

treatment prescribed for pests of that plant by the plant protection service of the exporting country and then grown for at least 9 months in the exporting country prior to importation of the descendent plants into the United States;

(v) Watered only with rainwater that has been boiled or pasteurized, with clean well water, or with potable water;

(vi) Rooted and grown in approved growing media listed in § 319.37-8(e)(1) on benches supported by legs and raised at least 46 cm above the floor;

(vii) Stored and packaged only in areas free of sand, soil, earth, and plant pests; and,

(viii) Inspected in the greenhouse and found free from evidence of plant pests and diseases by an APHIS inspector or an inspector of the plant protection service of the exporting country, no more than 30 days prior to the date of export to the United States.

* * * * *

(g) *Pest risk evaluation standards for plants established in growing media.* When evaluating a request to allow importation of additional taxa of plants established in growing media, the Animal and Plant Health Inspection Service will conduct the following analysis in determining the pest risks associated with each requested plant article and in determining whether or not to propose allowing importation into the United States of the requested plant article.

(1) *Collect commodity information.*

(i) Determine the kind of growing medium, origin and taxon of the regulated article.

(ii) Collect information on the method of preparing the regulated article for importation.

(iii) Evaluate history of past plant pest interceptions or introductions (including data from plant protection services of foreign countries) associated with each regulated article.

(2) *Catalog quarantine pests.* For the regulated article specified in an application, determine what plant pests or potential plant pests are associated with the type of plant from which the regulated article was derived, in the country and locality of origin. A plant pest that meets one of the following criteria is a quarantine pest and will be further evaluated in accordance with paragraph (g)(3) of this section:

(i) Non-indigenous plant pest not present in the United States;

(ii) Non-indigenous plant pest, present in the United States and capable of further dissemination in the United States;

(iii) Non-indigenous plant pest that is present in the United States and has

reached probable limits of its ecological range, but differs genetically from the plant pest in the United States in a way that demonstrates a potential for greater damage potential in the United States;

(iv) Native species of the United States that has reached probable limits of its ecological range, but differs genetically from the plant pest in the United States in a way that demonstrates a potential for greater damage potential in the United States; or

(v) Non-indigenous or native plant pest that may be able to vector another plant pest that meets one of the criteria in (g)(2)(i) through (iv) of this section.

(3) *Conduct individual pest risk assessments.* Each of the quarantine pests identified by application of the criteria in paragraph (g)(2) of this section will be evaluated based on the following estimates:

(i) Estimate the probability the quarantine pest will be on, with, or in the regulated article at the time of importation;

(ii) Estimate the probability the quarantine pest will survive in transit on the regulated article and enter the United States undetected;

(iii) Estimate the probability of the quarantine pest colonizing once entered into the United States;

(iv) Estimate the probability of the quarantine pest spreading beyond the colonized area; and

(v) Estimate the actual and perceived economic, environmental and social damage that would occur if the quarantine pest is introduced, colonizes, and spreads.

(4) *Determine overall estimation of risk based on compilation of component estimates.* This step will evaluate whether the pest risk of importing a regulated article established in growing media, as developed through the estimates of paragraph (g)(3) of this section, is greater than the pest risk of importing the regulated article with bare roots as allowed by § 319.37-8(a).

(i) If the pest risk is determined to be the same or less, the regulated article established in growing media will be allowed importation under the same conditions as the same regulated article with bare roots.

(ii) If the pest risk is determined to be greater for the regulated article established in growing media, APHIS will evaluate available mitigation measures to determine whether they would allow safe importation of the regulated article. Mitigation measures currently in use as requirements of this subsection, and any other mitigation methods relevant to the regulated article and plant pests involved, will be

compared with the individual pest risk assessments in order to determine whether requiring particular mitigation measures in connection with importation of the regulated article would reduce the pest risk to a level equal to or less than the risk associated with importing the regulated article with bare roots as allowed by § 319.37-8(a). If APHIS determines that use of particular mitigation measures could reduce the pest risk to this level, and determines that sufficient APHIS resources are available to implement or ensure implementation of the appropriate mitigation measures, APHIS will propose to allow importation into the United States of the requested regulated article if the appropriate mitigation measures are employed.

§ 319.37-9 [Amended]

5. In § 319.37-9, the phrase "is not intermixed with other approved packing material;" is removed.

Done in Washington, DC, this 9th day of January 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95-935 Filed 1-12-95; 8:45 am]

BILLING CODE 3410-34-P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 249

[Release Nos. 34-35204]

RIN 3235-AG10

Rulemaking for EDGAR System; Correction

AGENCY: Securities and Exchange Commission.

ACTION: Correction to final rules.

SUMMARY: This document contains a correction to the final rules that were published Friday, December 30, 1994 (59 FR 67752). Those rules relate to the implementation of the Electronic Data Gathering, Analysis and Retrieval ("EDGAR") system.

EFFECTIVE DATE: The EDGAR rules and amendments are effective January 30, 1995.

FOR FURTHER INFORMATION CONTACT: James R. Budge, Office of Disclosure Policy, Division of Corporation Finance at (202) 942-2910.

SUPPLEMENTARY INFORMATION:

Background

The disclosure form that is the subject of this correction was intended to be

amended in connection with the rulemaking to fully implement mandated electronic filing on the EDGAR system for registrants whose filings are processed by the Divisions of Corporation Finance and Investment Management and for those making filings with respect to such registrants. Development and implementation of the EDGAR system was effected pursuant to Section 35A of the Securities Exchange Act of 1934 (15 U.S.C. 781l).

Need for Corrections

This action is necessary to correct an internal cross reference within Form 8-A, for registration of certain classes of securities pursuant to Section 12(b) or (g) of the Securities Exchange Act of 1934. 15 U.S.C. 781(b) or (g).

Correction of Publication

Accordingly, the publication on December 30, 1994 of the final EDGAR rules, which were the subject of FR Doc. 94-31579, is corrected as follows:

1. On page 67765, second column, the amendatory language for amendment No. 35 is corrected to read as follows:

“35. By amending Form 8-A (referenced in § 249.208a), Instruction II.2 of Instructions as to Exhibits, by revising the phrase ‘pursuant to Instruction 3 above’ to read ‘pursuant to Instruction II.1, above.’”

Dated: January 9, 1995.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95-912 Filed 1-12-95; 8:45 am]

BILLING CODE 8010-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Neomycin Sulfate Oral Solution

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 use of a generic neomycin sulfate oral solution in the drinking water and milk for cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis. **EFFECTIVE DATE:** January 13, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457, filed ANADA 200-118, which provides for the use of neomycin oral solution (neomycin sulfate) in the drinking water and milk for cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate. Approval of ANADA 200-118 is as a generic copy of the Upjohn Co.'s approved NADA 11-315. The ANADA is approved as of November 29, 1994, and 21 CFR 520.1485(b) is amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, the heading of the section is editorially revised to reflect the name of the product.

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, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.1485 is amended by revising the section heading and paragraph (b) to read as follows:

§ 520.1485 Neomycin sulfate oral solution.

* * * * *

(b) *Sponsors.* See Nos. 000009 and 059130 in § 510.600(c) of this chapter.

* * * * *

Dated: January 3, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95-899 Filed 1-12-95; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Salinomycin In Combination

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the approval of three abbreviated new animal drug applications (ANADA's) filed by Hoechst-Roussel Agri-Vet Co. The ANADA's provide for using approved Type A medicated articles to make Type C medicated broiler feeds containing salinomycin with chlortetracycline and roxarsone, or salinomycin with chlortetracycline, or salinomycin with oxytetracycline.

EFFECTIVE DATE: January 13, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: Hoechst-Roussel Agri-Vet Co., P.O. Box 2500, Somerville, NJ 08876-1258, filed the following ANADA's:

ANADA 200-091, salinomycin with chlortetracycline and roxarsone, which provides for using approved single ingredient Type A medicated articles to make Type C medicated broiler feeds containing 40 to 60 grams per ton (g/t) salinomycin sodium activity, chlortetracycline calcium complex equivalent to 500 g/t chlortetracycline hydrochloride, and 45.4 g/t roxarsone for prevention of coccidiosis and as an aid in reduction of mortality due to certain *Escherichia coli* infections.

ANADA 200-095, salinomycin with chlortetracycline, which provides for using approved single ingredient Type A medicated articles to make Type C medicated broiler feeds containing 40 to 60 g/t salinomycin sodium activity with