§ 711.6 [Amended]

4. Section 711.6 is amended by removing subparagraphs (a)(1) and (2) and redesignating (b)(1) and (2) as (a) and (b), respectively.

Dated: October 12, 1982.

Rosemary Brady,

Secretary, National Credit Union Administration Board.

[FR Doc. 82-29288 Filed 10-25-82; 8:45 am]

BILLING CODE 7535-01-M

FEDERAL HOME LOAN BANK BOARD

12 CFR Part 571

[No. 82-676]

Employment Contracts; Correction

Date: October 6, 1982.

AGENCY: Federal Home Loan Bank Board.

ACTION: Final rule; correction.

SUMMARY: The Federal Home Loan Bank Board corrects the final amendments to its employment contracts regulations which were published at 47 CFR 17471 (April 23, 1982).

EFFECTIVE DATE: April 15, 1982.

FOR FURTHER INFORMATION CONTACT: Peter M. Barnett, (202-377-6445), Associate General Counsel, or Cynthia D. Farmer, (202-377-6441, Legal Assistant, Office of General Counsel, Federal Home Loan Bank Board, 1700 G Street NW., Washington, D.C., 20552.

SUPPLEMENTARY INFORMATION: On April 15, 1982, the Federal Home Loan Bank Board adopted amendments pertaining to employment contracts so that federal and state-chartered institutions are subject to the same rules governing employment contracts entered into by institutions and their officers. Board Resolution No. 82-268 (April 15, 1982); 47 FR 17471, Published (April 23, 1982). The final rule inadvertently referred to paragraph (e) of 12 CFR 571.5; however, paragraph (e) already had been redesignated as paragraph (d) by a final rule published on November 4, 1981 (46 FR 54724).

§ 571.5 [Corrected]

Accordingly, the Board is correcting FR Doc 82-11214, appearing at 47 FR 17471, by changing the reference to paragraph (e) of 12 CFR 571.5 to read as paragraph (d)

(Sec. 5, 48 Stat. 132, as amended (12 U.S.C. 1464); Sec. 402, 403, 407, 48 Stat. 1256, 1257, as amended (12 U.S.C. 1725, 1726, 1730); Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR, 1943-48 Comp., p. 1071).

By the Federal Home Loan Bank Board.

Thomas P. Vartanian,

General Counsel.

[FR Doc. 82-29352 Filed 10-25-82; 8:45 am]

BILLING CODE 6720-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 182 and 184

[Docket No. 77N-0037]

GRAS Status of Certain Red and Brown Algae and Their Extractives

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming, with specific limitations, that certain red and brown algae and alginic acid are generally recognized as safe (GRAS) as direct human food ingredients and is removing the brown algae *Nereocystis spp.* from the GRAS list. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency.

EFFECTIVE DATE: November 26, 1982.

FOR FURTHER INFORMATION CONTACT: Leonard C. Gosule, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204; 202-426-9463.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 4, 1978 (43 FR 34500), FDA published a proposal to affirm that the brown algae *Macrocystis pyrifera* is GRAS for use as a direct human food ingredient and to remove red algae, certain brown algae, and the extractives from red and brown algae (including alginic acid) from the list of direct food substances that are considered GRAS. 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 algae and the report of the Select Committee on GRAS Substances (the Select Committee) on certain red and brown algae have been made 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 have also been made 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 the brown algae *Macrocystis pyriferd*, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient use for these substances, other than for the proposed conditions of use. Persons asserting such 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 the prior-sanctioned use 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 such sanction at any future time.

No reports of prior-sanctioned uses for red and brown algae or alginic acid were submitted in response to the proposal. Therefore, in accordance with that proposal, any right to assert a prior sanction for uses of red and brown algae or alginic acid under conditions different from those set forth in the final regulation has been waived.

One hundred twenty-six comments were submitted on the agency's proposal on red and brown algae and their extractives. One hundred eleven of these comments were not relevant to the issues addressed in the proposal. Those comments discussed the consumption of algae directly as food, the purported but undocumented health benefits of algae consumption, or the widespread acceptance of algae as food by Americans of Oriental descent. The agency emphasizes that this document addresses only the use of algae, in conjunction with spices, seasonings, and flavorings, as a flavor enhancer or flavor adjuvant. This document does not address, and therefore does not affect, the consumption of algae directly as food. The other comments and the agency's conclusions are summarized below:

1. One comment objected to the treatment of seaweed extractives in the proposed regulation, claiming that they had been addressed previously in the **Federal Register** of January 1, 1978.

The agency notes that no **Federal Register** was published on January 1, 1978. This comment may have been referring to the proposed rule on alginates, which was published in the

Federal Register of January 27, 1978 (43 FR 3725). That proposal addressed the ingredients ammonium alginate, calcium alginate, potassium alginate, and sodium alginate, which are currently listed as GRAS for use as stabilizers. It did not address either alginic acid or the extractives of red and brown algae currently listed in 21 CFR 182.40 as GRAS for use in conjunction with spices, seasonings, and flavorings. Consequently, it is appropriate for the agency to address red and brown algae and alginic acid in this final rule.

2. Five comments referred to the annual poundages of algae involved in commercial trade. Of these, three comments reported the amounts of algae annually used in or imported into the United States, and two comments reported the amounts of algae annually produced or consumed in Japan. However, none of these comments identified the species of algae involved, intended technical effects, the specific uses, or the use levels. This information is required as a basis for developing FDA GRAS affirmation regulations. Consequently, the agency did not make any change in the final rule on the basis of this information.

3. Four comments contained nutrition information, general characteristics of a variety of algae, or references to the published literature on algae. Although these comments provide valuable additions to the agency's file on algae, they did not necessitate any substantive change in the regulation.

4. Four comments addressed the uses of algae as condiments or as flavorings and seasonings. In two of these comments, the species of algae used were identified. The species of brown algae mentioned were: *Analipus japonicus, Eisenia bicyclis, Hizikia fusiforme, Kjellmaniella gyrata, Laminaria angustata, Laminaria claustonia, Laminaria digitata, Laminaria japonica, Laminaria longicruris, Laminaria longissima, Laminaria ochotensis, Laminaria saccharina, Petalonia fasica, Scytosiphon lomentaria,* and *Undaria pinnatifida.* The species of red algae mentioned were: *Gloiopeltis furcata, Porphyra crispata, Porphyra deutata, Porphyra perforata, Porphyra suborbiculata, Porphyra tenera,* and *Rhodymenia palmata.*

All these species were reported to be consumed currently in the United States. Consequently, FDA has modified the proposed rule to affirm these species as GRAS for use as flavorings, seasonings, and spices. The agency is not aware of any current use of *Nereocystis spp.* as a flavoring, seasoning, or spice, however. Therefore, the agency is removing the use of this ingredient from the GRAS list as proposed.

5. One comment objected to revoking the use of red and brown algae as spices, flavoring, and seasonings because this action would affect the diet of many Americans of Asian descent. The comment provided no further elaboration concerning the types of effects expected.

FDA believes that the other comments on this proposed rule, which were discussed above, have identified the species of red and brown algae that are safe and that are currently used as spices, flavorings, and seasonings in the United States. These species are affirmed as GRAS in this final rule. Consequently, the agency believes this final rule will not adversely affect the diet of any group of Americans.

6. Three comments requested that algae not be removed from the GRAS list because of lack of use because there are no unfavorable safety data.

FDA has previously emphasized that use information is very important in assessing the safety of GRAS food ingredients (21 CFR 170.30 (i), (j), and (k) and 21 CFR 170.35(b)(1)). Consequently, the agency did not make any change in the regulations on the basis of these comments.

7. One comment requested a hearing to ascertain the facts on edible seaweed use in the United States.

The agency believes that ample opportunity has been provided to ascertain these facts during the proposal's comment period. Consequently, the agency believes no hearing is needed.

8. One comment reported the use of alginic acid as a tablet disintegrant in prescription drugs, over-the-counter drugs, vitamin tablets, mineral tablets, and various special dietary food tablets.

FDA's review of the safety of GRAS food ingredients addresses only the use of those ingredients in conventional food.[1] The agency does not consider the uses of alginic acid described in this comment to be conventional food uses. Consequently, these uses of alginic acid are not affected by this regulation.

9. Four comments addressed the uses of alginic acid in food. Of these, one comment from a confectioner's trade association questioned whether the absence of current uses for alginic acid justified its removal from GRAS status. One comment requested that alginic acid be affirmed as GRAS simply because certain aliginate salts have already been affirmed as GRAS. Three comments reported uses of alginic acid as a stabilizer and thickener or emulsifier in soups and soup mixes. Only one of these comments provided the quantitative use information required as a basis for evaluating the safe use of the ingredient. The comment indicated that alginic acid is used as a stabilizer and thickener in dehydrated oriental-style noodles at the level of 0.049 gram per two one-cup servings.

FDA has used data in Table 7 of U.S. Department of Agriculture Statistical Bulletin No. 616 to calculate that the density of canned soups is about 230 to 240 grams per cup, as served. Using these values, and the levels of alginic acid reported in the comment (0.049 grams per two one-cup servings), the agency has estimated the level of alginic acid in these products, as served, to be 0.01 percent. The agency concludes that sufficient safety data are contained in its GRAS safety reviews on alginates and red and brown algae to affirm this use of a alginic acid, which is derived from brown algae. However, because the calculated use level is based on an approximate value for the density of the finished product, the agency concludes it would be inappropriate to specify a precise use level for alginic acid in these products. Nevertheless, the agency considers that the restriction of this ingredient to use in soups and soup mixes does constitute a specific limitation on it use and is therefore consistent with the conditions under which inorganic salts of alginic acid have been affirmed as GRAS (see 47 FR 29946; July 9, 1982). Therefore, FDA has modified its proposed rule to affirm as GRAS the use of alginic acid in soups and soup mixes at a level not to exceed current good manufacturing practice.

10. Although FDA is affirming brown and red algae as GRAS for use in spices at levels that do not exceed current good manufacturing practice, it is doing so in accordance with § 184.1(b)(2) (21 CFR 184.1(b)(2)) and not § 184.1(b)(1), as is customarily the case. The agency is deviating from its usual practice because of its decision, announced in the proposal, to concur in the conclusion of the Select Committee. The Select Committee concluded that no evidence demonstrates or suggests reasonable grounds to suspect a hazard to the public when red and brown algae are used at current levels or at levels that might reasonably be expected in the future (see 43 FR 34502). Consistent with its agreement with this conclusion, FDA has not established any restriction on the levels at which these substances may be used other than that they be used at levels that are consistent with

[1] FDA is using the term "conventional food" to refer to food that would fall within any of the 43 categories listed in § 170.3(n) (21 CFR 170.3(n)).

current good manufacturing practice. However, the Select Committee conditioned its conclusion by adding the qualification that use of these substances be "confined to ingredients of spices, seasonings, and flavorings." The agency believes that this qualification constitutes a specific limitation on the use of red and brown algae as food ingredients, and therefore that the uses of these substances should be restricted in the manner set forth in § 184.1(b)(2). These restrictions apply only to the use of these substances as food ingredients and do not affect their use directly as foods.

11. Four comments addressed the specifications proposed for food-grade algae. Three of these comments reported the results of heavy metals determinations in several species of algae.

FDA stated in the proposed rule that it is aware of the Select Committee's concern that a harmful concentration of certain heavy metals may accumulate in commercial algae, particularly if the algae are harvested from coastal waters that are contaminated with significant levels of heavy metals. The agency also stated its intention to investigate background levels of individual heavy metals (arsenic, cadmium, lead, mercury, selenium, and zinc) in algae to determine whether the Food Chemicals Codex specification for "heavy metals (as Pb)" should be replaced by separate specifications for each heavy metal.

FDA has evaluated the results of its own analyses as well as those reported in the comments. On the basis of this evaluation, the agency concludes that the consumption of these metals from the kelp used in conjunction with flavorings, seasonings, or spices is low and poses no undue risk to the exposed population. The agency also believes that the data currently available are not sufficient to support the establishment of separate specifications for each of the heavy metals mentioned above. Therefore, the agency is taking no action at this time with regard to modifying the Food Chemicals Codex specifications for kelp. In addition, the agency notes that a third edition of the Food Chemicals Codex has been printed since publication of the proposal, and this edition has been incorporated by reference in the final rule.

12. Specifications for dulse (red algae) were proposed in one comment. These proposed specifications for dulse were in general agreement with the Food Chemicals Codex specifications for kelp, except that the "loss on drying" specification suggested in the comment for dulse was not more than 20 percent, and the corresponding iodine levels were between 0.005 percent and 0.05 percent. The Food Chemicals Codex monograph on kelp specifies a loss on drying of not more than 13 percent and iodine levels between 0.15 percent and 0.22 percent.

The Food Chemicals Codex procedure for determining iodine in kelp is not sensitive enough to measure accurately iodine at 0.005 percent in dulse. Furthermore, the agency finds no need to establish a lower limit on iodine levels in dulse to ensure safety. Consequently, this regulation does not establish a lower limit on the iodine level for dulse. However, FDA has modified the proposed rule to include the other food-grade specifications suggested by this comment for dulse. These specifications are identical to the Food Chemicals Codex specifications for kelp except that the agency has established a loss on drying of not more than 20 percent and an upper limit of 0.05 percent iodine.

The format of the regulations is different from that in previous GRAS affirmation regulations. The agency has modified the form in which the specific limitations on the use of these ingredients is presented. This change has no substantive effect but is made merely for clarity.

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

The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued prior to January 1, 1981, and is therefore exempt.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this rule, and the agency has determined that the rule is not a major rule as defined by the Order.

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.

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. In Part 182:

§ 182.30 [Removed]

a. By removing § 182.30 *Natural substances used in conjunction with spices and other natural seasonings and flavorings.*

§ 182.40 [Amended]

b. In § 182.40 *Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings* by removing the entries for "Algae, brown," Algae, red." "Dulse" and "Kelp (see algae, brown)."

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

2. In Part 184:

a. By adding new § 184.1011, to read as follows:

§ 184.1011 Alginic acid.

(a) Alginic acid is a colloidal, hydrophilic polysaccharide obtained from certain brown algae by alkaline extraction.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 13, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served)	Functional use
Soup and soup mixes, § 170.3(n)(40) of this chapter.	Not to exceed current good manufacturing practice.	Emulsifier, emulsifier salt, § 170.3(o)(8) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; stabilizer, thickener, § 170.3(o)(28) of this chapter.

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

b. By adding new § 184.1120, to read as follows:

§ 184.1120 Brown algae.

(a) Brown algae are seaweeds of the species *Analipus japonicus, Eisenia bicyclis, Hizikia fusiforme, Kjellmaniella gyrata, Laminaria angustata, Laminaria claustonia, Laminaria digitata, Laminaria japonica, Laminaria longicruris, Laminaria longissima, Laminaria ochotensis, Laminaria saccharina, Macrocystis pyrifera, Petalonia fascia, Scytosiphon lomentaria* and *Undaria pinnatifida.* They are harvested principally in coastal waters of the northern Atlantic and Pacific oceans. The material is dried and ground or chopped for use in food.

(b) The ingredient meets the specifications for kelp in the Food Chemicals Codex, 3d Ed. (1981), p. 157, 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)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served)	Functional use
Spices, seasonings, and flavorings, § 170.3(n)(26) of this chapter.	Not to exceed current good manufacturing practice.	Flavor enhancer, § 170.3(o)(11) of this chapter; flavor adjuvant, § 170.3(o)(12) of this chapter.

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

c. By adding new § 184.1121 to read as follows:

§ 184.1121 Red algae.

(a) Red algae are seaweeds of the species *Gloiopeltis furcata, Porphyra crispata, Porphyra deutata, Porphyra perforata, Porphyra suborbiculata, Porphyra tenera* and *Rhodymenia palmata. Porphyra* and *Rhodymenia* are harvested principally along the coasts of Japan, Korea, China, Taiwan, and the East and West coasts of the United States. *Gloiopeltis* is harvested principally in southern Pacific coastal waters. The material is dried and ground or chopped for use in food.

(b) The ingredient meets the specifications for kelp in the Food Chemicals Codex, 3d Ed. (1981), p. 157, which is incorporated by reference, except that the loss on drying is not more than 20 percent and the maximum allowable level for iodine is 0.05 percent. 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)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served)	Functional use
Spices, seasonings, and flavorings, § 170.3(n)(26) of this chapter.	Not to exceed current good manufacturing practice.	Flavor enhancer, § 170.3(o)(11) of this chapter; flavor adjuvant, § 170.3(o)(12) of this chapter.

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

Effective date. This regulation shall be effective November 26, 1982.

(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: September 17, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

Note.—Incorporation by reference approved by the Director of the Office of the Federal Register on March 31, 1982, and is on file at the Office of the Federal Register.

[FR Doc. 82-29222 Filed 10-25-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject to Certification; Pyrantel Pamoate Paste

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Pfizer. Inc., providing for safe and effective oral use of pyrantel pamoate paste as an anthelmintic in horses and ponies.

EFFECTIVE DATE: October 26, 1982.

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

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 E. 42d St., New York, NY 10017, filed an NADA (129–831) providing for use of a pyrantel pamoate paste in horses and ponies for removal and control of mature infections of large strongyles, small strongyles, pinworms, and large roundworms. The firm currently holds approval for use of pyrantel pamoate suspension formulation (NADA 91–739) in horses and ponies at the same dosage level and against the same parasites. The combination of a comparative critical (worm count) study (i.e., paste vs. suspension), clinical field studies, and copies of published literature constitutes sufficient evidence to conclude that Pfizer's pyrantel pamoate paste formulation is comparably effective against all the parasites now indicated for its suspension formulation. Approval of this NADA relies in part upon safety and effectiveness data contained in Pfizer's NADA, 91–739. The NADA is approved, and the regulations are amended to reflect the approval.

This approval does not change the approved use of the active ingredient, but instead provides an alternative drug vehicle containing an increased concentration of the active ingredient. Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), approval of this NADA has been treated as would an approval of a Category II supplement. Therefore, it did not require reevaluation of the safety and effectiveness data in NADA 91–739.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

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

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

List of Subjects in 21 CFR Part 520

Animal drugs, Oral.

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 Bureau of Veterinary Medicine (21 CFR 5.83), Part 520 is amended by adding new § 520.2044, to read as follows:

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

§ 520.2044 Pyrantel pamoate paste.

(a) *Specifications.* Each milliliter of paste contains 180 milligrams of pyrantel base (as pyrantel pamoate).

(b) *Sponsor.* See 000069 in § 510.600(c) of this chapter.

(c) *Conditioners of use.* It is used in horses and ponies as follows:

(1) *Amount.* Equivalent of 3 milligrams pyrantel base per pound of body weight.

(2) *Indications for use.* For removal and control of infections from the following mature parasites: large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*); small strongyles; pinworms (*Oxyuris equi*); and large roundworms (*Parascaris equorum*).

(3) *Limitations.* Administer as single dose by depositing paste on dorsum of the tongue using the dose syringe. Not for use in horses intended for food. It is recommended that severely debilitated animals not be treated with this preparation. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Effective date. October 26, 1982.

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

Dated: October 19, 1982.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 82-29338 Filed 10-25-82; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 931

Removal of Conditions of Approval of the New Mexico Permanent Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule.

SUMMARY: This document amends 30 CFR Part 931 to remove certain of the conditions of approval of the New Mexico permanent regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act).

New Mexico received approval of its permanent program effective December 31, 1980, subject to the State's satisfaction of 12 conditions of approval. On July 9, 1982, and July 29, 1982, New Mexico submitted to the Department of the Interior provisions to satisfy six conditions of approval. The Secretary is approving certain of the amendments submitted by the State and removing four conditions of approval. With regard to certain other amendments the Secretary has determined the provisions do not fully satisfy the conditions of approval which they are intended to satisfy and, therefore, the Secretary is granting the State additional time to submit further revisions.

EFFECTIVE DATE: October 26, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. Arthur W. Abbs, Chief, Division of State Program Assistance, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Avenue, NW., Washington, D.C. 20240, Telephone: (202) 343-5351.

SUPPLEMENTARY INFORMATION: On February 28, 1980, OSM received a proposed regulatory program from the State of New Mexico. On December 31, 1980, following a review of the proposed program as outlined in 30 CFR Part 732, the Secretary approved the proposed program conditioned on the correction of 12 minor deficiencies (45 FR 86459-86490).

In accepting the Secretary's conditional approval, New Mexico agreed to submit provisions to satisfy conditions "a"-"d" and "f"-"l" by July 1, 1981, and a provision to meet condition "e" by January 28, 1982. Subsequently, New Mexico requested that the deadline for the State to meet conditions "a"-"d" and "f"-"l" be extended until February 28, 1982. On October 30, 1981 (46 FR 54070), OSM announced its decision to grant New Mexico's request. In response to a further request by the State in December 1981, the Secretary reexamined conditions "a"-"c" and "e"-"l" in light of proposed and final changes to the Federal permanent program rules. As a result of that reexamination, the Secretary decided to remove conditions "a" and "k", to extend the deadline for the State to meet conditions "b", "c", "f", "g", "i" and "l" to July 31, 1982, and to extend the deadline for the State to meet conditions "e", "h", and "j" to March 15, 1983 (47 FR 23150-23153, May 27, 1982).

On February 28, 1982, New Mexico submitted to OSM a policy statement to satisfy condition "d". Following a review of that material as outlined in 30 CFR 732, the Secretary determined that the amendment submitted by the State satisfied condition "d". Notice of the Secretary's decision to remove that condition was published in the **Federal Register** on May 27, 1982 (47 FR 23153-23155).

On July 9, 1982, New Mexico submitted regulatory revisions adopted by the New Mexico Coal Surface Mining Commission on that date which are intended to satisfy conditions "b", "c", "f", "g", "i" and "l". On July 29, 1982, OSM issued notice in the **Federal Register** of a public hearing and comment period on those amendments (47 FR 32738-32739). Subsequently, OSM announced an extension of the comment period to allow opportunity for commenters to review additional materials submitted to OSM by New Mexico on July 29, 1982, in satisfaction of conditions "b", "c", "f", "g", "i" and "l" (47 FR 36226-36227, August 19, 1982).

Findings

After thoroughly reviewing the amendments submitted to OSM by New Mexico on July 9, 1982, and July 29, 1982, to satisfy the Secretary's conditions of approval as listed at 30 CFR 931.11 (b), (c), (f), (g), (i) and (l), and after reviewing the public comment received on those amendments, the Secretary has made the following determinations:

1. To satisfy condition "b", New Mexico has amended State regulation 4-17(a) by deleting the requirement that a hearing connected with an unsuitability petition be adjudicatory in nature. The Secretary finds this revision partially satisfies condition "b". As discussed in finding 4(k)(ii) in the December 31, 1980 **Federal Register** notice announcing conditional approval of New Mexico's program (45 FR 86474) the Secretary was concerned that the State's requirement that the hearing be adjudicatory conflicted with the provisions of 30 CFR 764.17 that the hearing be legislative and fact-finding in nature, without cross-examination of witnesses. While New Mexico has deleted the requirement at regulation 4-17(a) that a hearing be adjudicatory in nature, the State has not added any language to clarify just how the hearing will proceed.

Condition "b" of the Secretary's approval of New Mexico's program requires that the State provide written procedures and regulations detailing how the hearing will operate. As discussed in the December 31, 1980 notice, the Secretary acknowledged that the type of "adjudicatory" hearing which has a well-developed tradition in New Mexico regulatory agencies may be consistent with Federal requirements since any person can elect that the hearing, as it involves his or her testimony, be strictly legislative in nature and thus the procedure would not