Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health, Schering-Plough Corp., P.O. Box 529, Kenilworth, NJ 07033, has requested that NADA 47–486 Garasol® Injection (5 milligrams gentamicin per milliliter (mg/mL) for turkeys) be included in NADA 101–862 Garasol® Injection (50 and 100 mg/mL for chickens). The NADA's are combined as NADA 101–862. NADA 47–486 is withdrawn. Schering-Plough also filed supplemental NADA 101–862 providing for the use of 50 and 100 mg/mL gentamicin sulfate injection for turkeys at the same dosage and for the same indications as currently approved. The supplement is approved as of March 28, 1996. In addition, supplemental NADA 101–862 was approved on July 27, 1983, for the use of a 100 mg/mL injection in day-old chickens. However, this approval was not codified. At this time the regulation in § 522.1044 (21 CFR 522.1044) is amended to codify use of the 100 mg/mL injection in day-old chickens. Although the use was approved in chickens as well as turkeys, the regulations were not amended to provide for a tolerance for gentamicin residues in chickens. The regulations in 21 CFR 556.300 are amended to provide for tolerances for gentamicin residues in chickens as well as turkeys.

The approved, combined, and supplemented NADA 101-862 provides for use of Garasol® Injection (50 and 100 mg/mL gentamicin sulfate injection) in day-old chickens for the prevention of early mortality caused by *Escherichia coli*, *Salmonella typhimurium*, and *Pseudomonas aeruginosa* susceptible to gentamicin, and for use of Garasol® Injection (5, 50, and 100 mg/mL gentamicin sulfate injection) in 1- to 3-day-old turkeys for the prevention of early mortality due to *Arizona paracolon* infections susceptible to gentamicin.

In § 522.1044(d)(2)(i), the regulation is editorially amended to reflect the language used in § 522.1044(d)(3)(i).

Also, American Scientific Laboratories, A Division of Schering Corp., has been incorporated into Schering-Plough Animal Health, Schering-Plough Corp. Therefore, 21 CFR 510.600(c) is amended to remove the entries for American Scientific Laboratories, drug label code 000138.

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.

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

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 510, 522, and 556 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for ''American Scientific Laboratories'' and in the table in paragraph (c)(2) by removing the entry for ''000138''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

4. Section 522.1044 is amended by revising paragraphs (b), (d)(2)(i), and (d)(3)(i) to read as follows:

§ 522.1044 Gentamicin sulfate injection.

(b) *Sponsors.* (1) See No. 000061 in § 510.600(c) of this chapter for use of: 5-milligrams-per-milliliter solution in swine as in paragraph (d)(4) of this section, 50-milligrams-per-milliliter solution in dogs and cats as in paragraph (d)(1) of this section, 50- and 100-milligrams-per-milliliter solution in chickens and turkeys as in paragraphs (d)(2) and (d)(3) of this section.

(2) [Reserved]

* * * * *

(d) * * *

(2) Turkeys—(i) *Amount.* One milligram of gentamicin per 0.2 milliliter dose, using the 50- or 100-milligrams-per-milliliter product diluted with sterile saline to a concentration of 5 milligrams-per-milliliter.

* * * * *

(3) Chickens—(i) *Amount.* 0.2 milligram of gentamicin per 0.2 milliliter dose, using the 50- or 100-milligrams-per-milliliter product diluted with sterile saline to a concentration of 1.0 milligram-per-milliliter.

* * * * *

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

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

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

§ 556.300 [Amended]

6. Section 556.300 *Gentamicin sulfate* is amended in paragraph (a) by adding the phrase ''chickens and'' after ''tissues of''.

Dated: April 26, 1996.

Robert C. Livingston,

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

[FR Doc. 96–12154 Filed 5–14–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Parts 520 and 556

Animal Drugs, Feeds, and Related Products; Liquid Sul-Q-Nox (Sodium Sulfaquinoxaline 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 a supplemental new animal drug application (NADA) filed by I. D. Russell Co. Laboratories. The supplemental NADA provides for safe and effective use of a sodium

sulfaquinoxaline solution in medicating the drinking water of chickens, turkeys, calves, and cattle for either control or control and treatment of certain coccidial or bacterial diseases susceptible to sulfaquinoxaline. The approval reflects compliance with results of the National Academy of Sciences/ National Research Council (NAS/NRC), Drug Efficacy Study Group's (DESI) evaluation of the drug's effectiveness and FDA's conclusions concerning that evaluation. FDA is also amending the regulations to codify a tolerance for sulfaquinoxaline residues in edible tissues of chickens, turkeys, calves, and cattle.

EFFECTIVE DATE: May 15, 1996.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: I. D. Russell Co. Laboratories, 1301 Iowa Ave., Longmont, CO 80501, is the sponsor of NADA 6–891 which provides for the use of 34-percent Liquid Sul–Q–Nox (sodium sulfaquinoxaline solution). The drug product is used to medicate the drinking water of: (1) Chickens as an aid in the control of outbreaks of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima,* and *E. brunetti*; (2) turkeys as an aid in the control of outbreaks of coccidiosis caused by *E. meleagrimitis* and *E. adenoeides*; (3) chickens and turkeys as an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfaquinoxaline and fowl typhoid caused by *Salmonella gallinarum* susceptible to sulfaquinoxaline; and (4) calves and cattle for the control and treatment of outbreaks of coccidiosis caused by *E. bovis* or *E. zurnii*. The NADA was originally approved as safe on April 28, 1949.

In the Federal Register of July 9, 1970 (35 FR 11069), FDA published the results of a NAS/NRC DESI evaluation of several sulfaquinoxaline-containing veterinary drug products. The list of drug products included solutions which are similar to the subject solution. In that document, NAS/NRC evaluated the products as ''Probably effective as an aid in prevention and control of outbreaks of coccidiosis in chickens, turkeys, pheasants (and other game birds), cattle, and sheep (provided the specie of coccidia for the respective hosts are shown) * * *.'' Additionally, although it was inadvertently omitted from that document, NAS/NRC also evaluated such products as effective for control of acute fowl cholera in chickens, turkeys, pheasants, and other game birds and as effective for the control of fowl typhoid in chickens and turkeys. FDA concurred with the NAS/NRC findings.

The NAS/NRC evaluation was concerned only with the drugs' effectiveness and safety to the treated animal. It did not take into account the safety for human food use of food derived from drug-treated animals.

Subsequently, in the Federal Register of January 28, 1983 (48 FR 3962 at 3964), FDA established several sections for sulfaquinoxaline-containing drugs, including § 520.2325a (21 CFR 520.2325a), which specify those conditions of use found to be effective by NAS/NRC and FDA.

I. D. Russell Co. Laboratories has submitted information to comply with the NAS/NRC and FDA findings and has revised its labeling to conform to the currently approved conditions of use in § 520.2325a. On that basis, the subject supplemental NADA was approved as of March 6, 1996, and § 520.2325a is now amended to reflect the approval. The basis for this approval is discussed in the freedom of information summary.

Also, the section is amended to remove reserved paragraphs (a) and (b), to add a ''related tolerances'' paragraph, and to add a warning against use of sulfaquinoxaline-medicated drinking water in veal calves. The latter is part of a general effort to distinguish between ruminating and preruminating calves based on information indicating that withdrawal periods established in ruminating calves may not be adequate for preruminating calves.

Furthermore, the regulation contains an outdated paragraph citing the NAS/NRC status of these products. The Generic Animal Drug and Patent Term Restoration Act of 1988 changed that status. Therefore, the NAS/NRC paragraph is removed at this time.

Finally, the animal drug regulations are amended because FDA has noted that a tolerance for sulfaquinoxaline residues in edible tissues has not been codified. The tolerance for sulfaquinoxaline residues in all edible tissues from chickens, turkeys, calves, and cattle is 0.1 part per million (ppm). When sulfaquinoxaline was approved, a negligible tolerance of 0.1 ppm in all edible tissues was applied to animal drug residues based on subchronic (90-day) toxicological studies. This ''negligible tolerance'' concept is based on two precepts: (1) The residues are present at a level of insignificance and (2) the safety of the residues is supported by limited toxicological data. The toxicological data available for sulfaquinoxaline (90-day dog study) permit a tolerance for sulfaquinoxaline residues in edible tissues of 0.1 ppm. Therefore, this tolerance is being codified in new § 556.685.

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.

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 supplemental application does not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) and new human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

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

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

2. Section 520.2325a is amended by removing paragraph (d); by redesignating paragraphs (c), (e), and (f)

as paragraphs (a), (c), and (d), respectively; by revising newly redesignated paragraph (a); by amending newly redesignated paragraph (d) by adding two new sentences after the fifth sentence; and by adding a new paragraph (b) to read as follows:

§ 520.2325a Sulfaquinoxaline drinking water.

(a) *Sponsor.* See § 510.600(c) of this chapter for identification of the sponsors.

(1) No. 050749 for use of a 25-percent soluble powder and a 20-percent solution as provided for in paragraph (c) of this section.

(2) No. 060594 for use of 3.44- and 12.85-percent solutions as provided for in paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(i), and (c)(4)(ii) of this section.

(3) No. 017144 for use of a 34-percent solution as provided for in paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(i), and (c)(4)(ii) of this section.

(b) *Related tolerances.* See § 556.685 of this chapter.

* * * * *

(d) *Limitations.* * * * A withdrawal period has not been established for sulfaquinoxaline in preruminating calves. Do not use in calves to be processed for veal. * * *

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: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

4. New § 556.685 is added to subpart B read as follows:

§ 556.685 Sulfaquinoxaline.

A tolerance of 0.1 part per million is established for negligible residues of sulfaquinoxaline in the uncooked edible tissues of chickens, turkeys, calves, and cattle.

Dated: April 15, 1996.

Robert C. Livingston,

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

[FR Doc. 96–11927 Filed 5–14–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 520 and 558

Animal Drugs, Feeds, and Related Products; Monensin

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 supplemental new animal drug applications (NADA's) filed by Elanco Animal Health, Division of Eli Lilly and Co., Moorman Manufacturing Co., and Farmland Industries, Inc. Elanco's supplemental NADA provides for use of monensin Type C medicated feeds fed to pasture cattle weighing less than 400 pounds (lb) for increased rate of weight gain. Moorman's and Farmland's supplemental NADA's provide for use of monensin blocks for pasture cattle weighing less than 400 lb for increased rate of weight gain.

EFFECTIVE DATE: May 15, 1996.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1638.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 95–735, which provides for use of monensin Type A medicated articles to make monensin Type C medicated feeds containing 25 to 400 grams per ton monensin as monensin sodium to be fed at 50 to 200 milligrams per head per day to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) weighing less than 400 lb for increased rate of weight gain. Moorman Manufacturing Co., Quincy, IL 62301, filed supplemental NADA 115–581, and Farmland Industries, Inc., Kansas City, MO 64116, filed supplemental NADA 118–509, providing for free-choice feeding of monensin blocks, all to pasture cattle weighing less than 400 lb for increased rate of weight gain.

The supplemental NADA's provide for removal of the restriction concerning feeding of the products to animals weighing less than 400 lb body weight as currently approved. The supplemental NADA's are approved as of March 15, 1996, and the regulations are amended in 21 CFR 520.1448a(c) and 558.355(f)(3)(iii) and (f)(3)(v) to reflect the approvals. The basis for approval is discussed in the freedom of information summary for Elanco's supplemental NADA 95–735.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), approval of Elanco Animal Health's supplemental NADA 95–735 qualifies for 3 years of marketing exclusivity beginning March 15, 1996, because the supplement contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant. Marketing exclusivity applies only to the new use of the product.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), approval of Moorman's supplemental NADA 115–581 and Farmland's supplemental NADA 118–509 do not qualify for marketing exclusivity because the supplements do not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) or new human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

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.

The basis of approval of Moorman's and Farmland's supplemental NADA's are by authorization to reference data and information in Elanco's supplemental NADA 95–735. Therefore, a freedom of information summary of the data and information required for approval of these NADA's is available under Elanco's supplemental NADA 95–735.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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

21 CFR Part 520

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520 and 558 are amended as follows: