System (the Board) requested public comment on a proposed rule (the Proposed Rule) that would require foreign banks with only agencies and subsidiary commercial lending companies in the United States to select a home state, or have a home state designated by the Board. 60 FR 67100. The Proposed Rule also would remove a restriction on the ability of foreign banks to effect major bank mergers through U.S. subsidiary banks located outside the foreign banks' home states, and would delete certain outdated rules governing home state selection.

The comment period ended on February 5, 1996. The Board received a single public comment on the Proposed Rule from a trade association. The Board has considered the comment and has made changes to address it in the final rule. Except as discussed below, the Board's final rule remains unchanged from the Proposed Rule. In addition, the Board requested and received comments on other aspects of the Interstate Act as it applies to foreign banks. The Board will consider these comments in connection with future review of the provisions of Regulation K concerning the interstate operation of foreign banks.

The commenter generally supported the provisions of the Proposed Rule, including its provisions requiring certain foreign banks to select a home state as contemplated by the Interstate Act. The commenter suggested, however, that the deadline for home state selection by these banks be 60 days from the publication of the final rule, rather than March 31, 1996, as proposed in the Proposed Rule. The commenter requested this extension in order to give these banks adequate time to assess the consequences of their decision.

Although the Interstate Act removed the geographic restrictions of the IBA on the interstate acquisition of banks by foreign banks, the home state of a foreign bank continues to affect its options for establishing additional branches in the United States under the IBA. In particular, the location of a foreign bank's home state is a factor determining the ability of the foreign bank to establish further interstate branches pursuant to section 5 (a)(1) and 5 (a)(2) of the IBA, as amended by the Interstate Act. 12 U.S.C. § 3103 (a)(1), (a)(2).

Accordingly, the final rule allows additional time for home state selection by establishing June 30, 1996, as the deadline for such selection. This extension affords foreign banks affected by the rule ample time in which to make an informed home state selection.

The proposed rule provided that, in the event a foreign bank required to select a home state fails to do so, the Board would exercise its authority to determine a foreign bank's home state. In such cases, the Board generally will designate as a foreign bank's home state the state in which the total assets of all its offices, net of claims on affiliates or other offices of the foreign bank, is the largest, as reflected in the foreign bank's most recent report of condition, unless other circumstances warrant designation of a different home state.

Paperwork Reduction Act

In accordance with section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Ch. 35; 5 CFR 1320 Appendix A.1), the Board reviewed the rule under the authority delegated to the Board by the Office of Management and Budget. No collections of information pursuant to the Paperwork Reduction Act are contained in the rule.

Regulatory Flexibility Act Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601 *et seq.*), the Board certifies that the final rule would not have a significant economic impact on a substantial number of small entities that are subject to its regulation.

List of Subjects in 12 CFR Part 211

Exports, Federal Reserve System, Foreign banking, Holding companies, Investments, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, the Board amends 12 CFR Part 211 as set forth below:

PART 211—INTERNATIONAL BANKING OPERATIONS (REGULATION K)

1. The authority citation for Part 211 continues to read as follows:

Authority: 12 U.S.C. 221 *et seq.*, 1818, 1841 *et seq.*, 3101 *et seq.*, 3901 *et seq.*

2. In § 211.22, paragraph (a) is revised; paragraph (c) is removed; and paragraph (d) is redesignated as paragraph (c) to read as follows:

§ 211.22 Interstate banking operations of foreign banking organizations.

(a) *Determination of home state.* (1) A foreign bank (except a foreign bank to which paragraph (a)(2) of this section applies) that has any combination of domestic agencies or subsidiary commercial lending companies that were established before September 29, 1994, in more than one state and have been continuously operated shall select its home state from those states in which such offices or subsidiaries are located. A foreign bank shall do so by filing with the Board a declaration of home state by June 30, 1996. In the absence of such selection, the Board shall designate the home state for such foreign banks.

(2) A foreign bank that, as of September 29, 1994, had declared a home state or had a home state determined pursuant to the law and regulations in effect prior to that date shall have that state as its home state.

(3) A foreign bank that has any branches, agencies, subsidiary commercial lending companies, or subsidiary banks in one state, and has no such offices or subsidiaries in any other states, shall have as its home state the state in which such offices or subsidiaries are located.

* * * * *

By order of the Board of Governors of the Federal Reserve System, May 9, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96–12134 Filed 5–14–96; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, and 556

Animal Drugs, Feeds, and Related Products; Gentamicin 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 the following actions on two new animal drug applications (NADA's) held by Schering-Plough Animal Health: The combination of two NADA's into one and the withdrawal of the other, the codification of a supplemental NADA approved by letter, the approval of a supplemental NADA that provides for the use of two higher product concentrations at the same dosage and for the same indications, and the addition of a tolerance for residues of gentamicin in chickens.

The approved, combined, and supplemented NADA provides for use of gentamicin sulfate injection for the prevention of early mortality of day-old chickens and 1- to 3-day-old turkeys due to certain infections susceptible to gentamicin.

EFFECTIVE DATE: May 15, 1996

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug

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