

- (c) Market value, and the value of the underlying securities, of naked call contracts:
- (i) Listed.....
 - (ii) Unlisted.....
- (d) Market value, and the value of the underlying securities, of naked put contracts:
- (i) Listed.....
 - (ii) Unlisted.....
3. Futures:
- (a) U.S. Treasury and mortgage-backed securities futures.
 - (b) Other futures (specify)
4. Forwards:
- (a) U.S. Treasury and mortgage-backed securities.
 - (i) Aggregate current cost of replacing contracts by counterparty in which the Material Associated Person has a gain.
 - (ii) Per counterparty breakdown where credit risk exceeds the Materiality Threshold.
 - (b) Other forwards (specify).....
 - (i) Aggregate current cost of replacing contracts by counterparty in which the Material Associated Person has a gain.
 - (ii) Per counterparty breakdown where credit risk exceeds the Materiality Threshold.
- B. Interest Rate Swaps
1. U.S. dollar denominated swaps:
 - (a) Total notional or contractual amount.
 - (b) Aggregate current cost of replacing contracts by counterparty in which the Material Associated Person has a gain.
 - (c) Per counterparty breakdown where credit risk exceeds the Materiality Threshold.
 2. Cross currency swaps:
 - (a) Total notional or contractual amount.
 - (b) Aggregate current cost of replacing contracts by counterparty in which the Material Associated Person has a gain.
 - (c) Per counterparty breakdown where credit risk exceeds the Materiality Threshold.
- C. Foreign exchange
1. Swaps:
 - (a) Total notional or contractual amount.
 - (b) Aggregate current cost of replacing contracts by counterparty in which the Material Associated Person has a gain.
 - (c) Per counterparty breakdown where credit risk exceeds the Materiality Threshold.
 2. Notional or contractual amounts of commitments to purchase foreign currencies and U.S. dollar exchange:
 - (a) Future.....
 - (b) Forwards.....
 - (i) Aggregate current cost of replacing contracts by counterparty in which the Material Associated Person has a gain.
 - (ii) Per counterparty breakdown where credit risk exceeds the Materiality Threshold.
3. Allowance for losses for credit extensions.
- IV. Funding Sources
1. Short-term borrowings:
 - (a) Commercial paper.....
 - (b) Bank loans-secured.....
 - (c) Bank loans-unsecured.....
 - (d) Other.....
 - (e) Total.....
 2. Long and medium-term debt.....
 3. Committed lines of credit.....
 4. Amounts borrowed under credit lines.....
 5. Credit ratings for commercial paper
 - (a) Standard & Poor's Corporation.
 - (b) Moody's Investor Service.....
 - (c) Other Nationally Recognized Statistical Rating Organization.
- V. Real Estate
1. Real estate loans:
 - (a) Construction and land development.
 - (b) Secured by farmland.....
 - (c) Secured by residential properties.
 - (d) Commercial and industrial.....
 - (e) Other.....
 2. Real estate investments:
 - (a) Construction and land development.
 - (b) Farmland.....
 - (c) Residential properties.....
 - (d) Commercial and industrial.....
 - (e) Other.....
 3. Provide a separate listing of the above information by geographic region where the amount exceeds the Materiality Threshold.
 4. Provide information about risk concentration to a single borrower, location or property in the investment or loan portfolio where the amount exceeds the Materiality Threshold
- Dated: July 16, 1992.
By the Commission.
Jonathan G. Katz,
Secretary.
[FR Doc. 92-17151 Filed 7-20-92; 12:01 am]
BILLING CODE 8010-01-M
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- DEPARTMENT OF HEALTH AND HUMAN SERVICES
- Food and Drug Administration
- 21 CFR Part 73
- [Docket No. 89C-0506]
- Listing of Color Additives Exempt From Certification; Diluents for Color Additive Mixtures: Calcium Disodium EDTA (Calcium Disodium Ethylenediaminetetraacetate) and Disodium EDTA (Disodiummethylenediaminetetraacetate)**
- AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate) and disodium EDTA (disodium ethylenediaminetetraacetate) as diluents in color additive mixtures for use in food and ingested drugs. This action is in response to a petition filed by Warner-Jenkinson Co.

DATES: Effective August 21, 1992, except as to any provisions that may be stayed by the filing of proper objections; written objections by August 20, 1992.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Emily Florio, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9515.

SUPPLEMENTARY INFORMATION:**I. Introduction**

In a notice published in the *Federal Register* of January 10, 1990 (55 FR 908), FDA announced that a color additive petition (CAP 9C0218) had been filed by Warner-Jenkinson Co., P.O. Box 14538, St. Louis, MO 63178-4538, proposing that 21 CFR part 73 of the color additive regulations be amended to provide for the safe use of calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate) and disodium EDTA (disodium ethylenediaminetetraacetate) as diluents in color additive mixtures for use in food and ingested drugs. This amendment will provide for the use of these diluents in color additive mixtures for ingested drug use by the cross-reference already given in 21 CFR 73.1001(a)(1). The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

II. Conclusion

Based on data contained in the petition and other relevant information, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of calcium disodium EDTA and disodium EDTA as diluents in color additive mixtures for

use in food and ingested drugs. The agency also concludes on the basis of those data and existing regulations for uses of calcium disodium EDTA (21 CFR 172.120) and disodium EDTA (21 CFR 172.135), that the diluents will perform their intended effects as preservatives and sequestrants, and thus, are suitable for these uses. The agency, therefore, is amending the color additive regulations in 21 CFR 73.1(a)(3) to provide for use of the diluents disodium EDTA and calcium disodium EDTA.

FDA further concludes that color additive mixtures containing calcium disodium EDTA and disodium EDTA are exempted from batch certification subject to the condition that each straight color in the mixture has been exempted from batch certification or, if not so exempted, is from a batch that has previously been certified and that has not changed in composition since certification. Mixtures of certifiable color additives are further subject to the restrictions of 21 CFR 80.35(b), wherein the certified batch of straight color is simply mixed with the approved diluent(s) and the label of such color additive mixtures shall not bear the lot number assigned by FDA to the certified straight color components, but shall bear the manufacturer's control number through which the history of the straight color can be determined.

III. Inspection of Documents

In accordance with 21 CFR 71.15, the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition (address above) by appointment with the information contact person listed above. As provided in 21 CFR 71.15, the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

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.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before August 20, 1992, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the *Federal Register*.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: Secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 376).

2. Section 73.1 is amended in the table in paragraph (a)(3) by alphabetically

adding two new entries under the headings "Substances", "Definitions and specifications", and "Restrictions" to read as follows:

§ 73.1 Diluents in color additive mixtures for food use exempt from certification.

- (a) * * *
- (3) * * *

Substances	Definitions and specifications	Restrictions
Calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate).	Contains calcium disodium ethylenediaminetetraacetate dihydrate (CAS Reg. No. 6766-87-6) as set forth in the Food Chemicals Codex, 3d ed., p. 50, 1981.	May be used in aqueous solutions and aqueous dispersions as a preservative and sequestrant in color additive mixtures intended only for ingested use; the color additive mixture (solution or dispersion) may contain not more than 1 percent by weight of the diluent (calculated as anhydrous calcium disodium ethylenediaminetetraacetate).
Disodium EDTA (disodium ethylenediaminetetraacetate).	Contains disodium ethylenediaminetetraacetate dihydrate (CAS Reg. No. 6381-92-6) as set forth in the Food Chemicals Codex, 3d ed., p. 104, 1981.	May be used in aqueous solutions and aqueous dispersions as a preservative and sequestrant in color additive mixtures intended only for ingested use; the color additive mixture (solution or dispersion) may contain not more than 1 percent by weight of the diluent (calculated as anhydrous disodium ethylenediaminetetraacetate).

Dated July 15, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-17143 Filed 7-20-92; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 510 and 520

[Docket No. 92N-0271]

Animal Drugs, Feeds, and Related Products; Sulfadimethoxine Soluble Powder

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 Agri Laboratories, Ltd. The ANADA provides for the use of a generic sulfadimethoxine soluble powder as an antibacterial in drinking water for broiler and replacement chickens and meat-producing turkeys, and in drinking water and as a drench for dairy calves, dairy heifers, and beef cattle.

EFFECTIVE DATE: July 21, 1992.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8648.

SUPPLEMENTARY INFORMATION: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, is the sponsor of ANADA 200-031 which provides for the use of a generic sulfadimethoxine soluble powder as an antibacterial in drinking water for the treatment of broiler and replacement chickens for coccidiosis, fowl cholera, and infectious coryza; meat-producing turkeys for coccidiosis and fowl cholera; and in drinking water and as a drench for the treatment of dairy calves, dairy heifers, and beef cattle for shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.

Approval of ANADA 200-031 for Agri Laboratories, Ltd.'s, Sulfadimethoxine Antibacterial Soluble Powder is as a generic copy of Hoffmann-LaRoche's NADA 046-285 for Albion® Soluble Powder (sulfadimethoxine). The ANADA is approved as of June 17, 1992, and the regulations are amended in 21 CFR 520.2220a to reflect this approval. The basis for approval is discussed in the freedom of information summary.

In addition, Agri Laboratories, Ltd., has not previously been listed in 21 CFR 510.600(c) as a sponsor of an approved

application. That section is amended to add new entries for the firm.

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, room 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

21 CFR Part 510

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

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 parts 510 and 520 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, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for "Agri Laboratories, Ltd.," and in the table in paragraph (c)(2) by numerically adding a new entry for "057561" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

- (c) * * *
- (1) * * *

Firm name and address	Drug labeler code
Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503	057561

(2) * * *

Drug labeler code	Firm name and address
057561	Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

3. 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).

§ 520.2220a [Amended]

4. Section 520.2220a. Sulfadimethoxine drinking water and drench is amended in paragraph (b) by removing "(1)" after the word "follows:" and by adding the phrase "and 057561" after the number "000004".

Dated: July 9, 1992.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 92-17059 Filed 7-20-92; 12:01 pm]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Narasin and Bacitracin Methylene Disalicylate

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 new animal drug application (NADA) filed by A. L. Laboratories, Inc. The NADA provides for the use of two separately approved Type A medicated articles, one containing narasin and the other containing bacitracin methylene disalicylate, to make combination Type C medicated feeds for the prevention of coccidiosis, for increased rate of weight gain, and for improved feed efficiency in broiler chickens.

EFFECTIVE DATE: July 21, 1992.

FOR FURTHER INFORMATION CONTACT:

James F. McCormack, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8602.

SUPPLEMENTARY INFORMATION:

A. L. Laboratories, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, has filed NADA 140-853 which provides for the combination of separately approved narasin and bacitracin methylene disalicylate Type A medicated articles to make Type C medicated feeds containing 54 to 72 grams (g) of narasin per ton and 10 to 50 g of bacitracin methylene disalicylate per ton. The feed is used in broiler chickens for the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati*, *E. necatrix*, and *E. tenella*, for increased rate of weight gain, and for improved feed efficiency.

The NADA is approved as of May 22, 1992, and the regulations are amended in 21 CFR 558.76(d)(3) and 558.363(c)(1) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years exclusivity beginning May 22, 1992, because it contains reports of new clinical or field investigations essential to the approval of the application.

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), room 1-23, 12420 Parklawn Dr., 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)(ii) 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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

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

2. Section 558.76 is amended by revising paragraph (d)(3)(xiii) to read as follows:

§ 558.76 Bacitracin, methylene disalicylate.

* * * * *

(d) * * *

(3) * * *

(xiii) Narasin alone or in combination with roxarsone as in § 558.363.

3. Section 558.363 is amended by adding paragraph (c)(1)(vi) to read as follows:

§ 558.363 Narasin.

* * * * *

(c) * * *

(1) * * *

(vi) Amount per ton. Narasin 54 to 72 grams, and bacitracin methylene disalicylate 10 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati*, *E. necatrix*, and *E. tenella*, for increased rate of weight gain, and for improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Narasin as provided by 000986, bacitracin methylene disalicylate by 046573 in § 510.600(c) of this chapter.

* * * * *

Dated: June 22, 1992.

Richard H. Teske,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 92-17508 Filed 7-20-92; 12:01 pm]

BILLING CODE 4160-01-M#

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 19

[T.D. ATF-327]

Distilled Spirits for Fuel Use

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.