

By-Laws, and other rules of the association. The records maintained by such an association shall include an Official Herd Book or other recordkeeping format and Certificates of Registration or Recordation which identify an animal as a registered animal of that registered breed association.

A claimant is eligible to receive indemnity for cattle as registered animals if they are registered with a breed association listed in § 51.1(cc) of the regulations.

In addition to the registered breed associations already listed, it has been determined that the "National Beefmaster Association" is within the definition of a registered breed association in § 51.1(cc). Therefore, it is necessary to add this registered breed association to the list of registered breed associations in § 51.1(cc).

Emergency Action

Dr. John K. Atwell, Deputy Administrator of the Animal and Plant Health Inspection Service for Veterinary Services, has determined that an emergency situation exists which warrants publication of this interim rule without prior opportunity for public comment. It is necessary to make this interim rule effective immediately in order to allow for proper payment of indemnities to owners of cattle destroyed because of brucellosis, thereby encouraging the elimination of these reactor cattle as a disease source.

Further, pursuant to the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that prior notice and other public procedures with respect to this interim rule are impracticable and contrary to the public interest and good cause if found for making this interim rule effective upon publication in the Federal Register. Comments are solicited for 60 days following publication and a final document discussing comments received and any amendments required will be published in the Federal Register.

Executive Order 12291 and Regulatory Flexibility Act

This rule is issued in conformance with Executive Order 12291 and has been determined to be not a major rule. Based on information compiled by the Department, it has been determined that this rule will not have a significant effect on the economy; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based

enterprises to compete with foreign-based enterprises in domestic or export markets.

For this action, the Office of Management and Budget has waived its review process required by Executive Order 12291.

This change will affect less than one percent of the cattle annually destroyed because of brucellosis in the United States.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 9 CFR Part 51

Animal diseases, Bison, Cattle, Hogs, Indemnity payments, Brucellosis.

PART 51—ANIMALS DESTROYED BECAUSE OF BRUCELLOSIS

Under the circumstances referred to above, 9 CFR Part 51 is amended as follows:

1. The authority citation for Part 51 is revised to read:

Authority: 21 U.S.C. 111-113, 114, 114a, 114a-1, 120, 121, 125, 134b; 7 CFR 2.17, 2.51, and 371.2(d).

2. In § 51.1, paragraph (cc) is amended by inserting the "National Beefmaster Association," immediately after "Mid America RX, Cattle Company,".

Done at Washington, D.C., this 2nd day of May 1985.

G. J. Fichtner,

Acting Deputy Administrator, Veterinary Services.

[FR Doc. 85-10990 Filed 5-6-85; 8:45 am]

BILLING CODE 3410-34-M

9 CFR Part 78

[Docket No. 85-037]

Brucellosis in Cattle; State and Area Classifications

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule.

SUMMARY: This document affirms the interim rule which amended the regulations governing the interstate movement of cattle because of brucellosis by changing the classification of the State of Kansas from Class B to Class A. This rule is necessary because it has been determined that this State meets the standards for Class A status. This rule relieves certain restrictions on the interstate movement of cattle from the State of Kansas.

EFFECTIVE DATE: May 7, 1985.

FOR FURTHER INFORMATION CONTACT: Dr. Thomas J. Holt, Cattle Diseases Staff, VS, APHIS, USDA, Room 817, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-8711.

SUPPLEMENTARY INFORMATION:

Background

A document published in the Federal Register on February 11, 1985 (50 FR 5547-5548), amended the brucellosis regulations in 9 CFR Part 78 by changing the classification of the State of Kansas from Class B to Class A. The amendment, which was made effective February 11, 1985, relieves certain restrictions on the interstate movement of cattle from Kansas.

Comments were solicited for 60 days after publication of the amendment. No comments were received. The factual situation which was set forth in the document of February 11, 1985, still provides a basis for the amendment.

Executive Order and Regulatory Flexibility Act

This rule had been reviewed in accordance with Executive Order 12291 and has been determined to be not a major rule. Based on information compiled by the Department, it has been determined that this rule will not have a significant effect on the economy; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not have any significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this action, the Office of Management and Budget has waived its review process required by Executive Order 12291.

Cattle moved interstate are moved for slaughter, for use as breeding stock, or for feeding. Changing the status of the State of Kansas reduces certain testing and other requirements on the interstate movement of these cattle. Also, cattle from Certified Brucellosis-Free Herds moving interstate are not affected by the change in status. It has been determined that the change in brucellosis status made by this rule will not affect marketing patterns and will not have a significant economic impact on those persons affected by this document.

Under these circumstances, the Administrator of the Animal and Plant

Health Inspection Service has determined that this rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 9 CFR Part 78

Animal diseases, Cattle, Hogs, Quarantine, Transportation, Brucellosis.

PART 78—BRUCELLOSIS

Accordingly, the interim rule amending 9 CFR Part 78 which was published at 50 FR 5547-5548 on February 11, 1985, is adopted as a final rule without change.

Authority: 21 U.S.C. 111-113, 114a-1, 115, 120, 121, 125, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

Done at Washington, D.C., this 2nd day of May 1985.

G.J. Fichtner,

Acting Deputy Administrator, Veterinary Services.

[FR Doc. 85-10989 Filed 5-6-85; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Parts 404 and 416

[Reg. Nos. 4 and 16]

Disability Insurance and Supplemental Security Income; Determining Disability and Blindness; Multiple Impairments

Correction

In FR Doc. 85-5260 beginning on page 8726 in the issue of Tuesday, March 5, 1985, make the following corrections:

1. On page 8727, third column, in the heading for Part 404, third line, "(1950-2-)" should have read "(1950- —)".

§ 404.1520 [Corrected]

2. On page 8727, third column, in § 404.1520(c), eighth line, the semicolon following the word "are" should have been a comma.

3. On page 8728, first column, in § 404.1520(c), fourth line, insert the word "now" between "not" and "have".

§ 416.920 [Corrected]

4. On page 8728, third column, in § 416.920(b), fifth line, "mental" should have read "medical."

BILLING CODE 1505-01-M

Food and Drug Administration

21 CFR Parts 182 and 184

[Docket No. 81N-0381]

GRAS Status of Manganese Salts

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that manganese chloride, manganese citrate, manganese gluconate, and manganese sulfate are generally recognized as safe (GRAS) as direct human food ingredients. This rule also deletes manganese oxide from GRAS status for use as a nutrient supplement. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective June 6, 1985. The Director of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 184.1446, 184.1452, and 184.1461 effective on June 6, 1985.

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 December 17, 1982 (47 FR 56513), FDA published a proposal to affirm that manganese chloride and manganese sulfate are GRAS for use as direct human food ingredients. FDA also proposed to remove manganese citrate and manganese gluconate from the list of GRAS ingredients because there were no reports of their use in food and to remove manganese oxide from the list of GRAS ingredients because there are insufficient safety data to evaluate its use in human food. The proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review and the report of the Select Committee on GRAS Substances (the Select Committee) on manganese salts are available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents also are available for public purchase from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status of manganese chloride and manganese sulfate, FDA gave public notice that it was unaware of any prior-

sanctioned food uses for any of these manganese salts other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions, so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of manganese salts recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181) or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned uses for manganese salts were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for uses of manganese salts under conditions different from those set forth in this final rule has been waived.

Three comments were received in response to the proposal. A summary of these comments and the agency's response follows:

1. Two comments requested that FDA not delete manganese gluconate from the GRAS list. One comment, from a food manufacturer, reported that manganese gluconate is currently added to dairy product analogs as a nutrient at a level of 0.005 percent. The other comment, from a law firm on behalf of clients, submitted manufacturing information and poundage and exposure data on manganese gluconate.

The agency has reviewed these comments. The agency has determined that the safety data contained in the Select Committee's report and the manufacturing and poundage information in the comments provide an adequate basis on which to affirm that manganese gluconate is GRAS for use as a nutrient supplement in dairy product analogs. The final rule therefore affirms the GRAS status of this use of manganese gluconate.

2. One comment stated that it was not clear in the proposal whether manganese gluconate is GRAS for use in dietary supplements, but the comment interpreted the proposal to permit this use.

In the proposal, FDA tried to distinguish between the dietary supplement uses of manganese salts and

the nutrient uses of these ingredients. The agency pointed out that the proposal did not address the dietary supplement uses of manganese chloride, manganese citrate, manganese gluconate, manganous oxide, and manganese sulfate but only their nutrient uses in conventional food. Thus, this rulemaking has no effect on the dietary supplement uses of these ingredients, including manganese gluconate.

3. A comment from a chemical firm requested that food manufacturers be allowed to substitute manganese citrate and manganese gluconate for manganese chloride and manganese sulfate, and, in support of this request, the comment cited the conclusion of the Select Committee that the former two manganese salts are safe. In addition, the comment submitted estimates of potential exposure to manganese gluconate and manganese citrate that it based on the substitution of equivalent amounts of these salts for manganese chloride and manganese sulfate in the food categories in which, according to the National Academy of Sciences (NAS) survey of the food industry, the latter substances are used. The comment also submitted information about the manufacturing processes and specifications for manganese citrate and manganese gluconate.

The agency has reviewed the comment and the information on manufacturing processes, specifications, and estimated exposure for manganese gluconate and manganese citrate that were submitted in the comment. The agency finds that these data meet the requirements for usage data and manufacturing information on manganese gluconate and manganese citrate that were submitted in the comment. The agency finds that these data meet the requirements for usage data and manufacturing information on manganese citrate and manganese gluconate that FDA announced in the proposal would be necessary to affirm the GRAS status of these ingredients. After reviewing the data submitted, the agency concludes that these data, together with the use and safety information in the Select Committee's report, provide a sufficient basis on which to affirm the GRAS status of these ingredients for interchangeable use with manganese chloride and manganese sulfate in conventional food. FDA is therefore modifying the proposal to affirm the GRAS status of manganese citrate and manganese gluconate as nutrients in the following food categories: Baked goods, nonalcoholic beverages, dairy product analogs, fish

products, meat products, milk products, poultry products, and infant formulas.

In the proposal of December 17, 1982 (47 FR 56513), the agency erroneously listed alcoholic beverages as a food category for manganese sulfate. The agency actually reviewed the safety of the use of this ingredient in nonalcoholic beverages. The agency has listed the correct food category in this final rule. In addition, the agency has made minor editorial changes in § 184.1446.

No comments or new information were submitted in response to the proposal with regard to use of manganous oxide. Consequently, in accordance with the proposal, the agency is removing manganous oxide from the list of GRAS nutrients.

Because no food-grade specifications exist for manganese citrate at the present time, the agency will work with the Committee on Food Chemicals Codex of the National Academy of Sciences to develop acceptable specifications for this ingredient. If acceptable specifications are developed, the agency will incorporate them into this regulation at a later date. Until specifications are developed, FDA has determined that the public health will be adequately protected if commercial manganese citrate complies with the description in § 184.1449 (21 CFR 184.1449) and is of food-grade purity (21 CFR 182.1(b)(3) and 170.30(h)(1)).

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. FDA has not received any new information or comments that would alter its previous determination.

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 addition, the agency has considered the effects on small businesses of affirming manganese citrate and manganese gluconate as GRAS. The agency has determined that this action will not have a significant impact on small businesses.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of affirming manganese chloride and manganese

sulfate as GRAS. As announced in the proposal, the agency has determined that this action 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 has considered the economic impact of affirming manganese citrate and manganese gluconate as GRAS and has determined that this action is not a major rule as defined by the order.

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 (address above).

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) and redelegated to the Center for Food Safety and Applied Nutrition (21 CFR 5.61; see 49 FR 48183, December 11, 1984), Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§§ 182.8446, 182.8449, 182.8452, 182.8461, and 182.8464 [Removed]

1. Part 182 is amended by removing § 182.8446 *Manganese chloride*, § 182.8449 *Manganese citrate*, § 182.8452 *Manganese gluconate*, § 182.8461 *Manganese sulfate*, and § 182.8464 *Manganous oxide*.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

2. Part 184 is amended:

a. By adding new § 184.1446, to read as follows:

§ 184.1446 Manganese chloride.

(a) Manganese chloride ($MnCl_2 \cdot 4H_2O$, CAS Reg. No. 7773-01-5) is a pink, translucent, crystalline product. It is also known as manganese dichloride. It

is prepared by dissolving manganous oxide, pyrolusite ore (MnO_2), or reduced manganese ore in hydrochloric acid. The resulting solution is neutralized to precipitate heavy metals, filtered, concentrated, and crystallized.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 186, 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. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient may be used in infant formulas in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(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 § 184.1449, to read as follows:

§ 184.1449 Manganese citrate.

(a) Manganese citrate ($Mn_2(C_6H_5O_7)_2$), CAS Reg. No. 1002-46-65 is a pale orange or pinkish white powder. It is obtained by precipitating manganese carbonate from manganese sulfate and sodium carbonate solutions. The filtered and washed precipitate is digested first with sufficient citric acid solution to form manganous citrate and then with sodium citrate to complete the reaction.

(b) FDA is developing food-grade specifications for manganese citrate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter; dairy product analogs as defined in § 170.3(n)(10) of this chapter; fish products as defined in § 170.3(n)(13) of this chapter; meat products as defined in § 170.3(n)(29) of this chapter; milk products as defined in § 170.3(n)(31) of this chapter; and poultry products as defined in § 170.3(n)(34) of this chapter. The ingredient may be used in infant formulas in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

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

c. By adding new § 184.1452, to read as follows:

§ 184.1452 Manganese gluconate.

(a) Manganese gluconate ($C_{12}H_{22}MnO_{14} \cdot 2H_2O$, CAS Reg. No. 648-53-98) is a slightly pink colored powder. It is obtained by reacting manganese carbonate with gluconic acid in aqueous medium and then crystallizing the product.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 186, 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. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter; dairy product analogs as defined in § 170.3(n)(10) of this chapter;

fish products as defined in § 170.3(n)(13) of this chapter; meat products as defined in § 170.3(n)(29) of this chapter; milk products as defined in § 170.3(n)(31) of this chapter; and poultry products as defined in § 170.3(n)(34) of this chapter. The ingredient may be used in infant formulas in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

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

d. By adding new § 184.1461, to read as follows:

§ 184.1461 Manganese sulfate.

(a) Manganese sulfate ($MnSO_4 \cdot H_2O$, CAS Reg. No. 7785-87-7) is a pale pink, granular, odorless powder. It is obtained by reacting manganese compounds with sulfuric acid. It is also obtained as a byproduct in the manufacture of hydroquinone. Other manufacturing processes include the action of sulfur dioxide on a slurry of manganese dioxide in sulfuric acid, and the roasting of pyrolusite (MnO_2) ore with solid ferrous sulfate and coal, followed by leaching and crystallization.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 188, 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. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter; dairy product analogs as defined in § 170.3(n)(10) of this chapter; fish products as defined in § 170.3(n)(13) of this chapter; meat products as defined in § 170.3(n)(29) of this chapter; milk products as defined in § 170.3(n)(31) of

this chapter; and poultry products as defined in § 170.3(n)(34) of this chapter.

The ingredient may be used in infant formulas in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(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 shall become effective June 6, 1985.

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

Dated: April 12, 1985.

John M. Taylor,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-10983 Filed 5-6-85; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject To Certification; Crufomate Liquid

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is removing that portion of the animal drug regulations which reflects approval of the new animal drug application (NADA) for Dow Chemical's crufomate liquid (Ruelene Wormer Drench). In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of this NADA.

EFFECTIVE DATE: May 17, 1985.

FOR FURTHER INFORMATION CONTACT: David N. Scarr, Center for Veterinary Medicine (HFV-214), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1846.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of NADA 13-514 for crufomate liquid held by Dow Chemical U.S.A. The NADA, originally approved January 14, 1965, provides for use of the product as a wormer drench for cattle, sheep, and goats. This document removes that portion of the regulation reflecting approval of this NADA.

List of Subjects in 21 CFR Part 520

Animal drugs, Oral use.

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

§ 520.512 [Removed]

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e))) 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 5.84), Part 520 is amended by removing § 520.512 *Crufomate liquid*.

Effective Date. May 17, 1985.

[Sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e))]

Dated: April 30, 1985.

Gerald B. Guest,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 85-10950 Filed 5-6-85; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject to Certification; Febantel-Praziquantel 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 Bayvet Division of Miles Laboratories, Inc., providing for safe and effective use of febantel-praziquantel oral paste as an anthelmintic for dogs and cats.

EFFECTIVE DATE: May 7, 1985.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV-112), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Bayvet Division of Miles Laboratories, Inc., P.O. Box 390, Shawnee Mission, KS 66201, filed NADA 133-953, which provides for use of a febantel-praziquantel oral paste to treat dogs and cats for infections of certain nematode and cestode parasites. 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 Docket 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 a statement of exemption (pursuant to 21 CFR 25.1(f)(1)(ii)(a)), may be seen in the Dockets Management Branch (address above).

List of Subjects in 21 CFR Part 520

Animal drugs, Oral use.

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), Part 520 is amended as follows:

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

1. The authority citation for Part 520 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)), unless otherwise noted.

2. By adding new § 520.903d to read as follows:

§ 520.903d Febantel-praziquantel paste.

(a) *Specifications.* Each gram of paste contains 34 milligrams of febantel and 3.4 milligrams of praziquantel.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount—(i)* Dogs and cats (over 6 months of age): 10 milligrams of febantel and 1 milligram of praziquantel per kilogram of body weight (1 gram of paste per 7.5 pounds body weight) administered by mouth or in the food once daily for 3 days.

(ii) Puppies and kittens (less than 6 months of age): 15 milligrams of febantel and 1.5 milligrams of praziquantel per kilogram of body weight (1 gram of paste per 5 pounds body weight) administered by mouth on a full stomach once daily for 3 days.

(2) *Indications for use.* (i) Dogs and puppies: For removal of hookworms (*Ancylostoma caninum*), whipworms (*Trichuris vulpis*), ascarids (*Toxocara canis*), and tapeworms (*Dipylidium caninum* and *Taenia pisiformis*).