the product in cats 6 weeks of age or greater and 1.5 pounds of body weight or greater. This supplemental NADA approval provides for 5.75, 11.5, and 23.0 milligram tablets, given orally, once a month, for the prevention of heartworm disease caused by *Dirofilaria immitis* and the removal of adult *Toxocara cati* (roundworm) and *Ancylostoma tubaeforme* (hookworm) infections in cats 6 weeks of age or greater and 1.5 pounds body weight or greater. The supplemental NADA is approved as of April 13, 1998, and the regulations are amended in 21 CFR 520.1445 by revising paragraph (a) and the heading of paragraph (c) and by adding paragraph (d) to reflect the approval for cats. 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.

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 qualifies for 3 years of marketing exclusivity beginning April 13, 1998, because the application contains substantial evidence of effectiveness of the drug involved and studies of animal safety required for approval and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(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 520

Animal drugs.

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

2. Section 520.1445 is amended by revising paragraph (a) and the heading of paragraph (c) and by adding paragraph (d) to read as follows:

§ 520.1445 Milbemycin oxime tablets.

(a) *Specifications*—(1) *Dogs.* Each tablet contains 2.3, 5.75, 11.5, or 23.0 milligrams of milbemycin oxime.

(2) *Cats.* Each tablet contains 5.75, 11.5, or 23.0 milligrams of milbemycin oxime.

* * * * *

(c) *Conditions of use in dogs.* * * *

(d) *Conditions of use in cats*—(l) *Amount.* 0.91 milligram per pound of body weight (2.0 milligrams per kilogram).

(2) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis* and the removal of adult *Toxocara cati* (roundworm) and *Ancylostoma tubaeforme* (hookworm) infections in cats 6 weeks of age or greater and 1.5 pounds body weight or greater.

(3) *Limitations.* Do not use in kittens less than 6 weeks of age or 1.5 pounds body weight. Administer once a month. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: May 11, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–14182 Filed 5–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Guaifenesin Injection

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 Phoenix Scientific, Inc. The ANADA provides for intravenous use of guaifenesin injection in horses as a skeletal muscle relaxant.

EFFECTIVE DATE: May 29, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center For Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–230 that provides for intravenous use of guaifenesin injection in horses as a skeletal muscle relaxant.

Approval of Phoenix Scientific, Inc.'s, ANADA 200–230 for guaifenesin injection is as a generic copy of Summit Hill Laboratories' NADA 48–854 for Gecolate (guaifenesin) Injection. The ANADA is approved as of April 8, 1998, and the regulations are amended in 21 CFR 522.1086(b) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, paragraph (c) is redesignated as paragraph (d) and paragraph (c) is reserved.

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(d)(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 522

Animal drugs.

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.1086 [Amended]

2. Section 522.1086 *Guaifenesin injection* is amended in paragraph (b) by removing ''No. 037990'' and adding in its place ''Nos. 037990 and 059130'', by redesignating paragraph (c) as paragraph (d), and by reserving paragraph (c).

Dated: May 12, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–14183 Filed 5–28–98; 8:45 am]

BILLING CODE 4160–01–F

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022, 4041, 4050

RIN: 1212–AA87

PBGC Recoupment and Reimbursement of Benefit Overpayments and Underpayments

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation is amending its regulation governing recoupment of benefit overpayments in trusteed plans to stop the reduction of monthly benefits under its actuarial recoupment method once the amount of the benefit overpayment is repaid. The amendment also makes other related changes.

EFFECTIVE DATE: May 29, 1998.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, or James L. Beller, Attorney, Office of the General Counsel, PBGC, 1200 K Street, NW., Washington, DC 20005–4026, 202–326–4024. (For TTY/TTD users, call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: On December 18, 1997, the PBGC published a proposed rule in the **Federal Register** (62 FR 66319) amending its benefit payments regulation to provide that recoupment will cease when the amount of the overpayment is repaid. The amendment also gives the PBGC flexibility to waive recoupment of *de minimis* amounts and to accept repayment ahead of the recoupment schedule, and modifies the rules governing calculation of net overpayments and underpayments.

The PBGC received comments on the proposed rule from two commenters: the American Association of Retired Persons (''AARP'') and the Association of Former Pan Am Employees, Inc. (''AFPAE''). AARP supported the proposed regulation and commended the PBGC for its action. AFPAE, which also commended the PBGC for proposing changes, recommended a number of revisions.

The final regulation follows the proposed regulation with the following modifications:

- As requested by AFPAE, the final rule clarifies that in determining whether the net overpayment has been fully repaid, interest on the net overpayment is disregarded.
- In response to an inquiry in a pending case in which participants received both underpayments and overpayments, the final regulation provides that the PBGC will always pay interest on underpayments to the extent they exceed overpayments. In addition, for months beginning after May 29, 1998, the PBGC will pay interest at the applicable federal mid-term rate. For earlier months, the PBGC will continue to pay interest using the immediate annuity rate established for lump sum valuations.
- Consistent with an AFPAE suggestion, the final regulation provides that the PBGC generally will not seek recovery from the estate of a participant who dies post-termination. (The existing regulation precludes recovery from the estate only for a participant who dies after the PBGC initiates recoupment.)
- For administrative convenience, the final regulation provides that the PBGC will not collect any final partial monthly installment.
- AFPAE expressed concerns about the provision allowing repayment ahead of the recoupment schedule, arguing that, because the PBGC charges no interest under the recoupment schedule, early repayment will never be advantageous to the participant. The PBGC will discontinue its current practice of routinely offering a lump sum repayment option as part of its recoupment notice. However, the PBGC will retain the early repayment option for those participants who, for whatever reason, want to eliminate debt. As suggested by AFPAE, the PBGC intends to explain to those participants who ask about the early repayment option that there may be financial disadvantages to early repayment.

The PBGC has carefully considered AFPAE's other comments and has decided not to adopt them.

- AFPAE suggested that the PBGC not seek recoupment from a surviving beneficiary unless recoupment has been initiated before the participant's death. AFPAE offered no reason why the PBGC's recoupment rules should distinguish in this manner between a survivorship benefit and the underlying benefit from which the survivorship benefit derives. The regulation minimizes hardship in the case of recoupment from a survivorship benefit because the monthly recoupment amount is reduced in proportion to any other applicable reduction in the deceased participant's benefit (*e.g.*, a 50% reduction under a joint and survivor annuity) and is generally capped at 10% of the survivorship payment.
- AFPAE suggested that the PBGC eliminate its discretion to recover overpayments by methods other than recoupment. The regulation provides that the PBGC will normally exercise its discretion only where net benefits paid exceed plan entitlements (*e.g.*, where a participant entitled to $1,200 per month as the full plan benefit and $1,000 per month under Title IV has received clearly erroneous payments of $5,000 per month). Any further limitation on the PBGC's discretion could result in unacceptably large losses in particular cases.
- AFPAE suggested that recoupment be permitted only if (1) the participant is notified of the possibility of recoupment no later than 30 days after the PBGC makes a final decision to seek an involuntary termination, and (2) recoupment begins no more than one year after the termination date. This suggestion is impracticable. The PBGC often encounters significant delays in obtaining the participant information needed to provide notice and the benefit and asset information needed to complete the complex and time-consuming process of determining final benefit entitlements. The PBGC will continue to provide notice to participants, and to initiate recoupments, as soon as possible.
- In response to the provision in the proposed rule giving the PBGC discretion to waive *de minimis* amounts, AFPAE suggested that the regulation specify a dollar threshold under which recoupment is automatically waived. The PBGC has decided to retain the discretion provided in the proposed rule in order to allow maximum flexibility. After gaining experience under the *de minimis* waiver provision, the PBGC may decide to specify a fixed dollar threshold in the regulation.
- AFPAE suggested broadening the scope of the recoupment and reimbursement regulation to cover underpayments made before the plan termination date. The Title IV single-employer insurance program does not cover pre-termination underpayments. These underpayments represent a claim on plan assets that are satisfied before those assets are used to satisfy Title IV benefits under the allocation rules of ERISA section 4044 and 29 CFR Part 4044. Thus, to the extent assets are available, pre-termination underpayments are fully reimbursed.

AFPAE made several other comments suggesting revisions to the benefit