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

articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency.

EFFECTIVE DATE: December 19, 1997.

FOR FURTHER INFORMATION CONTACT: Jeffrey M. Gilbert, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1602.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of ANADA 200–213 that provides for combining approved decoquinate and bacitracin zinc Type A medicated articles to make Type C medicated feeds for broilers containing decoquinate 27.2 grams per ton (g/t) and bacitracin zinc 10 to 50 g/t. The Type C medicated feed is used as an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for increased rate of weight gain; and improved feed efficiency.

ANADA 200–213, filed by Alpharma Inc., is approved as a generic copy of Rhone Poulenc's NADA 45–348. The ANADA is approved as of September 19, 1997, and the regulations are amended in the table in 21 CFR 558.195(d) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.195 [Amended]

2. Section 558.195 *Decoquinate* is amended in the table in paragraph (d), in the entry for ''27.2 (0.003 pct)'', in the second column, in the entry for ''Bacitracin 10 to 50'', under the column ''Limitations'' by removing ''No. 000061'' and adding in its place ''Nos. 046573 and 011716''.

Dated: December 8, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–33095 Filed 12–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 175

[DoD Instruction 4165.67]

RIN 0790–AF62

Revitalizing Base Closure Communities and Community Assistance

AGENCY: Department of Defense, Office of the Deputy Under Secretary of Defense (Industrial Affairs and Installations).

ACTION: Final rule.

SUMMARY: This rule establishes procedures for implementing section 2837 of the National Defense Authorization Act for FY96 concerning the Federal Agency leaseback of property transferred to Local Redevelopment Authorities (LRAs) at installations approved for closure or realignment, and informs communities affected by base closure of these procedures.

EFFECTIVE DATE: December 19, 1997.

FOR FURTHER INFORMATION CONTACT: Jennifer Atkin, Base Closure and Community Reinvestment Office, 400 Army-Navy Drive, Suite 200, Arlington, VA 22202, telephone (703) 604–2400.

SUPPLEMENTARY INFORMATION:

Regulatory History and Background Information

DoD published a proposed rule on February 21, 1997 (62 FR 7966) implementing section 2837 of the National Defense Authorization Act for FY96 (Pub. L. 104–106). Public comments were accepted until April 22, 1997. This final rule addresses the comments received on the proposed rule.

Discussion of Public Comments

During the public comment period, the Department received over 40 public comments from 14 sources, including numerous LRAs. The comments are summarized generically below. Changes that have been made to the rule in response to public comments are noted. The comments fall into eight broad categories including:

Federal Tenant Procurement Authority

Many comments requested that the rule revise the provisions regarding what services a Federal tenant may pay for and how the services can be obtained. Examples include: (1) The rule should authorize LRAs to charge Federal leaseback tenants a Common Area Maintenance Fee; (2) the rule should authorize Federal tenants to sole source for ''landlord'' services; and, (3) the rule should require Federal tenants to pay for services if the Agency paid for the services when it owned the property (note: this would only apply to existing Federal tenants rather than agencies relocating to the site).

Response: The Federal Government cannot pay for municipal services that are provided by a locality to its population using tax revenues. Doing so would, in effect, result in a taxing of the Federal Government. But, as evidenced by numerous Supreme Court Cases interpreting the Supremacy Clause of Article VI of the United States Constitution, States cannot tax the Federal Government. With respect to other services, Federal tenants can only pay for those services that are a requirement of the Federal Government. Paying a Common Area Maintenance Fee could result in the Federal tenant paying for services that are above and beyond what is needed to use the property being leased. For those services that are necessary, the leaseback authority does not remove the Federal Government's responsibility to abide by existing procurement laws. As a result, such services must be acquired using existing procurement laws and regulations. In some circumstances, a sole source contract may be allowable.

Leaseback Transfer Approval/Rejection Authority

Out of concern that prospective Federal tenants will reject an LRA's request for a leaseback transfer with virtually no justification, some comments requested that the rule establish criteria that would have to be