

List of Subjects in 9 CFR Part 53

Animal diseases, Indemnity payments, Livestock and livestock products, Poultry and poultry products, Exotic Newcastle disease, Foot-and-mouth disease, Highly pathogenic avian influenza, Pleuropneumonia.

Accordingly, the interim rule concerning lethal avian influenza which was published at 49 FR 3446-3448 on January 27, 1984, is adopted without change as a final rule.

Authority: Sec. 3, 23 Stat. 32, as amended, sec. 2, 32 Stat. 792, as amended, sec. 11, 58 Stat. 734, as amended; 21 U.S.C. 111, 114, 114a, unless otherwise noted; 7 CFR 2.17, 2.51, and 371.2(d).

Done at Washington, D.C., this 26th day of June 1984.

W. E. Ketter,

Acting Deputy Administrator, Veterinary Services.

[FR Doc. 84-17427 Filed 6-28-84; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Airspace Docket No. 84-ACE-5]

Designation of Federal Airways, Area Low Routes, Controlled Airspace, and Reporting Points; Realignment of VOR Federal Airways V-73 and V-256

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This rule realigns VOR Federal Airway V-73 from the Tulsa VORTAC direct to the Wichita VORTAC. It also realigns VOR Federal Airway V-256 from Tulsa direct to the FRAKS Intersection direct to the Pioneer VORTAC. This action is taken to reestablish a lower minimum en route altitude (MEA) and more effectively utilize available airspace.

DATES: Effective date—August 30, 1984. Comments must be received on or before August 13, 1984.

ADDRESSES: Send comments on the rule in triplicate to: Director, FAA, Central Region, Attention: Manager, Air Traffic Division, Docket No. 84-ACE-5, Federal Aviation Administration, 601 East 12th Street, Federal Building, Kansas City, MO 64106.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. The FAA Rules Docket is located in the Office of the Chief

Counsel, Room 916, 800 Independence Avenue, SW., Washington, D.C.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Gene Falsetti, Airspace and Air Traffic Rules Branch (AAT-230), Airspace-Rules and Aeronautical Information Division, Air Traffic Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone: (202) 426-8783.

SUPPLEMENTARY INFORMATION:**Request for Comments on the Rule**

Although this action is in the form of a final rule, which involves a minor realignment of two VOR Federal Airways and, thus, was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the FAA will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule and determining whether additional rulemaking is needed. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy aspects of the rule that might suggest the need to modify the rule.

The Rule

The purpose of this amendment to § 71.123 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is to realign two VOR Federal Airways to achieve more efficient use of available airspace. The Wichita, KS, VORTAC was relocated and commissioned on November 4, 1983. When the associated airways were realigned, it was decided to change only that portion of V-73 between FRAKS Intersection and the Wichita VORTAC. V-73 from FRAKS to the Tulsa VORTAC remained in the original position. As a result, the airway now has a one degree dogleg in it at FRAKS and it was necessary to increase the MEA from 3,400 feet to 6,500 feet. The increase was required because the navigational changeover point was established at FRAKS Intersection rather than the midpoint location. The realignment affecting V-73 and FRAKS Intersection also creates a need to realign V-256. Section 71.123 of Part 71 of the Federal Aviation Regulations was

republished in FAA Handbook 7400.8 dated January 3, 1984.

This action reduces a burden on airspace users and is so minor in nature that the FAA does not anticipate significant public interest. Therefore, I find that notice or public procedure under 5 U.S.C. 553(b) is unnecessary and that good cause exists for making this amendment effective coincident with the next charting date.

List of Subjects in 14 CFR Part 71

Aviation safety, VOR Federal airways.

Adoption of the Amendment**PART 71—[AMENDED]**

Accordingly, pursuant to the authority delegated to me, § 71.123 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended, effective 0901 GMT, August 30, 1984, as follows:

§ 71.123 [Amended]**V-73 [Amended]**

By deleting the words "via INT Tulsa 319" and Wichita, KS, 136° radials;" and substituting the words "Wichita, KS;"

V-256 [Amended]

By deleting the word "319" and substituting the word "318" (Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); (49 U.S.C. 106(g) [Revised, Pub. L. 97-449, January 12, 1983]); and 14 CFR 11.69)

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in Washington, D.C., on June 22, 1984.

John W. Baier,

Acting Manager, Airspace—Rules and Aeronautical Information Division.

[FR Doc. 84-17331 Filed 6-28-84; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 182 and 184**

(Docket No. 77N-0132)

GRAS Status of Calcium Hydroxide and Calcium Oxide**AGENCY:** Food and Drug Administration.**ACTION:** Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that calcium hydroxide and calcium oxide are generally recognized as safe (GRAS) as direct human food ingredients. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency. **DATES:** Effective July 30, 1984. The Director of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 184.1205 and 184.1210 effective on July 30, 1984.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 16, 1977 (42 FR 41299), FDA published a proposal to affirm that calcium hydroxide and calcium oxide are GRAS for use as direct human food ingredients, and that calcium hydroxide is GRAS for use as an indirect human food ingredient. The proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients. However, the proposal failed to propose to delete calcium hydroxide from Part 182 (21 CFR Part 182). Consequently, in the Federal Register of June 25, 1982 (47 FR 27818), FDA published a tentative final rule in which the agency announced its intention to delete calcium hydroxide as well as calcium oxide from Part 182. The tentative final rule explained that the statement of intent to remove calcium hydroxide from Part 182 had inadvertently been omitted from the August 16, 1977 proposal. In addition, the tentative final rule proposed not to include a separate listing of the indirect uses of calcium hydroxide and calcium oxide in 21 CFR Part 186 because the indirect uses of these substances are authorized under §§ 184.1205, 184.1210, and 184.1(a) (21 CFR 184.1205, 184.1210, and 184.1(a)). However, the tentative final rule made no changes in the conditions of use in the proposed GRAS

affirmation regulations for these substances. Both proposed § 184.1205 and proposed § 184.1210 contained food categories, maximum use levels, and technical effects. FDA provided an opportunity for public comment on the contents of the tentative final rule.

Two comments were submitted in response to the tentative final rule.

1. Both comments requested that FDA delete the description of the current good manufacturing practice conditions of use for calcium hydroxide and calcium oxide from the GRAS affirmation regulations. One of the comments asserted that in similar cases, the agency had adopted GRAS affirmation regulations that stated only that the ingredients were to be used in food in accordance with current good manufacturing practice. The comments further pointed out that the Select Committee on GRAS Substances (the Select Committee) of the Federation of American Societies for Experimental Biology (FASEB) had concluded that calcium oxide and calcium hydroxide are safe, and that FDA had concurred with that conclusion. One comment asserted that listing specific conditions of use in the regulation restricts innovative uses of these ingredients. The comment requested that if FDA did decide to deny the request for no use limitation other than current good manufacturing practice, it should increase the maximum use levels for calcium hydroxide in dairy product analogs from 0.45 percent to 1.5 percent.

FDA has reviewed these comments. In the Federal Register of October 19, 1983 (48 FR 48457, 48458), FDA published a final rule that amended the GRAS procedural regulations to clarify the circumstances in which the agency would describe the current good manufacturing practice conditions of use for a substance in a GRAS affirmation regulation. Based on the considerations discussed in that document, the agency has determined that it is appropriate to delete the food categories, maximum use levels, and technical effects from the GRAS affirmation regulations for calcium hydroxide and calcium oxide. Both the Select Committee and the agency have concluded that a large margin of safety exists for the use of these ingredients, and that a reasonably foreseeable increase in the level of consumption of these ingredients will not adversely affect human health. Further, both of these ingredients have multiple purposes in food and are used in a large number of food categories. Accordingly, the agency has concluded that listing conditions of use for these ingredients is not necessary to ensure their safe use. Therefore, the agency has

modified §§ 184.1205 and 184.1210 by deleting the conditions of use other than current good manufacturing practice from these regulations in accordance with § 184.1(b)(1).

With regard to innovative or increased uses of these ingredients, the agency concludes that the listing of these ingredients in Part 184 with no conditions of use other than current good manufacturing practice gives ample latitude for innovative or increased uses of these ingredients.

2. One comment requested that calcium hydroxide not be deleted from Part 182.

FDA has reviewed this request. FDA finds that the comment has not provided any basis for continuing to list this substance as GRAS in Part 182 instead of affirming it as GRAS in Part 184. Accordingly, the agency is denying this request.

The agency has previously determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by the Order. The agency has not received any new information or comments that would alter its previous determination.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

List of Subjects**21 CFR Part 182**

Generally recognized as safe (GRAS) food ingredients, Spices and flavorings.

21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 182 and 184 are amended as follow:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE**1. Part 182 is amended:****§ 182.90 [Amended]**

a. In § 182.90 *Substances migrating to food from paper and paperboard products* by removing "Calcium hydroxide (lime)" from the list of substances.

§§ 182.1205, 182.1210, 182.8210 [Removed]

b. By removing § 182.1205 *Calcium hydroxide*, § 182.1210 *Calcium oxide*, and § 182.8210 *Calcium oxide*.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE**2. Part 184 is amended:**

a. By adding new § 184.1205, to read as follows:

§ 184.1205 Calcium hydroxide.

(a) Calcium hydroxide (Ca(OH)₂, CAS Reg. No. 1305-62-0) is also known as slaked lime or calcium hydrate. It is produced by the hydration of lime.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 52, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

b. By adding new § 184.1210, to read as follows:

§ 184.1210 Calcium oxide.

(a) Calcium oxide (CaO, CAS Reg. No. 1305-78-8) is also known as lime, quick lime, burnt lime, or calx. It is produced from calcium carbonate, limestone, or oyster shells by calcination at temperatures of 1,700–2,450 °F.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 55, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Effective date. This regulation is effective July 30, 1984.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a)))

Dated: June 18, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84-17318 Filed 6-28-84; 8:45 am]

BILLING CODE 4180-01-M

21 CFR Part 520**Oral Dosage Form New Animal Drugs Not Subject to Certification; Trimethoprim and Sulfadiazine Oral Paste**

AGENCY: Food and Drug Administration.

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 Syntex Agribusiness, Inc., providing for safe and effective oral use in horses of a combination antibacterial drug containing trimethoprim and sulfadiazine.

EFFECTIVE DATE: June 29, 1984.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (formerly Bureau of Veterinary Medicine) (HFV-114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: Syntex Agribusiness, Inc., 3401 Hillview Ave.,

Palo Alto, CA 94304, filed NADA 136-342 providing for oral use of Di-Trim® 400 Oral Paste (67 milligrams of trimethoprim and 333 milligrams of sulfadiazine per gram of paste) for treating certain bacterial infections in horses. The firm also holds approval for use of Di-Trim® Tablets and Di-Trim® 24% injection in dogs, and Di-Trim® 48% injection in horses. Use of the drug in horses is indicated where control of bacterial infections is required during treatment of acute strangles, respiratory infections, acute urogenital infections, wound infections, and abscesses. The NADA is approved, and the regulations are amended to reflect the approval. The basis of approval of the NADA is discussed in the freedom of information summary.

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. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Center for Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs, Oral use.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION**§ 520.2611 [Amended]**

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.83), § 520.2611 *Trimethoprim and sulfadiazine oral paste* is amended in paragraph (b) by adding before the number "017220" the phrase "000033 and."

Effective date. June 29, 1984.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: June 19, 1984.

Lester M. Crawford,
Director, Center for Veterinary Medicine.
[FR Doc. 84-17320 Filed 6-28-84; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs Not Subject to Certification; Furosemide Injection

AGENCY: Food and Drug Administration.
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 Med-Tech, Inc., providing for a safe and effective use of furosemide injection for treating horses for acute noninflammatory tissue edema.

EFFECTIVE DATE: June 29, 1984.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: Med-Tech, Inc., P.O. Box 338, Elwood, KS 66024 filed NADA 127-034 providing for use of furosemide injection for treating horses for acute noninflammatory tissue edema. The NADA is approved and the regulations are amended to reflect the approval. The basis for approval of this NADA is discussed in the freedom of information summary.

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. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Center for Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 522

Animal drugs, Injectable.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

§ 522.1010 [Amended]

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.83), § 522.1010 *Furosemide injection* is amended in paragraph (b) by inserting after "000864" the phrase "and 013983."

Effective date. June 29, 1984.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: June 25, 1984.

Lester M. Crawford,
Director, Center for Veterinary Medicine.
[FR Doc. 84-17317 Filed 6-28-84; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Parts 522 and 556

Animal Drugs, Feeds, and Related Products; Fenprostalene Solution

AGENCY: Food and Drug Administration.
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 Syntex Agribusiness, Inc., providing for use of fenprostalene solution as an estrus synchronizer for beef and nonlactating dairy cattle in addition to use as an abortifacient in pregnant feedlot heifers. FDA is also establishing safe concentrations for fenprostalene residues in edible cattle tissues.

EFFECTIVE DATE: June 29, 1984.

FOR FURTHER INFORMATION CONTACT: Adriano R. Gabuten, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4913.

SUPPLEMENTARY INFORMATION: Syntex Agribusiness, Inc., 3401 Hillview Ave., Palo Alto, CA 94304, filed supplemental NADA 128-549 providing for subcutaneous use of Bovilene™ (fenprostalene) solution for estrus synchronization in beef and nonlactating dairy cattle. The product is currently approved for use as an abortifacient in pregnant feedlot heifers. The supplement is approved, and the regulations are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Additionally, the regulations are amended to establish the safe concentrations for fenprostalene residues in edible tissues of cattle. The safe concentrations refer to the concentrations of total residues considered safe in edible tissues. The agency has determined that a tolerance for a marker residue in a target tissue is not necessary because the level of residues in the edible tissues would not exceed the safe concentrations even with any foreseeable misuse of the drug.

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. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Center for Veterinary Medicine 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 and that an environmental impact statement therefore will not be prepared. The Center's finding of no significant impact and the evidence supporting this finding, contained in an environmental assessment (pursuant to 21 CFR 25.31, proposed December 11, 1979; 44 FR 71742) may be seen in the Dockets Management Branch (address above).

List of Subjects

21 CFR Part 522

Animal drugs, Injectable.

21 CFR Part 556

Animal drugs, Foods, Residues.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.83), Parts 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. Part 522 is amended in § 522.914 by redesignating paragraphs (c) and (d) as paragraphs (d) and (e), by adding new paragraph (c), and by revising redesignated paragraph (e), to read as follows: