

that infant formula should be used as directed by a physician; and directions for preparation and use, including pictograms and a symbol to indicate the need for dilution. An exemption from certain labeling requirements is provided for individual containers containing infant formula in a ready-to-feed form in multiunit packages.

Section 107.10, which contains nutrient labeling requirements, and the amendment to remove § 105.65 (c), (d), and (e) (21 CFR 105.65 (c), (d), and (e)) were the only portions of the final rule that were promulgated under the formal rulemaking procedures of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)) and therefore subject to objections and requests for a hearing. Any person who would be adversely affected by these provisions could have, at any time on or before February 13, 1985, filed written objections and requested a public hearing on the specific provisions to which there were objections. No objections or requests for a hearing were received.

List of Subjects

21 CFR Part 105

Dietary foods, Food labeling, Infant foods, Nutrition, Vitamins and minerals.

21 CFR Part 107

Food labeling, Infant formula, Nutrient information.

PART 105—FOOD FOR SPECIAL DIETARY USE

PART 107—INFANT FORMULA

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201 (n) and (aa), 403 (a) and (j), 412, 701 (a) and (e), 52 Stat. 1041 as amended, 1047 as amended, 1048, 1055, 70 Stat. 919 as amended, 94 Stat. 1190 (21 U.S.C. 321 (n) and (aa), 343 (a) and (j), 350a, 371(a) and (e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Food Safety and Applied Nutrition (21 CFR 5.62), notice is given that the removal of § 105.65 (c), (d), and (e) and the addition of § 107.10 published in the *Federal Register* of January 14, 1985 (50 FR 1833) will become effective January 14, 1986.

Dated: March 29, 1985.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-8131 Filed 4-2-85; 3:19 pm]

BILLING CODE 4160-01-M

21 CFR Part 178

[Docket No. 84F-0169]

Indirect Food Additives; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ethylene-methyl acrylate copolymer resins as a food-contact surface in aseptic packaging systems employing hydrogen peroxide as a sterilizing agent. This action responds to a petition filed by the Gulf Oil Corp.

DATES: Effective April 5, 1985; objections by May 6, 1985.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of June 13, 1984 (49 FR 24446), FDA announced that a petition (FAP 4B3803) had been filed by Gulf Oil Corp., P.O. Box 1166, Pittsburgh, PA 15230, proposing that § 178.1005 (21 CFR 178.1005) be amended to provide for the safe use of ethylene-methyl acrylate copolymer resins as a food-contact surface in aseptic packaging systems employing hydrogen peroxide as a sterilizing agent. One comment was received in response to the notice of filing. It favored the proposed use.

FDA has evaluated data in the petition and other relevant material and concludes that the proposed food additive use is safe and that the regulations should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), 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 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency 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 is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging, Sanitizing solutions.

PART 178—INDIRECT FOOD ADDITIVES; ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director of the Center for Food Safety and Applied Nutrition (21 CFR 5.61), Part 178 is amended in § 178.1005 by revising paragraph (e)(1), to read as follows:

§ 178.1005 Hydrogen peroxide solution

(e) *Conditions of use.* (1) Hydrogen peroxide solution identified in and complying with the specifications in this section may be used by itself or in combination with other processes to treat food-contact surfaces prepared from ionomeric resins complying with § 177.1330 of this chapter, ethylene-methyl acrylate copolymer resins complying with § 177.1340 of this chapter, ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter, olefin polymers complying with § 177.1520 of this chapter, and polyethylene terephthalate polymers complying with § 177.1630 of this chapter (excluding polymers described in § 177.1630(c)) to attain commercial sterility at least equivalent to that attainable by thermal processing for metal containers as provided for in Part 113 of this chapter.

Any person who will be adversely affected by the foregoing regulation may at any time on or before May 6, 1985 submit to the Dockets Management Branch (address above) written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made.

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 regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective April 5, 1985.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

Dated: March 11, 1985.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-8141 Filed 4-4-85; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 182 and 184

[Docket No. 78N-0281]

GRAS Status of Magnesium Carbonate, Magnesium Chloride, Magnesium Hydroxide, Magnesium Oxide, Magnesium Phosphate, Magnesium Stearate, and Magnesium Sulfate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that certain magnesium salts 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 May 6, 1985. The Director of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 184.1425, 184.1426, 184.1428, 184.1431, 184.1434, 184.1440, and 184.1443 effective on May 6, 1985.

FOR FURTHER INFORMATION CONTACT: Leonard C. Gosule, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: In the Federal Register of January 21, 1983 (48 FR 2782), FDA published a proposal to affirm that magnesium carbonate, magnesium chloride, magnesium hydroxide, magnesium oxide, magnesium phosphate, magnesium stearate, and magnesium sulfate are GRAS for use as direct human food ingredients. 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 magnesium 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 magnesium carbonate, magnesium chloride, magnesium hydroxide, magnesium oxide, magnesium phosphate, magnesium stearate, and magnesium sulfate, FDA gave public notice that it was unaware of any prior-sanctioned food uses for these ingredients 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 these ingredients 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 these magnesium salts were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of these ingredients under conditions different from those set forth in this final rule has been waived.

Four comments were received in response to the agency's proposal on magnesium salts.

1. One comment indicated that all the magnesium salts are currently used in

other food categories in addition to those reported in the proposal. The comment requested that the agency modify the regulations for all of the listed magnesium salts to affirm their use as GRAS with no food categories specified.

The agency has reviewed this comment. FDA has decided that it is not necessary to list the food categories in which these magnesium salts are used. Both the Select Committee and the agency have concluded that a large margin of safety exists for the use of magnesium salts. In addition, FDA has concluded that a reasonably foreseeable increase in the level of consumption of magnesium salts, including the increase that would result from not listing food categories, will not adversely affect human health. However, the GRAS affirmation regulations for magnesium carbonate, magnesium hydroxide, magnesium stearate, and magnesium sulfate do not state that these ingredients may be used in infant formulas because FDA has no specific information that these ingredients are used in these products, and the agency has not evaluated these uses.

The agency has therefore modified the regulations by removing the food categories and affirming the use of magnesium salts as GRAS when they are used in accordance with current good manufacturing practice under § 184.1(b)(1) (21 CFR 184.1(b)(1)). To make clear, however, that the affirmation of the GRAS status of magnesium salts is based on the evaluation of currently known uses, the regulations set forth the technical effects that FDA has evaluated.

2. The comment also reported that all the magnesium salts are used as nutrient supplements and requested that FDA modify the regulations for these substances to reflect this fact.

The agency points out that the proposal listed the technical effect of nutrient supplement in the regulations for all of the magnesium salts except magnesium stearate. The comment has reported that, in fact, magnesium stearate also is used for this technical effect. Based on its review of the report of the Select Committee and its own review of the relevant data, FDA is affirming this use of magnesium stearate as GRAS and has amended § 184.1440(c)(1) (21 CFR 184.1440(c)(1)) accordingly.

3. One comment reported use of magnesium carbonate, magnesium hydroxide, and magnesium oxide in a proprietary formulation that is used for color retention in canned peas. The comment supported FDA's proposed

rule and did not request any modifications because the proposal included use of all three of these ingredients in processed vegetables.

FDA has thoroughly reviewed this comment and finds that magnesium carbonate, magnesium hydroxide, and magnesium oxide contribute to color retention in this formulation because they may be used to adjust the pH of canned peas. This use was addressed in a recent regulation on the standard of identity for canned peas, published in the Federal Register of April 8, 1983 (48 FR 15241). FDA also included the use of these three ingredients as pH control agents in the GRAS affirmation proposal. Therefore, the agency is not modifying the proposal based upon this comment.

4. One comment reported the use of magnesium sulfate in the brewing of beer at a maximum level of 0.0068 percent. The comment reported that a substantial portion of the added magnesium sulfate is used by yeast in brewing the beer and is removed when the yeast is removed after fermentation. The comment requested that FDA modify the proposed rule for magnesium sulfate to include its use as a processing aid in alcoholic beverages.

FDA agrees that this use is best described by the technical effect "processing aid," as defined in 21 CFR 170.3(o)(24). The agency additionally notes that it listed the technical effect of processing aid for magnesium sulfate in the proposal. Moreover, it is unnecessary for the agency to include the food category alcoholic beverages in § 184.1443 (21 CFR 184.1443) because, as explained in paragraph 1, the agency has decided not to specify food categories in the GRAS affirmation regulations on magnesium salts. Thus, FDA has not modified § 184.1443 in response to this comment.

5. One comment reported use of magnesium oxide as an anticaking and free-flow agent in tea mixes at levels not to exceed current good manufacturing practice. The comment requested that FDA modify the proposed rule to include this use.

As discussed in paragraph 1 above, the additional listing of the food category tea mixes is no longer necessary. Although the proposed rule for magnesium oxide did not include its use as an anticaking and free-flow agent as defined in § 170.3(o)(1) (21 CFR 170.3(o)(1)), it did include its use for similar technical effects that require similar chemical properties. FDA has concluded that these chemical properties are consistent with the use of magnesium oxide as an anticaking and free-flow agent, and that this use is

GRAS. Therefore, FDA has modified § 184.1431 (21 CFR 184.1431) to include this technical effect.

6. FDA has, on its own initiative, reconsidered the specifications for magnesium stearate set forth in proposed § 184.1440(b). The agency has concluded that the tests for chick-edema factor, which are described in § 172.860(b)(2) (21 CFR 172.860(b)(2)) and which are included by reference in proposed § 184.1440(b), are specific for free fatty acids and are not applicable to salts of fatty acids such as magnesium stearate. The agency notes that the food additive regulation for salts of fatty acids (21 CFR 172.863) requires that each fatty acid, rather than its salt, conform to the provisions of § 172.860.

Consequently, FDA has modified § 184.1440(a) (21 CFR 184.1440(a)) to require that sodium stearate be derived from stearic acid that conforms to § 172.860(b)(2) and has modified § 184.1440(b) by removing the requirement that magnesium stearate meet the specifications of § 172.860(b)(2).

The agency is making these changes to clarify the regulation. Therefore, the agency finds that further public procedure on this regulation is unnecessary.

Additionally, the agency has also made a minor editorial change in the proposed magnesium oxide regulation to correct the Chemical Abstracts Registry number in this final rule.

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 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 (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), Parts 182 and 184 are amended as follows:

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 the entries for "Magnesium carbonate," "Magnesium chloride," "Magnesium hydroxide," and "Magnesium sulfate."

§§ 182.1425, 182.1428, 182.1431, 182.1440, 182.8431, 182.8434, 182.8443 [Removed]

b. By removing § 182.1425 *Magnesium carbonate*, § 182.1428 *Magnesium hydroxide*, § 182.1431 *Magnesium oxide*, § 182.1440 *Magnesium stearate*, § 182.8431 *Magnesium oxide*, § 182.8434 *Magnesium phosphate*, and § 182.8443 *Magnesium sulfate*.

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

2. Part 184 is amended:

a. By adding new § 184.1425, to read as follows:

§ 184.1425 Magnesium carbonate.

(a) Magnesium carbonate (molecular formula approximately $\text{MgCO}_3 \cdot \text{Mg}(\text{OH})_2 \cdot 5\text{H}_2\text{O}$, CAS Reg. No. 39409-82-0) is also known as magnesium carbonate hydroxide. It is a white powder formed either by adding an alkaline carbonate (such as sodium carbonate) to a solution of magnesium sulfate or by carbonation of a slurry of

magnesium hydroxide followed by boiling of the resulting magnesium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 177, 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 an anticaking and free-flow agent as defined in § 170.3(o)(1) of this chapter; a flour treating agent as defined in § 170.3(o)(13) of this chapter; a lubricant and release agent as defined in § 180.3(o)(18) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; a pH control agent as defined in § 170.3(o)(23) of this chapter; a processing aid as defined in § 170.3(o)(24) of this chapter; and a synergist as defined in § 170.3(o)(31) of this chapter.

(2) The ingredient is used in foods at levels not to exceed 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 § 184.1426, to read as follows:

§ 184.1426 Magnesium chloride.

(a) Magnesium chloride ($MgCl_2 \cdot 6H_2O$, CAS Reg. No. 7786-30-3) is a colorless, deliquescent, crystalline material that occurs naturally as the mineral bischofite. It is prepared by dissolving magnesium oxide, hydroxide, or carbonate in aqueous hydrochloric acid solution and crystallizing out magnesium chloride hexahydrate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 117, 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 flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter and a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient also may be used in infant formula 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 § 184.1428, to read as follows:

§ 184.1428 Magnesium hydroxide.

(a) Magnesium hydroxide ($Mg(OH)_2$, CAS Reg. No. 1409-42-8) occurs naturally as the colorless, crystalline mineral brucite. It is prepared as a white precipitate by the addition of sodium hydroxide to a water soluble magnesium salt or by hydration of reactive grades of magnesium oxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 178, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Avenue NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L Street 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; a pH control agent as defined in § 170.3(o)(23) of this chapter; and a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed 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.

d. By adding new § 184.1431, to read as follows:

§ 184.1431 Magnesium oxide.

(a) Magnesium oxide (MgO , CAS Reg. No. 1309-48-4) occurs naturally as the colorless, crystalline mineral periclase. It is produced either as a bulky white powder (light) or a relatively dense white powder (heavy) by heating magnesium hydroxide or carbonate. Heating these magnesium salts under moderate conditions (400° to 900° C for a few hours) produces light magnesium oxide. Heating the salts under more rigorous conditions (1200° C for 12 hours) produces heavy magnesium oxide. Light magnesium oxide is converted to heavy magnesium oxide by sustained heating at high temperatures.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 178, 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 an anticaking and free-flow agent as defined in § 170.3(o)(1) of this chapter; a firming agent as defined in § 170.3(o)(10) of this chapter; a lubricant and release agent as defined in § 170.3(o)(18) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; and a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient also may be used in infant formula 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.

e. By adding new § 184.1434, to read as follows:

§ 184.1434 Magnesium phosphate.

(a) Magnesium phosphate includes both magnesium phosphate, dibasic, and magnesium phosphate, tribasic. Magnesium phosphate, dibasic ($MgHPO_4 \cdot 3H_2O$, CAS Reg. No. 7782-75-4) occurs naturally as the white, crystalline mineral newberyite. It is prepared commercially as a precipitate formed by treating a solution of magnesium sulfate with disodium phosphate under controlled conditions. Magnesium phosphate, tribasic ($Mg_3(PO_4)_2 \cdot xH_2O$, CAS Reg. No. 7727-87-1) may contain 4, 5, or 8 molecules of water of hydration. It is produced as a precipitate from a solution of magnesite with phosphoric acid.

(b) Magnesium phosphate, dibasic, meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 179, which is incorporated by reference. Magnesium phosphate, tribasic, meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 180, 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 Street, 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 ingredients 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 and a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient also may be used in infant formula 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.

f. By adding new § 184.1440, to read as follows:

§ 184.1440 Magnesium stearate.

(a) Magnesium stearate ($Mg[C_{17}H_{35}COO]_2$, CAS Reg. No. 557-04-0) is the magnesium salt of stearic acid. It is produced as a white precipitate by the addition of an aqueous solution of magnesium chloride to an aqueous

solution of sodium stearate derived from stearic acid that is obtained from edible sources and that conforms to the requirements of § 172.860(b)(2) of this chapter.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 182, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Avenue, NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L Street, 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 lubricant and release agent as defined in § 170.3(o)(18) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; and a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed 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.

g. By adding new § 184.1443, to read as follows:

§ 184.1443 Magnesium sulfate.

(a) Magnesium sulfate ($MgSO_4 \cdot 7H_2O$, CAS Reg. No. 10034-99-8) occurs naturally as the mineral epsomite. It is prepared by neutralization of magnesium oxide, hydroxide, or carbonate with sulfuric acid and evaporating the solution to crystallization.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 183, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Avenue NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L Street 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 flavor enhancer as defined in § 170.3(o)(11) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; and a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed 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 shall be effective May 6, 1985.

(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: March 12, 1985.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-8142 Filed 4-4-85; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 520**Oral Dosage Form New Animal Drugs Not Subject to Certification; Phenylbutazone Gel**

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 International Multifoods Corp. providing for safe and effective oral use of phenylbutazone gel for relief of inflammatory conditions associated with the musculoskeletal system in horses.

EFFECTIVE DATE: April 5, 1985.

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: International Multifoods Corp., 8th and Marquette Sts., Minneapolis, MN 55402, filed NADA 118-979 providing for oral use in horses of phenylbutazone for relief of inflammatory conditions associated with the musculoskeletal system. The drug product consists of a calibrated plastic syringe containing 4 grams (g) of phenylbutazone in 30 g of gel. The drug is administered at a rate of 1 to 2 g of phenylbutazone per 500 pounds of body weight, not to exceed 4 g daily. Based on the data and information submitted, the NADA is approved and the regulations are