursuant to 5 U.S.C. 553(b)(B), notice and public procedure are unnecessary; further, for the same reasons, good cause exists for dispensing with a delayed effective date under 5 U.S.C. 553(d)(1) and (3). 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.*). Furthermore, this amendment does not meet the criteria for a ''significant regulatory action'' as specified in Executive Order 12866.

List of Subjects in 19 CFR Part 4

Cargo vessels, Customs duties and inspection, Maritime carriers, Vessels.

Amendment to the Regulations

Part 4, Customs Regulations (19 CFR part 4), is amended as set forth below.

PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADES

1. The general authority for Part 4 and relevant specific authority continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1431, 1433, 1434, 1624; 46 U.S.C. App. 3, 91.

* * * * *

Section 4.22 also issued under 46 U.S.C. App. 121, 128, 141;

* * * * *

§ 4.22 [Amended]

2. Section 4.22 is amended by adding ''Hong Kong'' in appropriate alphabetical order.

Dated: December 15, 1997

Harold M. Singer,

Chief, Regulations Branch.

[FR Doc. 97–33169 Filed 12–18–97; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 211

[Docket No. 94N–0421]

Revocation of Regulation on Positron Emission Tomography Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; revocation.

SUMMARY: The Food and Drug Administration (FDA) is revoking a regulation on positron emission tomography (PET) radiopharmaceutical drug products. The regulation permits FDA to approve requests from manufacturers of PET drugs for exceptions or alternatives to provisions of the current good manufacturing practice (CGMP) regulations. FDA is taking this action in accordance with provisions of the Food and Drug Administration Modernization Act of 1997 (Modernization Act). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice revoking two notices concerning certain guidance documents on PET drugs and the guidance documents to which the notices relate.

EFFECTIVE DATE: December 21, 1997.

FOR FURTHER INFORMATION CONTACT: Brian L. Pendleton, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5649.

SUPPLEMENTARY INFORMATION: On November 21, 1997, President Clinton signed into law the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115). Section 121(c)(1)(A) of the Modernization Act directs FDA to develop appropriate procedures for the approval of PET drugs as well as CGMP requirements for such drugs, taking into account any relevant differences between not-for-profit institutions that compound PET drugs and commercial manufacturers. FDA is to establish these procedures and requirements not later than 2 years after the date of enactment. In doing so, the agency must consult with patient advocacy groups, professional associations, manufacturers, and persons licensed to make or use PET drugs.

Under section 121(c)(2) of the Modernization Act, FDA cannot require the submission of new drug applications or abbreviated new drug applications for compounded PET drugs that are not adulterated under section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) for a period of 4 years after the date of enactment, or 2 years after the date that the agency adopts special approval procedures and CGMP requirements for PET drugs, whichever is longer.

Section 121(d) of the Modernization Act requires FDA, within 30 days of enactment, to publish in the **Federal Register** a notice terminating the application of FDA's final rule, published in the **Federal Register** of April 22, 1997 (62 FR 19493), permitting the agency to approve requests from manufacturers of PET drug products for exceptions or alternatives to provisions of FDA's CGMP regulations (21 CFR 211.1(d)). FDA already has received one such request for an exception or alternative to the CGMP requirements for PET drugs in the form of a citizen petition submitted by Case Western Reserve University (CWRU) (Docket No. 97P–0198/CP1). As required by the Modernization Act, the final rule on exceptions and alternatives is hereby revoked, which also renders the CWRU citizen petition moot. The information and views presented in the CWRU citizen petition will be considered as a part of the rulemaking proceeding to establish appropriate CGMP requirements for PET drugs under section 121(c)(1)(A)(ii) of the Modernization Act.

Section 121(d) of the Modernization Act also directs FDA to terminate the application of two notices concerning certain guidance documents on PET drugs. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice revoking these two notices and the guidance documents to which the notices relate.

The revocation of the final rule on CGMP exceptions or alternatives for PET drugs is effective December 21, 1997.

In accordance with section 121(c)(1)(A) of the Modernization Act, FDA intends to begin the development of new PET drug approval procedures and CGMP requirements immediately and will obtain appropriate public input during this process.

List of Subjects in 21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 211 is amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

1. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 356, 357, 360b, 371, 374.

§ 211.1 [Amended]

2. Section 211.1 *Scope* is amended by removing paragraph (d).

Dated: December 16, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–33187 Filed 12–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Decoquinate and Bacitracin Zinc

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Alpharma Inc. The ANADA provides for using approved decoquinate and bacitracin zinc Type A medicated