

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feed; Halofuginone Hydrobromide and 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 new animal drug application (NADA) filed by Hoechst-Roussel Agri-Vet Co. The NADA approves for using approved single ingredient Type A medicated articles to make Type C medicated turkey feeds containing halofuginone hydrobromide and bambermycins.

EFFECTIVE DATE: May 16, 1996.

FOR FURTHER INFORMATION CONTACT: James F. McCormack, Center For Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1607.

SUPPLEMENTARY INFORMATION: Hoechst-Roussel Agri-Vet Co., P.O. Box 2500, Route 202-206, Somerville, NJ 08876-1258, filed NADA 140-918 which provides for use of approved Stenorol® (2.72 grams (g) of halofuginone hydrobromide activity per pound) and approved Flavomycin® (4 and 10 g of bambermycins activity per pound) Type A medicated articles to make Type C medicated turkey feeds containing 1.36 to 2.72 g of halofuginone hydrobromide and 2 g of bambermycins per ton. The Type C medicated turkey feed is used for prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagriditis*, and *E. gallopavonis*, and for increased rate of weight gain in growing turkeys. The NADA is approved as of May 16, 1996, and the regulations are amended in 21 CFR 558.265 by adding new paragraph (c)(2)(iii) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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.

This approval is for use of single ingredient Type A medicated articles to make Type C medicated feeds. Halofuginone hydrobromide is a Category II drug which, as provided in 21 CFR 558.4, requires an approved form FDA 1900 for making a Type C medicated feed. Therefore, use of halofuginone hydrobromide and bambermycins Type A articles to make Type C medicated turkey feeds as in NADA 140-918 requires an approved form FDA 1900.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), approval of this application qualifies for 3 years of marketing exclusivity beginning May 16, 1996, because the application contains reports of new clinical or field investigations (other than bioequivalence or residue studies) or human food safety studies (other than bioequivalence or residue studies) essential to the approval 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).

2. Section 558.265 is amended by adding new paragraph (c)(2)(iii) to read as follows:

§ 558.265 Halofuginone hydrobromide.

* * * * *

(c) * * *

(2) * * *

(iii) *Amount per ton.* 1.36 to 2.72 grams of halofuginone hydrobromide plus 2 grams of bambermycins.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagriditis*,

and *E. gallopavonis*, and for increased rate of weight gain in growing turkeys.

(B) *Limitations.* Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to laying chickens or waterfowl. Halofuginone hydrobromide is toxic to fish and other aquatic life. Keep out of lakes, ponds, and streams. Halofuginone hydrobromide is an eye and skin irritant. Avoid contact with skin, eyes, and clothing.

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Dated: May 1, 1996.

Michael J. Blackwell,
Acting Director, Center for Veterinary Medicine.

[FR Doc. 96-12262 Filed 5-15-96; 8:45 am]

BILLING CODE 4160-01-F

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 2627

RIN 1212-AA77

Disclosure to Participants

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This document amends the PBGC's regulation on disclosure to participants (29 CFR part 2627) to describe changes in the way participants can obtain the booklet "Your Guaranteed Pension."

EFFECTIVE DATE: May 16, 1996.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, or Catherine B. Klion, Attorney, Office of the General Counsel, PBGC, 1200 K Street, NW., Washington, DC 20005-4026, 202-326-4024 (202-326-4179 for TTY and TDD).

SUPPLEMENTARY INFORMATION: The PBGC's regulation on disclosure to participants (29 CFR Part 2627) implements section 4011 of ERISA. Section 4011 requires certain underfunded plans to provide notice to plan participants and beneficiaries of the plan's funding status and the limits on the PBGC's guarantee. Plans with more than 100 participants were first subject to the notice requirement for the 1995 plan year; plans with 100 or fewer participants will first be subject to the requirement for the 1996 plan year.

The PBGC is amending the regulation to reflect the fact that the booklet "Your Guaranteed Pension" can now be obtained without charge by writing to the Consumer Information Center. (Previously, the booklet cost \$1.25.) The PBGC also is amending the regulation to

allow plan administrators to include a statement in the Participant Notice that the booklet can be obtained on the PBGC's new Homepage on the World Wide Web.

This rule also makes corresponding changes to the Model Participant Notice (Appendix A to Part 2627). The PBGC is republishing the Model Participant Notice and the Table of Maximum Guaranteed Benefits (Appendix B to Part 2617) in their entirety. (Information on 1996 maximum guaranteed benefit amounts was added to this table on December 15, 1995 (60 FR 64324).)

In light of the minor nature of the changes, and plan administrators' current need for a regulation that includes correct information, the PBGC has for good cause found that notice and public procedure are unnecessary and contrary to the public interest. The PBGC also has determined for these reasons that good cause exists for making these amendments effective immediately. For a reasonable time period, the PBGC will treat a plan administrator that uses the existing regulation (including the existing Model Participant Notice) as satisfying the Participant Notice requirements.

The PBGC has determined that this action is not a "significant regulatory action" under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this regulation, the Regulatory Flexibility Act does not apply (5 U.S.C. 601(2)).

List of Subjects in 29 CFR Part 2627

Pension insurance, Pensions.

Accordingly, 29 CFR Part 2627 is amended as follows:

PART 2627—DISCLOSURE TO PARTICIPANTS

1. The authority citation for part 2627 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3), 1311.

2. § 2627.10, paragraph (h) introductory text is republished and paragraph (b)(9) is revised to read as follows:

§ 2627.10 Form of notice.

* * * * *

(b) *Content.* The Participant Notice for a plan year shall include—

* * * * *

(9) A statement that further information about the PBGC's guarantee may be obtained by requesting a free copy of the booklet "Your Guaranteed Pension" from Consumer Information Center, Dept. YGP, Pueblo, Colorado

81009. The Participant Notice may include a statement that the booklet may be obtained through electronic access via the World Wide Web from the PBGC Homepage at <http://www.pbgc.gov/ygp.htm>.

* * * * *

3. Appendix A to Part 2627 is amended to read as follows (and Appendix B is republished for the convenience of the public):

Appendix A to Part 2627—Model Participant Notice

The following is an example of a Participant Notice that satisfies the requirements of § 2627.10 when the required information is filled in (subject to §§ 2627.10(d)-(e), where applicable).

NOTICE TO PARTICIPANTS OF [PLAN NAME]

The law requires that you receive information on the funding level of your defined benefit pension plan and the benefits guaranteed by the Pension Benefit Guaranty Corporation (PBGC), a federal insurance agency.

YOUR PLAN'S FUNDING

As of [DATE], your plan had [INSERT NOTICE FUNDING PERCENTAGE (DETERMINED IN ACCORDANCE WITH § 2627.10(c))] percent of the money needed to pay benefits promised to employees and retirees.

To pay pension benefits, your employer is required to contribute money to the pension plan over a period of years. A plan's funding percentage does not take into consideration the financial strength of the employer. Your employer, by law, must pay for all pension benefits, but your benefits may be at risk if your employer faces a severe financial crisis or is in bankruptcy.

[INCLUDE THE FOLLOWING PARAGRAPH ONLY IF, FOR ANY OF THE PREVIOUS FIVE PLAN YEARS, THE PLAN HAS BEEN GRANTED AND HAS NOT FULLY REPAID A FUNDING WAIVER.]

Your plan received a funding waiver for [LIST ANY OF THE FIVE PREVIOUS PLAN YEARS FOR WHICH A FUNDING WAIVER WAS GRANTED AND HAS NOT BEEN FULLY REPAID]. If a company is experiencing temporary financial hardship, the Internal Revenue Service may grant a funding waiver that permits the company to delay contributions that fund the pension plan.

[INCLUDE THE FOLLOWING WITH RESPECT TO ANY UNPAID OR LATE PAYMENT THAT MUST BE DISCLOSED UNDER § 2627.10(b)(6):]

Your plan was required to receive a payment from the employer on [LIST APPLICABLE DUE DATE(S)]. That payment [has not been made] [was made on [LIST APPLICABLE PAYMENT DATE(S)]].

PBGC GUARANTEES

When a pension plan ends without enough money to pay all benefits, the PBGC steps in to pay pension benefits. The PBGC pays most people all pension benefits, but some people

may lose certain benefits that are not guaranteed.

The PBGC pays pension benefits up to certain maximum limits.

- The maximum guaranteed benefit is [INSERT FROM TABLE IN APPENDIX B] per month or [INSERT FROM TABLE IN APPENDIX B] per year for a 65-year-old person in a plan that terminates in [INSERT APPLICABLE YEAR].

- The maximum benefit may be reduced for an individual who is younger than age 65. For example, it is [INSERT FROM TABLE IN APPENDIX B] per month or [INSERT FROM TABLE IN APPENDIX B] per year for an individual who starts receiving benefits at age 55. [IN LIEU OF AGE 55, YOU MAY ADD OR SUBSTITUTE ANY AGE(S) RELEVANT UNDER THE PLAN. FOR EXAMPLE, YOU MAY ADD OR SUBSTITUTE THE MAXIMUM BENEFIT FOR AGES 62 OR 60 FROM THE TABLE IN APPENDIX B. IF THE PLAN PROVIDES FOR NORMAL RETIREMENT BEFORE AGE 65, YOU MUST INCLUDE THE NORMAL RETIREMENT AGE.]

[IF THE PLAN DOES NOT PROVIDE FOR COMMENCEMENT OF BENEFITS BEFORE AGE 65, YOU MAY OMIT THIS PARAGRAPH.]

- The maximum benefit will also be reduced when a benefit is provided for a survivor.

The PBGC does not guarantee certain types of benefits.

[INCLUDE THE FOLLOWING GUARANTEE LIMITS THAT APPLY TO THE BENEFITS AVAILABLE UNDER YOUR PLAN.]

- The PBGC does not guarantee benefits for which you do not have a vested right when a plan ends, usually because you have not worked enough years for the company.

- The PBGC does not guarantee benefits for which you have not met all age, service, or other requirements at the time the plan ends.

- Benefit increases and new benefits that have been in place for less than a year are not guaranteed. Those that have been in place for less than 5 years are only partly guaranteed.

- Early retirement payments that are greater than payments at normal retirement age may not be guaranteed. For example, a supplemental benefit that stops when you become eligible for Social Security may not be guaranteed.

- Benefits other than pension benefits, such as health insurance, life insurance, death benefits, vacation pay, or severance pay, are not guaranteed.

- The PBGC does not pay lump sums exceeding \$3,500.

WHERE TO GET MORE INFORMATION

Your plan, [EIN-PN], is sponsored by [CONTRIBUTING SPONSOR(S)]. If you would like more information about the funding of your plan, contact [INSERT NAME, TITLE, BUSINESS ADDRESS AND PHONE NUMBER OF INDIVIDUAL OR ENTITY].

For more information about the PBGC and the benefits it guarantees, you may request a free copy of "Your Guaranteed Pension" by

writing to Consumer Information Center, Dept. YGP, Pueblo, Colorado 81009.
[THE FOLLOWING SENTENCE MAY BE INCLUDED:]

“Your Guaranteed Pension” is also available from the PBGC Homepage on the World Wide Web at <http://www.pbgc.gov/ygp.htm>.

Issued: [INSERT AT LEAST MONTH AND YEAR]
Appendix B to Part 2627—Table of Maximum Guaranteed Benefits

If a plan terminates in—	The maximum guaranteed benefit for an individual starting to receive benefits at the age listed below is the amount (monthly or annual) listed below:							
	Age 65		Age 62		Age 60		Age 55	
	Monthly	Annual	Monthly	Annual	Monthly	Annual	Monthly	Annual
1995	\$2,573.86	\$30,886.32	\$2,033.35	\$24,400.20	\$1,673.01	\$20,076.12	\$1,158.24	\$13,898.88
1996	2,642.05	31,704.60	2,087.22	25,046.64	1,717.33	20,607.96	1,188.92	14,267.04

The maximum guaranteed benefit for an individual starting to receive benefits at ages other than those listed above can be determined by applying the PBGC’s regulation on computation of maximum guaranteeable benefits (29 CFR § 2621.4).

Issued in Washington, DC, this 13th day of May, 1996.

Martin Slate,
Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 96-12335 Filed 5-15-96; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 585

Federal Republic of Yugoslavia (Serbia and Montenegro) and Bosnian Serb-Controlled Areas of the Republic of Bosnia and Herzegovina Sanctions Regulations; Suspension of Sanctions Against the Bosnian Serbs

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule; amendments.

SUMMARY: This rule amends the Federal Republic of Yugoslavia (Serbia and Montenegro) and Bosnian Serb-Controlled Areas of the Republic of Bosnia and Herzegovina Sanctions Regulations to authorize prospectively all transactions with respect to property and interests in property of the Bosnian Serb forces and authorities and any dealing by U.S. persons relating to trade with or in, and the exportation of services to, the areas of the Republic of Bosnia and Herzegovina that the Bosnian Serb forces control.

EFFECTIVE DATE: May 10, 1996.

FOR FURTHER INFORMATION CONTACT:

Steven I. Pinter, Chief of Licensing, tel.: 202/622-2480, Dennis P. Wood, Chief of Compliance Programs, tel.: 202/622-2490, or William B. Hoffman, Chief Counsel, tel.: 202/622-2410, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

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Background

On January 16, 1996, the Treasury Department suspended prospectively sanctions imposed against the Federal Republic of Yugoslavia (Serbia and Montenegro) (the “FRY (S&M)”). Sanctions against the Bosnian Serb forces and authorities and the areas of the Republic of Bosnia and Herzegovina that they control were to remain in effect until their troop withdrawal to agreed borders, consistent with the General Framework Agreement for

Peace in Bosnia and Herzegovina and the Annexes thereto (collectively the “Peace Agreement”), which was initialled on November 21, 1995, and signed on December 4, 1995, and with paragraph 2 of United Nations Security Council Resolution 1022 of November 22, 1995 (the “Resolution”).

On February 26, in keeping with paragraph 2 of the Resolution, the United Nations Secretary-General transmitted to the Security Council the report of the commander of the international force deployed in accordance with the Peace Agreement stating that all Bosnian Serb forces had withdrawn behind the zones of separation established by that Agreement. Accordingly, the Office of Foreign Assets Control is amending the Federal Republic of Yugoslavia (Serbia and Montenegro) and Bosnian Serb-Controlled Areas of the Republic of Bosnia and Herzegovina Sanctions Regulations, 31 CFR part 585 (the “Regulations”), by adding § 585.527 to the Regulations to authorize prospectively those transactions previously prohibited with respect to the Bosnian Serb forces and authorities and entities organized or located in those areas of the Republic of Bosnia and Herzegovina under their control; entities owned or controlled directly or indirectly by any person in, or resident in, those areas; and any person acting for or on behalf of any of the foregoing. U.S. persons are also authorized to engage in transactions involving the areas of the Republic of Bosnia and Herzegovina under the control of the Bosnian Serb forces, and services may be exported either from the United States or by U.S. persons to those areas. Property and interests in property previously blocked due to an interest of any person described in § 585.201 remain blocked.

Because the Regulations involve a foreign affairs function, Executive Order 12866 and the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed