service via the specified electronic means.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 556

Oral Dosage Form New Animal Drugs; Neomycin Sulfate

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 Pharmacia & Upjohn Co. The supplemental NADA provides for use of neomycin sulfate in turkey drinking water for the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin sulfate in growing turkeys. The regulations are also amended to provide for a tolerance for neomycin residues in edible turkey tissues and an acceptable daily intake (ADI).

EFFECTIVE DATE: June 11, 1999.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7570.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed supplemental NADA 11–315 that provides for use of Neomix® 325 and Neomix® AG 325 (neomycin sulfate) soluble powder in turkey drinking water for the control of mortality associated with *E. coli* organisms susceptible to neomycin sulfate in growing turkeys. The supplemental NADA is approved as of May 5, 1999, and 21 CFR 520.1484 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, a tolerance for residues of neomycin in edible tissues of turkeys has not been previously established. Section 556.430 is amended editorially to reflect current format, to provide tolerances for neomycin residues in edible turkey tissue, and to provide an ADI for neomycin.

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 supplemental application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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 supplemental approval for use in turkey drinking water qualifies for 3 years of marketing exclusivity beginning May 5, 1999, because the supplemental application contains 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 this approval and conducted or sponsored by the applicant. The 3 years marketing exclusivity is limited to use of the drug for the control of mortality associated with *E. coli* organisms susceptible to neomycin sulfate in growing turkeys.

FDA has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment. Therefore, an environmental impact statement is not required. FDA'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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 520

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 parts 520 and 556 are 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 520.1484 is revised to read as follows:

§ 520.1484 Neomycin sulfate soluble powder.

(a) *Specifications.* Neomycin sulfate soluble powder contains 20.3 grams of neomycin sulfate (equivalent to 14.2 grams of neomycin base) per ounce.

(b) *Sponsors.* See 000069, 046573, 050604, and 051259 in § 510.600(c) of this chapter for use as in paragraph (d)(1) of this section. See 000009 for use as in paragraphs (d)(1) and (d)(2) of this section.

(c) *Related tolerances.* See § 556.430 of this chapter.

(d) *Conditions of use*–(1) *Cattle (excluding veal calves), swine, sheep, and goats.*

(i) *Amount.* 10 milligrams of neomycin sulfate per pound of body weight per day (22 milligrams per kilogram) in divided doses for a maximum of 14 days.

(ii) *Indications for use.* For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep, and goats.

(iii) *Limitations.* Add to drinking water or milk; not for use in liquid supplements. Prepare a fresh solution daily. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days. Discontinue treatment prior to slaughter as follows: Cattle (not for use in veal calves), 1 day; sheep, 2 days; swine and goats, 3 days.

(2) *Turkeys*–(i) *Amount.* 10 milligrams of neomycin sulfate per pound of body weight per day (22 milligrams per kilogram) for 5 days.

(ii) *Indications for use.* For the control of mortality associated with *E. coli* organisms susceptible to neomycin sulfate in growing turkeys.

(iii) *Limitations.* Add to drinking water; not for use in liquid supplements. Prepare a fresh solution daily. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 5 consecutive days.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.430 is revised to read as follows:

§ 556.430 Neomycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of neomycin is 6 micrograms per kilogram of body weight per day.

(b) *Tolerances.* Tolerances are established for residues of parent neomycin in uncooked edible tissues as follows:

(1) *Cattle, swine, sheep, and goats.* 7.2 parts per million (ppm) in kidney (target tissue) and fat, 3.6 ppm in liver, and 1.2 ppm in muscle.

(2) *Turkeys.* 7.2 ppm in skin with adhearing fat, 3.6 ppm in liver, and 1.2 ppm in muscle.

(3) *Milk.* A tolerance is established for residues of parent neomycin of 0.15 ppm.

Dated: May 28, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–14924 Filed 6–10–99; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[DC036–2017; FRL–6356–4]

Approval and Promulgation of Air Quality Implementation Plans; District of Columbia; Enhanced Inspection and Maintenance Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: We are converting the conditional approval of the District of Columbia's (the District's) enhanced vehicle inspection and maintenance (I/M) program which was granted on June 2, 1998 (63 FR 29955) to a full approval. The District's I/M program was conditionally approved as a revision to its State Implementation Plan (SIP) in the rule published on June 2, 1998. The sole condition imposed in EPA's June 2, 1998 conditional approval was that the District's enhanced I/M program begin on or before April 30, 1999. The District began testing vehicles on April 26, 1999, and fulfilled its condition for full approval of the I/M program. The District's program meets all the requirements of the Clean Air Act for enhanced I/M.

DATES: This rule is effective on August 10, 1999, unless EPA receives adverse written comment by July 12, 1999. If adverse comment is received, we will publish a timely withdrawal of the rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Send written comments to: David L. Arnold, Chief, Ozone and Mobile Sources Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. You may inspect copies of the documents relevant to this action during normal business hours at the following locations: Air Protection Division, 14th floor, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and District of Columbia Department of Public Health, Air Quality Division, 2100 Martin Luther King Avenue, S.E., Washington, DC 20020. Please contact Catherine L., Magliocchetti at (215) 814–2174 if you wish to arrange an appointment to view the docket at the Philadelphia office.

FOR FURTHER INFORMATION CONTACT: Catherine L. Magliocchetti, (215) 814–2174 , or by e-mail at magliocchetti.catherine@epa.gov.

SUPPLEMENTARY INFORMATION: This Supplementary Information section is organized as follows:

What Action is EPA Taking Today?

In this action, we are converting our conditional approval of the District's I/M program as a revision to the SIP to a full approval. The District's enhanced I/M program was conditionally approved and made part of the District's SIP in a rule published on June 2, 1998 (63 FR 29955).

The sole condition imposed in the June 2, 1998 conditional approval was that the District's enhanced I/M program begin on or before April 30, 1999. The District began testing vehicles on April 26, 1999, and thereby has fulfilled the sole condition necessary for full approval of the I/M program. Because the District has fulfilled the condition imposed in the June 2, 1998 rule, we are converting our conditional approval of the I/M SIP to a full approval.

Who is Affected by This Action?

It is important to note that our action today does not impose any new requirements on District residents; we are merely giving full versus conditional federal approval to the District law and regulations that are already in place to implement an enhanced I/M program. Those laws and regulations were made part of the District's SIP by the final rule published on June 2, 1998 (63 FR 29955).

Who Will Benefit From This Program?

The residents of the District will benefit from this program, which is designed to keep vehicles maintained and operating within pollution control standards. And, since air pollution does not recognize political boundaries, neighboring states' residents will also benefit from implementation of this program which is designed to prevent excessive vehicle pollution.

EPA Action

EPA is converting its conditional approval approval of the District's enhanced I/M SIP to full approval. An extensive discussion of the District's I/M plan and our rationale for its approval was provided in the previous final rule which conditionally approved the I/M SIP (see 63 FR 29955 and 63 FR 15118) and in our Technical Support Document, dated March 10, 1998. This action to convert our conditional approval to full approval is being published without prior proposal because we view this as a noncontroversial revision and we anticipate no adverse comment. However, in a separate document in this **Federal Register** publication, we are proposing to this action should adverse written comments be filed. This action will be effective without further notice unless we receive relevant adverse comment by July 12, 1999. Should we receive such comments, we will publish a withdrawal and inform the public that this action will not take effect. Anyone interested in commenting on this action should do so at this time. If no such comments are received, you are advised that this action will be effective on August 10, 1999.

Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from review under E.O. 12866, entitled ''Regulatory Planning and Review.''

B. Executive Order 12875

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If EPA complies by consulting, E.O. requires EPA to provide to the Office of Management and Budget