

basis of the farm yield to be sufficient to produce the total farm poundage quota: *Provided further*, That if the total of all such increases in individual farm poundage quotas exceed 10 per centum of the national poundage quota for the marketing year, the Secretary shall adjust such increases so that the total of all increases does not exceed 10 per centum of the national poundage quota.

Current regulations provide that undermarketings be computed based upon the effective farm poundage quota which would include undermarketings carried over from the previous crop years. This causes a "pyramiding" effect with respect to the poundage quota and section 358(o) has been interpreted not to permit this type of continued carryover or "pyramiding" of undermarketings.

The first sentence of section 358(o) quoted above established an annual farm poundage quota for each farm and the second sentence provides for a temporary one year increase in such quota by the amount of undermarketings of quota peanuts from the production of the "immediately preceding marketing year." There is no indication in the statutory language that the temporary increase in the annual quota resulting from the carryover of undermarketings is to be cumulative.

Such a position with respect to the carryover of undermarketings is confirmed by the substance of the three provisos, all marketings in any given year may not exceed the actual production from the farm acreage allotment for that year. Such a limitation is inconsistent with the concept of "pyramiding," since adding the undermarketings for several years would probably result in excessively large total farm poundage quotas. The actual production of peanuts from the farm acreage allotment would probably be insufficient to cover this quota, and as a result, undermarketings would continue to be carried forward.

Similarly, it is implicit in the second proviso of section 358(o) that growers are expected to plant a sufficient amount of peanuts in each marketing year to produce the total farm poundage quota. Such an expectation is not consistent with the concept of "pyramiding," since the accumulation of carryover quota would produce situations in which the grower would have insufficient acreage (within the acreage allotment) to produce the necessary volume of peanuts to meet the cumulative total farm poundage quota in any one year.

Finally, the third proviso in section 358(o) is a limitation on the overall amount of the national carryover of poundage quota for each marketing

year. If "pyramiding" were contemplated, such a limitation would not have been provided since its application would result in inequities in the case of producers who were not involved in undermarketing situations until after the ceiling was reached as the result of the "pyramiding" of undermarketings of other producers in prior marketing years.

Accordingly, it has been determined that the regulations governing the carryover of undermarketings will be adopted as published in the *Federal Register* on October 5, 1979.

Final Rule

Effective for the 1978 and subsequent crop of peanuts, the regulations in 7 CFR Part 729 are amended to read as follows:

(1) Section 729.3(l)(1) is revised to read as follows:

§ 729.3 Definitions.

* * * * *

(II) *Undermarketings* (1) *Actual undermarketings*. The pounds by which the effective farm poundage quota (minus any undermarketings from the preceding year which were added to such quota) exceeds the larger of (i) the total production of segregation 1 peanuts on the farm or (ii) the total amount of quota peanuts which are marketed from the farm.

* * * * *

(2) Section 729.46 is amended by adding a new paragraph (d) which reads as follows:

§ 729.46 Penalty rate.

* * * * *

(d) *Penalty for unintentional error*. The penalty rate for the (i) 1978 crop of peanuts shall be 10 percent of the basic support price for quota peanuts which is determined to be \$42 per ton or 2.1 cents per pound, (ii) 1979 crop of peanuts shall be 20 percent of the basic support price for quota peanuts which is determined to be \$84 per ton or 4.2 cents per pound.

(3) Section 729.47(a)(1) is revised to read as follows:

§ 729.47 Peanuts on which penalty is due.

(a) * * *

(1) The quantity of peanuts which is marketed or considered to be marketed from a farm for domestic edible use in excess of the effective farm poundage quota for the farm: *Provided*, That if the marketing of quota peanuts for which a penalty is to be assessed was done unintentionally or unknowingly by the producer and/or handler, the penalty shall be assessed at a reduced rate provided for in § 729.46(d), upon a determination by the county ASC committee that the error in excess

marketing was unknowingly or unintentionally made and that a reduction in the amount of penalty would not impair the effective operation of the price support program for peanuts. The provisions of this subparagraph shall be applicable only to producers or handlers who made a good faith effort to comply fully with the terms and conditions of the program and review of the assessment of such penalties shall be handled in accordance with Part 711 of this chapter.

* * * * *

(Secs. 301, 358, 358a, 359, 361-368, 373, 375, 377, 52 Stat. 38, as amended, 55 Stat. 88, as amended, 81 Stat. 658, 55 Stat. 90, as amended, 70 Stat. 206, as amended (7 U.S.C. 1301, 1358, 1358a, 805, 806, 91 Stat. 944) (7 U.S.C. 1358, 1358a, 1359, 1373, 1377); and Sec. 359, 93 Stat. 81 (7 U.S.C. 1359 note).)

Note.—This final rule has been reviewed under the USDA criteria established to implement Executive Order 12044, "Improving Government Regulations." A determination has been made that this action should not be classified "significant" under those criteria. A Final Impact Statement has been prepared and is available from Paul P. Kume (ASCS) 202-447-4695.

Signed at Washington, D.C. on January 21, 1980.

Ray Fitzgerald,

Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 80-2491 Filed 1-24-80; 8:45 am]

BILLING CODE 3410-05-M

Agricultural Marketing Service

7 CFR Part 910

[Lemon Regulation 236]

Lemons Grown in California and Arizona; Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation establishes the quantity of fresh California-Arizona lemons that may be shipped to market during the period January 27-February 2, 1980. Such action is needed to provide for orderly marketing of fresh lemons for this period due to the marketing situation confronting the lemon industry.

EFFECTIVE DATE: January 27, 1980.

FOR FURTHER INFORMATION CONTACT: Malvin E. McGaha, 202-447-5975.

SUPPLEMENTARY INFORMATION: *Findings.* This regulation is issued under the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona. The agreement and order are effective under the Agricultural Marketing Agreement

Act of 1937, as amended (7 U.S.C. 601-674). The action is based upon the recommendations and information submitted by the Lemon Administrative Committee, and upon other information. It is hereby found that this action will tend to effectuate the declared policy of the act.

The committee met on January 22, 1980, to consider supply and market conditions and other factors affecting the need for regulation and recommended a quantity of lemons deemed advisable to be handled during the specified week. The committee reports the demand for lemons is easier.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the *Federal Register* (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation is based and the effective date necessary to effectuate the declared policy of the act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting. It is necessary to effectuate the declared purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

Further, in accordance with procedures in Executive Order 12044, the emergency nature of this regulation warrants publication without opportunity for further public comment. The regulation has not been classified significant under USDA criteria for implementing the Executive Order. An Impact Analysis is available from Malvin E. McGaha, 202-447-5975.

§ 910.536 Lemon Regulation 236.

Order. (a) The quantity of lemons grown in California and Arizona which may be handled during the period January 27, 1980, through February 2, 1980, is established at 200,000 cartons.

(b) As used in this section, "handled" and "carton(s)" mean the same as defined in the marketing order.

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674).

Dated: January 23, 1980.

D. S. Kuryloski,

Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 80-2748 Filed 1-24-80; 12:09 pm]

Animal and Plant Health Inspection Service

9 CFR Part 79

Scrapies in Sheep; Area Quarantined

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The purpose of this amendment is to quarantine a portion of Tulsa County in Oklahoma because of the existence of vectors of scrapie in such area. Therefore, in order to prevent the dissemination of scrapie it is necessary to quarantine this area.

EFFECTIVE DATE: January 18, 1980.

FOR FURTHER INFORMATION CONTACT:

Dr. J. R. Pitcher, Chief Staff Veterinarian, Sheep, Goat, Equine, and Ectoparasites Staff, USDA, APHIS, VS, Federal Building, Room 737, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-8321.

SUPPLEMENTARY INFORMATION: This amendment quarantines a portion of Tulsa County in Oklahoma because of the existence of vectors of scrapie in such area. The restrictions pertaining to the interstate movement of sheep from quarantined areas, contained in 9 CFR Part 79, as amended, apply to the quarantined area.

Section 1 of the Act of March 3, 1905, as amended, (21 U.S.C. 123), authorizes the Secretary of Agriculture to quarantine any State, Territory, or the District of Columbia or any portion thereof, when he determines that any animals and/or live poultry in such area are affected with any contagious, infectious, or communicable disease of livestock or poultry, or that the contagion of any such disease exist in such area or that vectors which may disseminate the disease exist in such area. Consequently, § 79.2 is revised to better reflect this statutory authority.

Accordingly, Part 79, Title 9, Code of Federal Regulations, as amended, restricting the interstate movement of sheep because of scrapie, is hereby amended in the following respect:

Section 79.2, is revised to read as follows:

§ 79.2 Notice of quarantine.

(a) Notice is hereby given that the contagion or vectors of scrapie, a contagious, infectious and communicable disease, exist in the following areas or that sheep affected with scrapie exist in the following areas, and, therefore, the following areas are

hereby quarantined because of said disease:

(1) The premises of Duane Smith, Route 1, Box 332A, Bixby, Tulsa County, Oklahoma, S½ of the SW¼ of the NW¼ of Sec. 32, T. 17 N., R. 14 E.

(Sec. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132 (21 U.S.C. 111-113, 115, 117, 120, 121, 123-126, 134b, 134f); 37 FR 28464, 28477; 38 FR 19141.)

The amendment imposes certain further restrictions necessary to prevent the interstate spread of scrapie in sheep from such area and must be made effective immediately to accomplish its purpose in the public interest. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to this Department.

Therefore, pursuant to the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to this final rule are impracticable and contrary to the public interest and good cause is found for making this final rule effective less than 30 days after publication of this document in the *Federal Register*.

Further, this final rule has not been designated as "significant," and is being published in accordance with the emergency procedures in Executive Order 12044 and Secretary's Memorandum 1955. It has been determined by J. K. Atwell, Assistant Deputy Administrator, Animal Health Programs, APHIS, VS, USDA, that the emergency nature of this final rule warrants publication without opportunity for public comment or preparation of an impact analysis statement at this time.

This final rule implements the regulations in Part 79. It will be scheduled for review in conjunction with the periodic review of the regulations in that Part required under the provisions of Executive Order 12044 and Secretary's Memorandum 1955.

Done at Washington, D.C., this 18th day of January 1980.

J. K. Atwell,

Acting Deputy Administrator, Veterinary Services.

[FR Doc. 80-2280 Filed 1-24-80; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF ENERGY

Economic Regulatory Administration

10 CFR Part 507

[Docket No. ERA-R-78-19E]

Powerplant and Industrial Fuel Use Act of 1978; Deferral of Reports Required Under 10 CFR Part 507

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Deferral of Deadline for Filing Certain Reports.

SUMMARY: On May 8, 1979, the Economic Regulatory Administration (ERA) of the Department of Energy issued interim rules which would exclude certain fuels from the terms "natural gas" and "petroleum" for purposes of the Powerplant and Industrial Fuel Use Act. (Part 507, Fuel Classification and Reporting Requirement; 44 FR 29016, May 17, 1979). Incorporated in Part 507 are several reporting requirements due January 30 and 31, 1980, relating to natural gas and petroleum which are considered to be commercially unmarketable (§§ 507.6 and 507.7) and natural gas produced from small wells and used by powerplants (§ 507.5).

We believe that it would be in the public interest to defer filing the reports pursuant to 10 CFR Parts 507.5, 507.6 and 507.7 for such time as is necessary to gain experience in implementing the remaining provisions of Part 507. Such reports will be deferred until further notice is published in the Federal Register.

DATES: The January 30 and 31, 1980 deadlines for filing the appropriate reports pursuant to Part 507 are deferred until further notice.

FOR FURTHER INFORMATION CONTACT: John Dean (Office of Fuels Conversion), Economic Regulatory Administration, Department of Energy, 2000 M Street, NW., Room 3322-H, Washington, D.C. 20461 (202) 634-6526.

Issued in Washington, D.C. January 19, 1980

F. Scott Bush,

Assistant Administrator, Regulations and Emergency Planning, Economic Regulatory Administration.

[FR Doc. 80-2427 Filed 1-24-80; 8:45 am]

BILLING CODE 6450-01-M

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Parts 182, 184 and 186

[Docket No. 78N-0013]

Sulfuric Acid and Ammonium, Calcium, Potassium, and Sodium Sulfates; Affirmation of GRAS Status

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

SUMMARY: The Food and Drug Administration (FDA) is affirming that sulfuric acid and ammonium, calcium, and potassium sulfates are generally recognized as safe (GRAS) as direct human food ingredients. The agency also affirms that sodium sulfate is GRAS as an indirect human food ingredient. The safety of these ingredients has been evaluated under the agency's comprehensive safety review.

EFFECTIVE DATE: February 25, 1980.

FOR FURTHER INFORMATION CONTACT: Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 28, 1978 (43 FR 12874), FDA proposed to affirm that sulfuric acid and ammonium, calcium, potassium, and sodium sulfates are GRAS when used as direct and/or indirect 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 on sulfates, a mutagenic evaluation report on potassium sulfate, which was not available at the time the proposal was published, and the report of the Select Committee on GRAS Substances (the Select Committee) have been made available for public review in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

In addition to proposing the above actions, the FDA gave public notice that it was unaware of any prior-sanctioned food ingredient uses for sulfuric acid and ammonium, calcium, potassium, and sodium sulfates for 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 the sanction so that the safety of any prior-sanctioned uses could be determined at this time. That notice was also an opportunity to have prior-sanctioned uses of sulfuric acid and ammonium, calcium, potassium, and sodium sulfates approved by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181), if the prior-sanctioned use could be affirmed as safe on the basis of information and data now available to FDA. Notice was also given that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert the sanction at any future time.

No reports of prior-sanctioned uses for sulfuric acid and ammonium, calcium, potassium, and sodium sulfates were submitted in response to the proposal. Therefore, in accordance with that proposal, any right to assert a prior sanction for use of sulfuric acid or ammonium, calcium, potassium, and sodium sulfates under conditions different from those set forth in this regulation has been waived.

One comment was submitted in response to the FDA proposal on sulfuric acid and ammonium, calcium, potassium, and sodium sulfates. The comment requested that sodium sulfate be listed under Part 184 as a GRAS substance for direct food use on the grounds that its toxicity is similar to the toxicity of sodium chloride, and it is currently used in the manufacture of starch and in caramel production. To support GRAS status further, the comment stated that sodium sulfate also occurs naturally in foods. The comment more specifically requested GRAS affirmation for sodium sulfate as a processing aid in the chemical modification of food starch by propylene oxide. Sodium sulfate is used to inhibit swelling of the starch granules during chemical modification and is allegedly the safest, most effective, and most economical agent for this purpose. The comment was concerned that if this use of sodium sulfate does not receive GRAS affirmation, then any residual sodium sulfate remaining in food starch after chemical modification would be an unapproved food additive.

FDA agrees with the comment that, because direct food uses of sodium sulfate were not addressed in the proposal, the regulatory status of sodium sulfate as a processing aid in starch modification needs to be clarified. An existing FDA food additive regulation (§ 172.892 (21 CFR 172.892)) deals with a starch modification process employing phosphorus oxychloride, propylene,

propylene oxide, and sodium sulfate. That process (§ 172.892(f)) involves the use of sodium sulfate at levels up to 5 percent, followed by thorough washing of the modified starch product to remove residues of sodium sulfate and other reaction ingredients. At the time FDA approved the propylene oxide-phosphorus oxychloride procedure, it considered the use of sodium sulfate in that procedure to be GRAS and thus not a food additive use. Sodium sulfate was not listed specifically in § 172.892(e) because, at the time that regulation was published, FDA policy was to list only food additives in food additive regulations, not substances whose use was considered to be GRAS. FDA still considers sodium sulfate, when used in the chemical modification of food starch by propylene oxide authorized in § 172.892(f), to be GRAS and, thus, not a food additive. Rather than formally list this restricted direct food use of sodium sulfate in the GRAS regulations at this time, the agency plans to cover this and other unlisted direct food uses of sodium sulfate in the forthcoming cyclic review of direct food additives.

In its original proposal, FDA proposed to establish food-grade specifications for the indirect use of sodium sulfate. Since then, however, the agency has reconsidered the necessity for imposing food-grade specifications on indirect GRAS substances, such as sodium sulfate. The agency has concluded that, as a general rule, food-grade specifications are not necessary to ensure the safety of an indirect GRAS substance, provided the substance is of a purity suitable for its intended use in accordance with § 170.30(h)(1). This conclusion is based on the fact that indirect uses generally result in extremely low levels of consumer exposure to the additive and correspondingly low levels of exposure to any impurities that may be present. If food-grade specifications are found necessary in a particular case to ensure the safety of an indirect GRAS ingredient, the agency will include them in the regulation. In the case of sodium sulfate, FDA concludes that specifications are not necessary. Therefore, the final regulation governing the use of sodium sulfate as an indirect GRAS ingredient has been modified in proposed § 186.1797(b) by removing the specifications. The agency intends to publish a proposal in the near future to amend its procedural regulations in Part 186 to reflect this new policy regarding specifications for indirect GRAS substances.

Consistent with its traditional practice, FDA proposed originally to

establish separate regulations for sulfuric acid and calcium sulfate in Parts 184 and 186 to govern their direct and indirect GRAS uses, respectively. Under § 184.1(a), however, ingredients affirmed as GRAS for direct food use in Part 184 are considered to be GRAS for indirect uses without there being a separate listing in Part 186. In light of § 184.1(a), FDA has reconsidered its traditional practice of establishing separate listings in Part 186 for substances it affirms as GRAS for direct use in Part 184 and has concluded that the duplicative listing in Part 186 is unnecessary, as a general rule, and may cause confusion. Thus, unless it is necessary based on safety considerations to impose specific purity specifications or other restrictions on the indirect use of a GRAS substance, FDA will no longer list in Part 186 substances that are affirmed as GRAS for direct use in Part 184. In keeping with this change in policy, FDA will not promulgate § 186.1095 and 186.1230 as originally proposed. The indirect uses of sulfuric acid and calcium sulfate proposed for inclusion in §§ 186.1095 and 186.1230 are authorized under §§ 184.1095 and 184.1230, respectively, and § 184.1(a).

The agency also has determined that an indirect substance whose GRAS status for indirect use is based on its affirmation as GRAS in Part 184 need not comply, as a general rule, with the purity specifications made applicable to the direct use of the substance in the Part 184 regulation, as long as it is of a purity suitable for its intended indirect use in accordance with § 170.30(h)(1). This conclusion is based on the fact that indirect uses generally result in extremely low levels of consumer exposure to the additive and correspondingly low levels of exposure to any impurities that may be present. As noted in the preceding paragraph, however, if specific purity specifications for the indirect use of a GRAS substance are necessary based on safety considerations, a regulation establishing such specifications will be promulgated in Part 186. In the case of sulfuric acid and calcium sulfate, no specific purity specifications are necessary for their indirect use.

Although the policies discussed in the two preceding paragraphs are not inconsistent with FDA's current regulations, FDA will publish a proposal in the near future to amend its procedural regulations in Parts 184 and 186 to reflect clearly the current policies.

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 5.1), Parts 182, 184, and 186 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. Part 182 is amended:

§ 182.70 [Amended]

a. In § 182.70 *Substances migrating from cotton and cotton fabrics used in dry food packaging* by deleting the entry for "Sodium sulfate."

§ 182.90 [Amended]

b. In § 182.90 *Substances migrating to food from paper and paperboard products* by deleting the entries for "Calcium sulfate," "Sodium sulfate," and "Sulfuric acid."

§§ 182.1095, 182.1143, 182.1643, and 182.5230 [Deleted]

c. By deleting § 182.1095 *Sulfuric acid*, § 182.1143 *Ammonium sulfate*, § 182.1643 *Potassium sulfate*, and § 182.5230 *Calcium sulfate*.

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

2. Part 184 is amended by adding new §§ 184.1095, 184.1143, 184.1230, and 184.1643, to read as follows:

§ 184.1095 Sulfuric acid.

(a) Sulfuric acid (H_2SO_4 , CAS Reg. No. 7664-93-9), also known as oil of vitriol, is a clear, colorless, oily liquid. It is prepared by reacting sulfur dioxide (SO_2) with oxygen and mixing the resultant sulfur trioxide (SO_3) with water, or by reacting nitric oxide (NO) with sulfur dioxide and water.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972),¹ which is incorporated by reference.

(c) The ingredient is used as a pH control agent as defined in § 170.3(o)(23) of this chapter and processing aid as defined in § 170.3(o)(24) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with

§ 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.014 percent for alcoholic beverages as defined in § 170.3(n)(2) of this chapter and 0.0003 percent for cheeses as defined in § 170.3(n)(5) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in

¹ Copies may be obtained from: National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20037.

this section do not exist or have been waived.

§ 184.1143 Ammonium sulfate.

(a) Ammonium sulfate ($(\text{NH}_4)_2\text{SO}_4$, CAS Reg. No. 7783-20-2) occurs naturally and consists of colorless or white, odorless crystals or granules. It is prepared by the neutralization of sulfuric acid and with ammonium hydroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d. Ed. (1972) as amended by the first supplement (1974),¹ which are incorporated by reference.

(c) The ingredient is used as a dough strengthener as defined in § 170.3(o)(6) of this chapter, firming agent as defined in § 170.3(o)(10) of this chapter, and processing aid as defined in § 170.3(o)(24) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.15 percent for baked goods as defined in § 170.3(n)(1) of this chapter and 0.1 percent for gelatins and puddings as defined in § 170.1(n)(22) of this chapter.

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

§ 184.1230 Calcium sulfate.

(a) Calcium sulfate (CaSO_4 , CAS Reg. No. 778-18-9 or $\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$, CAS Reg. No. 10101-41-4), also known as plaster of Paris, anhydrite, and gypsum, occurs naturally and exists as a fine, white to slightly yellow-white odorless powder. The anhydrous form is prepared by complete dehydration of gypsum, below 300° C, in an electric oven.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972) as amended by the first supplement (1974),¹ which are incorporated by reference.

(c) The ingredient is used as an anticaking agent as defined in § 170.3(o)(1) of this chapter, color and coloring adjunct as defined in § 170.3(o)(4) of this chapter, dough strengthener as defined in § 170.3(o)(6) of this chapter, drying agent as defined in § 170.3(o)(7) of this chapter, firming agent as defined in § 170.3(o)(10) of this chapter, flour treating agent as defined in § 170.3(o)(13) of this chapter, formulation aid as defined in § 170.3(o)(14) of this chapter, leavening agent as defined in § 170.3(o)(17) of this chapter, nutrient supplement as defined in § 170.3(o)(20) of this chapter, pH control agent as defined in § 170.3(o)(23)

of this chapter, processing aid as defined in § 170.3(o)(24) of this chapter, stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, synergist as defined in § 170.3(o)(31) of this chapter, and texturizer as defined in § 170.3(o)(32) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 1.3 percent for baked goods as defined in § 170.3(n)(1) of this chapter, 3.0 percent for confections and frostings as defined in § 170.3(n)(9) of this chapter, 0.5 percent for frozen dairy desserts and mixes as defined in § 170.3(n)(20) of this chapter, 0.4 percent for gelatins and puddings as defined in § 170.3(n)(22) of this chapter, 0.5 percent for grain products and pastas as defined in § 170.3(n)(23) of this chapter, 0.35 percent for processed vegetables as defined in § 170.3(n)(36) of this chapter, and 0.07 percent or less for all other food categories.

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

§ 184.1643 Potassium sulfate.

(a) Potassium sulfate (K_2SO_4 , CAS Reg. No. 7778-80-5) occurs naturally and consists of colorless or white crystals or crystalline powder having a bitter, saline taste. It is prepared by the neutralization of sulfuric acid with potassium hydroxide or potassium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972) as amended by the first supplement (1974),¹ which are incorporated by reference.

(c) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.015 percent for nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter.

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

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. Part 186 is amended by adding new § 186.1797 to read as follows:

§ 186.1797 Sodium sulfate.

(a) Sodium sulfate (Na_2SO_4 , CAS Reg. No. 7757-82-6), also known as Glauber's salt, occurs naturally and exists as colorless crystals or as a fine, white crystalline powder. It is prepared by the neutralization of sulfuric acid with sodium hydroxide.

(b) The ingredient is used as a constituent of paper and paperboard used for food packaging, and cotton and cotton fabric used for dry food packaging.

(c) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 186.1(b)(1).

(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 February 25, 1980.

(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: January 16, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

Note.—Incorporations by reference were approved by the Director of the Office of the Federal Register on July 10, 1973, and June 27, 1977, and are on file in the Federal Register Library.

[FR Doc. 80-2037 Filed 1-24-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject to Certification; Levamisole Hydrochloride Effervescent Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The agency amends the animal drug regulations to reflect approval of a new animal drug application (NADA) filed for Cyanamid Agricultural de Puerto Rico, Inc., providing for safe and effective use of levamisole hydrochloride effervescent tablets in swine drinking water for treating nematode infections.

EFFECTIVE DATE: January 25, 1980.

FOR FURTHER INFORMATION CONTACT: Charles E. Haines, Bureau of Veterinary Medicine (HFV-138), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3410.

SUPPLEMENTARY INFORMATION: Cyanamid Agricultural de Puerto Rico, Inc. (CAPRI), Manati, PR 00701, is the sponsor of an NADA (107-085) filed by