form of Type B feed did not require reevaluation of the safety or effectiveness data supporting the NADA or the submission of any new data. Therefore, a freedom of information summary is not required.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval does not qualify for marketing exclusivity because the supplement does not contain substantial evidence of the effectiveness of the drug involved, any 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 agency has determined under 21 CFR 25.24(d)(1)(ii) 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: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.342 [Amended]

2. Section 558.342 *Melengestrol acetate* is amended in paragraph (c)(5)(ii)(C) by removing the word ''pelleted''.

Dated: January 31, 1997.

Robert C. Livingston,

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

[FR Doc. 97–4514 Filed 2–24–97; 8:45 am]

BILLING CODE 4160–01–F

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 Agri-Vet Co. The supplement provides for using liquid bambermycins Type B medicated feeds to make Type C medicated feeds for cattle fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: February 25, 1997.

FOR FURTHER INFORMATION CONTACT: Russell G. Arnold, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1674.

SUPPLEMENTARY INFORMATION: Hoechst-Roussel Agri-Vet Co., Route 202–206, P.O. Box 2500, Somerville, NJ 08876–1258, filed supplemental NADA 141–034 that provides for using 10-gram per pound (g/lb) Flavomycin® (bambermycins) Type A medicated articles to make 40 to 800 g/ton liquid Type B medicated feeds, the liquid Type B feeds used to make dry Type C medicated feeds. The Type C feeds containing 1 to 4 g/ton bambermycins are for cattle fed in confinement for slaughter to provide 10 to 20 milligrams bambermycins per head per day for increased rate of weight gain and improved feed efficiency. The regulations are amended in § 558.95 (21 CFR 558.95) by adding new paragraph (a)(5), by redesignating paragraph (b) as paragraph (d), and by revising newly redesignated paragraph (d)(4)(i)(*b*) to reflect the approval.

Furthermore, use of liquid Type B feeds to make Type C feeds requires publication of specifications and expiration information. New § 558.95(b) is established to reflect the Type B feed specifications and expiration information. In the interest of issuing uniform regulations in the future, new § 558.95(c) is also established at this time and reserved for future use.

Approval of this supplement did not require submission of additional safety or efficacy data. A freedom of information (FOI) summary as in 21 CFR part 20 and 514.11(e)(2)(ii) is not required. An FOI summary submitted to support approval of the original 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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food producing animals does not qualify for marketing exclusivity because the supplement does not contain substantial evidence of effectiveness of the drug involved, any studies of animal safety or human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.24(d)(1)(iii) 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: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.95 is amended by adding new paragraph (a)(5), by redesignating paragraph (b) as paragraph (d), by adding new paragraph (b), by adding and reserving paragraph (c), and by adding a new fourth sentence to newly redesignated paragraph (d)(4)(i)(*b*), to read as follows:

§ 558.95 Bambermycins.

(a) * * *

(5) 10 grams of activity per pound to 012799 in § 510.600(c) of this chapter to make 40 to 800 gram/ton Type B feeds for use as in paragraph (d)(4)(i) of this section.

(b) *Special considerations.* (1) Bambermycins liquid Type B feeds may be manufactured from dry bambermycins Type A articles. The liquid Type B feeds must have a pH of 3.8 to 7.5, moisture content of 30 to 45 percent.

(2) The expiration date for the liquid Type B feed is 8 weeks after date of manufacture. The expiration date for the dry Type C feed made from the liquid Type B feed is 1 week after date of manufacture.

(c) [Reserved]

(d) * * *

(4) * * *

(i) * * *

(*b*) * * * Liquid Type B feeds containing bambermycins may be used in the preparation of dry complete ration Type C feeds.

* * * * *

Dated: February 10, 1997.

Robert C. Livingston,

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

[FR Doc. 97–4512 Filed 2–24–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 47 and 55

[T.D. ATF–387]

RIN 1512–AB63

Implementation of Public Law 104–132, the Antiterrorism and Effective Death Penalty Act of 1996, Relating to the Marking of Plastic Explosives for the Purpose of Detection (96R–029P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Temporary rule (Treasury decision) and request for comments.

SUMMARY: This temporary rule implements certain provisions of the Antiterrorism and Effective Death Penalty Act of 1996 (Pub. L. 104–132). These regulations implement the law by requiring detection agents for plastic explosives. The temporary rule also authorizes the use of four specific detection agents to mark plastic explosives and provides for the designation of other detection agents. The temporary rule will remain in effect until superseded by final regulations.

In the Proposed Rules section of this Federal Register, ATF is also issuing a notice of proposed rulemaking inviting comments on the temporary rule for a 90-day period following the publication date of this temporary rule.

DATES: The temporary regulations are effective April 24, 1997. Comments due by May 27, 1997.

ADDRESSES: Send written comments to: Chief, Regulations Branch; Bureau of Alcohol, Tobacco and Firearms; Washington, DC 20091–0221.

FOR FURTHER INFORMATION CONTACT: James P. Ficaretta, Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226 (202–927–8230).

SUPPLEMENTARY INFORMATION:

Background

Public Law 104–132, 110 Stat. 1214, the Antiterrorism and Effective Death Penalty Act of 1996 (hereafter, ''the Act'') was enacted on April 24, 1996. Title VI of the Act, ''Implementation of Plastic Explosives Convention,'' added new requirements to the Federal explosives laws in 18 U.S.C. Chapter 40. Section 607 of the Act states that, except as otherwise provided, the amendments made by Title VI shall take effect 1 year after the date of enactment, i.e., on April 24, 1997. The stated purpose of Title VI is to fully implement the Convention on the Marking of Plastic Explosives for the Purpose of Detection, Done at Montreal on 1 March 1991 (hereafter, ''the Convention'').

The Convention represents an important achievement in international cooperation in response to the threat posed to the safety and security of international civil aviation by virtually undetectable plastic explosives in the hands of terrorists. Such explosives were used in the tragic destruction of Pan Am flight 103 over Lockerbie, Scotland, in December 1988, and UTA flight 772 in September 1989.

In the aftermath of these bombings, the international community moved to draft a multilateral treaty to ensure that plastic explosives would thereafter contain a chemical marking agent to render them detectable.

The new statutory provisions and the regulation changes necessitated by the law are as follows:

(1) *Definitions.* Section 602 of the Act added three definitions to section 841 of title 18, U.S.C. The term ''Convention on the Marking of Plastic Explosives'' is defined in the law to mean the Convention on the Marking of Plastic Explosives for the Purpose of Detection, Done at Montreal on 1 March 1991.

The term ''detection agent'' is defined as any one of the following substances when introduced into a plastic explosive or formulated in such explosive as a part of the manufacturing process in such a manner as to achieve homogeneous distribution in the finished explosive:

(1) Ethylene glycol dinitrate (EGDN), $C_2H_4(NO_3)_2$, molecular weight 152, when the minimum concentration in the finished explosive is 0.2 percent by mass;

(2) 2,3–Dimethyl-2,3-dinitrobutane (DMNB), $C_6H_{12}(NO_2)_2$, molecular weight 176, when the minimum concentration in the finished explosive is 0.1 percent by mass;

(3) Para-Mononitrotoluene (p-MNT), $C_7H_7NO_2$, molecular weight 137, when the minimum concentration in the finished explosive is 0.5 percent by mass;

(4) Ortho-Mononitrotoluene (o-MNT), $C_7H_77NO_2$, molecular weight 137, when the minimum concentration in the finished explosive is 0.5 percent by mass; and

(5) any other substance added by the Secretary of the Treasury by regulation, after consultation with the Secretary of State and the Secretary of Defense. Permitting the Secretary to designate detection agents other than the four listed in the statute would facilitate the use of other substances without the need for legislation. However, as specified in the law, only those substances which have been added to the table in Part 2 of the Technical Annex to the Convention on the Marking of Plastic Explosives may be designated as approved detection agents. ATF would have no authority to issue a regulation adding to the list of approved detection agents until the Technical Annex has been so modified.

The last term added to section 841 of title 18, U.S.C., ''plastic explosive,'' is defined as an explosive material in flexible or elastic sheet form formulated with one or more high explosives which in their pure form has a vapor pressure less than 10^{-4} Pa at a temperature of 25 °C, is formulated with a binder material, and is as a mixture malleable or flexible at normal room temperature. Pursuant to Part I of the Technical Annex to the Convention, high explosives include, but are not restricted to, cyclotetramethylenetetranitramine (HMX), pentaerythritol tetranitrate (PETN), and cyclotrimethylenetrinitramine (RDX).

The above changes to the regulations are prescribed in § 55.180.

(2) *Requirement of Detection Agents for Plastic Explosives.* The Act amended the Federal explosives laws in 18 U.S.C. Chapter 40 by adding new subsections (l)–(o) to section 842. Section 842(l) makes it unlawful for any person to manufacture any plastic explosive that does not contain a detection agent.

Section 842(m) makes it unlawful for any person to import or bring into the U.S. or export from the U.S. any plastic explosive that does not contain a detection agent. The provisions of this section do not apply to the importation or bringing into the U.S. or the exportation from the U.S. of any plastic explosive that was imported or brought into or manufactured in the U.S. prior to the date of enactment of the Act by or on behalf of any agency of the U.S. performing military or police functions (including any military reserve component) or by or on behalf of the