In making its reviews of the pilot program, the Commission should focus specific attention on the restrictions imposed on option contract design and strategies. The success of risk management tools is partly dependent upon the ability of users to tailor contracts to meet specific business concerns. The Commission has made some changes from its proposed rules to provide additional flexibility in contract design. However, the pilot program should afford participants even greater flexibility to negotiate specific contract terms and strategies, subject only to general guidelines.

In addition, the $10 million net worth requirement necessary to trigger an exemption from the regulations should be scrutinized more closely. My view is that there may be a more appropriate net worth level at which to set exemption eligibility. I therefore would recommend a reconsideration of the net worth amount within one year following the effective date of the interim rules, if not sooner.

Finally, I believe we have made significant progress towards transforming the November proposal into a less complex, shorter and more workable program. The fact that the program is, by its terms, a pilot program, provides the Commission and the industry with an opportunity to address individual situations that arise in the marketplace. To this end, I am hopeful that the agricultural community, the futures exchanges and others involved in the futures industry will remain in close contact with the Commission during the interim period. It is important that we maintain open lines of communication and that the Commission is apprised of the needs of the private sector. In this manner, adjustments to the pilot program may be made, as appropriate.

Dated: April 7, 1998.

David D. Spears.

Commissioner.

Concurring Remarks of Commissioner Barbara Pedersen Holum, Interim Final Rules, Trade Options on the Enumerated Agricultural Commodities

I agree with and join in the action the Commission is taking to permit exchange trading of options on physicals on the enumerated agricultural commodities. In particular, I believe this important initiative recognizes the potential of exchanges in offering more flexible option contracts. Exchanges in the past have demonstrated an exceptional ability to meet the demands of the market. I am therefore confident, now that the prohibition is to be lifted, the exchanges will work with the end-users to develop option contracts with the necessary flexibility to meet their individualized needs.

While I also join in the Commission's lifting of the prohibition on the offer and sale of off-exchange trade options on the enumerated agricultural commodities, I have serious concerns about the extensive regulatory provisions included in the interim rules. Specifically, these interim rules create a regulatory infrastructure essentially duplicating that which already exists on the exchanges. While the Commission has acted to exempt other off-exchange transactions from much of the centralized regulatory structure, these interim rules impose new, extensive, and costly regulatory mandates. In my opinion, the imposition of this far-reaching regulatory structure, and its additional costs, will limit participation and deny producers and processors the very risk management tools that lifting the ban envisions.

Dated: April 8, 1998.

Barbara Pedersen Holum,

Commissioner.

[FR Doc. 98–9879 Filed 4–15–98; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use In Animal Feeds; Bambermycins

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 a supplemental new animal drug application (NADA) filed by Hoechst Roussel Vet. The supplement provides for using bambermycins Type A medicated articles to make a bambermycins free-choice Type C medicated feed for pasture cattle (slaughter, stocker, and feeder) for increased rate of weight gain.

EFFECTIVE DATE: April 16, 1998.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, filed supplemental NADA 141–034 which provides for using 10-grams per pound Flavomycin® (bambermycins) Type A medicated articles to make free-choice Type C medicated feeds for pasture cattle (slaughter, stocker, and feeder). The Type C medicated feeds are fed to provide 10 to 20 milligrams bambermycins per head per day for increased rate of weight gain. The supplement is approved as of March 10, 1998, and the regulations are amended by adding 21 CFR 558.95(d)(4)(iv) to reflect the approval.

As required by 21 CFR 510.455, each use of a Type A medicated article to make a free-choice medicated Type C feed requires an approved NADA or supplemental NADA. Under section 512(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250), free-choice medicated Type C feeds must be manufactured in a licensed feed mill.

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, from 9 a.m. to 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the act, this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning March 10, 1998, because the supplement contains substantial evidence of the effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the use of bambermycins with the proprietary free-choice Type C feeds as approved in this supplemental NADA.

The agency has determined under 21 CFR 25.33(a)(3) 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.

2. Section 558.95 is amended by adding paragraph (d)(4)(iv) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(d) * * *

(4) * * *

(iv) Use free-choice Type C medicated feeds for pasture cattle (slaughter, stocker, and feeder) as follows:

(*a*) *Amount.* Feed continuously to provide 10 to 20 milligrams of bambermycins per head per day.

(*b*) *Indications for use.* For increased rate of weight gain.

(*c*) *Limitations.* Not for use in animals intended for breeding. Each use in a free-choice Type C medicated feed must be the subject of an approved new animal drug application (NADA) or supplemental NADA as required by 21 CFR 510.455.

* * * * *

Dated: March 31, 1998.

Andrew J. Beaulieu,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 98–10033 Filed 4–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 806

[Docket No. 91N–0396]

Medical Devices; Reports of Corrections and Removals; Lift of Stay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; lift of stay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is lifting a stay of the effective date of certain provisions in a final rule on establishing procedures for submission of reports of corrections and removals of medical devices. The Office of Management and Budget (OMB) has approved the collection of information requirements contained in the final rule.

EFFECTIVE DATE: May 18, 1998.

FOR FURTHER INFORMATION CONTACT: Rosa M. Gilmore, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2970.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 19, 1997 (62 FR 27183), FDA published a final rule to establish procedures for implementing the reports of corrections and removals for medical devices by requiring that manufacturers, importers, and distributors report promptly to FDA any corrections or removals of a device undertaken to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act caused by the device which may present a risk to health. In the final rule, FDA requested comments by July 18, 1997 (62 FR 27183 at 27190), on the collection of information requirements contained in the final rule. FDA reviewed and responded to four comments received in response to this request. In the **Federal Register** of November 26, 1997 (62 FR 63182), FDA announced that the information collection requirements contained in the final rule had been submitted to OMB for approval under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). In a separate document published on December 24, 1997 (62 FR 67274), FDA announced that it was staying the effective date of the information collection requirements pending OMB clearance for §§ 806.10 and 806.20 (21 CFR 806.10 and 806.20).

On January 30, 1998, OMB sent FDA a notice stating that the collection of information requirements are approved for use through January 31, 2001, under OMB control number 0910–0359. FDA announced OMB approval of the collection of information provisions in the **Federal Register** of February 17, 1998 (63 FR 7811).

Therefore, under sections 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393) and under authority delegated to the Commissioner of Food and Drugs, the stay for §§ 806.10 and 806.20 that was published at 62 FR 67274, December 24, 1997, is lifted and these provisions will become effective May 18, 1998.

Dated: April 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–10034 Filed 4–15–98; 8:45 am]

BILLING CODE 4160–01–F

PANAMA CANAL COMMISSION

35 CFR Parts 113 and 115

RIN 3207–AA26

Vessels Carrying Dangerous Packaged Goods Board of Local Inspectors; Composition and Functions

AGENCY: Panama Canal Commission.

ACTION: Final rule.

SUMMARY: The Panama Canal Commission is amending its rules in part 113 to prohibit the loading or off-loading of explosive cargo not destined for U.S. Government use at Commission facilities. The changes to 35 CFR part 113 are required by recent changes to commercial ports in the Republic of Panama which now provide a sufficiency of safe anchorages and facilities for the loading and unloading of explosive cargo for cargo not consigned to the Commission. As a result of these changes, the Commission is required to cease offering such services under the Panama Canal Treaty of 1977.

The Commission is also changing, in part 115, the requirement that the Administrator or his designee perform certain appointment functions and transferring those functions to the Marine Operations Director. This change makes this section consistent with the nomenclature changes called for by an internal reorganization at the Commission and the changes to 35 CFR part 115, published January 14, 1998.

DATES: Effective April 16, 1998.

FOR FURTHER INFORMATION CONTACT: John A. Mills, Secretary, Panama Canal Commission, 1825 I Street NW., Suite 1050, Washington, DC 20006–5402; Telephone: (202) 634–6441; Facsimile: (202) 634–6439; or John L. Haines, Jr., General Counsel, Panama Canal Commission, Facsimile: 011–507–272–3748.

SUPPLEMENTARY INFORMATION: The change to 35 CFR part 115 is a result of an internal reorganization of the Panama Canal Commission. The Board of Local Inspectors (BLI) has existed at the Panama Canal pursuant to statute or executive order since 1912, two years before the waterway opened its doors to world shipping. One of the BLI's primary functions is the investigation of marine accidents. Since 1966, the agency's Marine Director has served, ex officio, as Supervising Inspector and, in that latter capacity, has overseen the operations of the BLI.

As a result of this internal reorganization, the Marine Director (previously an active-duty or retired U.S. Naval officer) is to be known as the Maritime Operations Director. Duties previously carried out by the Supervising Inspector had been assumed by the Administrator or his designee. This change removes the Administrator from the system of appointments for a BLI chairman when the designated Chairman is absent or circumstances require the appointment of a specially qualified individual to serve on the BLI.

Because these changes are technical or internal in nature and do not place a burden on Canal users, the Commission has determined to promulgate a final rule without opportunity for comment.