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