methacrylate)-dye copolymers in coloring contact lenses became effective February 6, 1984.

Dated: March 15, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84-8769 Filed 4-2-84; 8:45 am]

BILLING CODE 4160-01-M

---

21 CFR Parts 74, 81 and 82

[Docket Nos. 76N-0366 and 83C-0128]

D & C Yellow No. 10; Listing as a Color Additive in Drug and Cosmetics; Termination of Stay, Confirmation of Effective Date, and Further Amendment

Correction

In FR Doc. 84-6183, beginning on page 8429, in the issue of Wednesday, March 7, 1984, on page 8431, in the second column, in the third complete paragraph in the fifth line "§ 74.2710" should read "§ 74.1710".

BILLING CODE 1505-01-M

---

21 CFR Part 175

[Docket No. 82F-0161]

Indirect Food Additives: Adhesive Coatings and Components

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 sulfated castor oil as a miscellaneous material in resinous and polymeric coatings for food-contact use. This action responds to a petition filed by NL Chemicals/NL Industries, Inc.

DATES: Effective April 3, 1984; objections by May 3, 1984.

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: James H. Maryanski, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St SW., Washington, D.C. 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 15, 1982 (47 FR 25772), FDA announced that a petition (FAP 2B3628) had been filed by NL Chemicals/NL Industries, Inc., Wyckoff Mills Road, Hightstown, NJ 08520, proposing that the food additive regulations be amended to provide for the safe use of sulfated castor oil as a miscellaneous material in resinous and polymeric coatings for food-contact use.

FDA has evaluated data in the petition and other relevant material and concludes that the proposed food additive 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 Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h)(2), 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 175

Adhesives, Food additives, Food packaging.

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 Bureau of Foods (21 CFR 5.61), Part 175 is amended in § 175.300(b)(3)(xxxiii) by alphabetically inserting a new item in the list of substances to read as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVE COATINGS AND COMPONENTS

§ 175.300 Resinous and polymeric coatings.

* * * * *

(b) * * *

(3) * * *

(xxxiii) * * *

Castor oil, sulfated, sodium salt (CAS Reg. No. 8002-33-3), for use only in coatings for containers intended for repeated use.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before May 3, 1984 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 is effective April 3, 1984.

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

Dated: March 13, 1984.

Richard J. Ronk,

Acting Director, Bureau of Foods.

[FR Doc. 84-8771 Filed 4-2-84; 8:45 am]

BILLING CODE 4160-01-M

---

21 CFR Part 177

[Docket No. 83F-0098]

Indirect Food Additives; Polymers

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 octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate at increased levels as an antioxidant and/or stabilizer in acrylic and modified acrylic plastics intended to contact food. This action responds to a petition filed by the Ciba-Geigy Corp.

DATES: Effective April 3, 1984; objections by May 3, 1984.

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: Vir Anand, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC. 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of April 12, 1983 (48 FR 15720), FDA announced that a petition (FAP 3B3714) has been filed by Ciba-Geigy Corp., Three Skyline Dr., Hawthorne, NY. 10532, proposing that the food additive regulations be amended to provide for the safe use of octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate as an antioxidant and/or stabilizer in acrylic and modified acrylic plastics complying with § 177.1010 (21 CFR 117.1010) intended for use in contact with food.

The current regulation provides for the use of the additive at levels not exceeding 0.01 percent by weight in rigid and semirigid acrylic and modified acrylic plastics intended for repeated food-contact use. The petition requested that § 177.1010 be amended to: (1) Increase the permitted amount of the additive to 0.2 percent by weight, and (2) permit the use of the additive in single use applications. However, the petitioner did not submit data in support of the single use of the additive with foods containing more than 15 percent alcohol. Accordingly, above 15 percent alcohol, the existing limitation remains in effect, that is, the additive is restricted to use in articles for repeated food-contact use. Additionally, the Chemical Abstracts Registry Number for the additive has been included in the regulation to ensure correct identification.

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 Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h)(2), 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 therefore 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 177

Food additives, Polymeric food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784–1788 (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 Bureau of Foods (21 CFR 5.61), Part 177 is amended in § 177.1010(a)(5) by revising the entry for octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate to read as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

§ 177.1010 Acrylic and modified acrylic plastics, semirigid and rigid.

* * * * *

(a) * * *

(5) * * *

Octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate (CAS Reg. No. 2082-79-3): For use only: (1) At levels not exceeding 0.2 percent by weight in semirigid and rigid acrylic and modified acrylic plastics, where the finished articles contact foods containing not more than 15 percent alcohol; and (2) at levels not exceeding 0.01 percent by weight in semirigid and rigid acrylic and modified acrylic plastics intended for repeated food-contact use where the finished article may be used for foods containing more than 15 percent alcohol.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before May 3, 1984 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 becomes effective April 3, 1984.

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

Dated: March 13, 1984.

Richard J. Ronk,

Acting Director, Bureau of Foods.

[FR Doc. 84-8772 Filed 4-2-84; 8:45 am]

BILLING CODE 4160-01-M

---

21 CFR Parts 182 and 184

[Docket No. 80N-0362]

GRAS Status of Propionic Acid, Calcium Propionate, and Sodium Propionate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that propionic acid, calcium propionate, and sodium propionate are generally recognized as safe (GRAS) as direct human food ingredients. The safety of these ingredients has been evaluated under a comprehensive safety review conducted by the agency.

DATES: Effective May 3, 1984. The Director of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 184.1081, 184.1221, and 184.1784 on May 3, 1984.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION: In the Federal Register on August 13, 1982 (47 FR 35243), FDA published a proposal to affirm that propionic acid, calcium propionate, and sodium propionate are generally recognized as safe (GRAS) 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 on propionates; a teratogenic evaluation of calcium propionate; mutagenic evaluations of propionic acid, calcium propionate, and sodium propionate; and the report of the Select

Committee on GRAS Substances (the Select Committee) 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 propionic acid, calcium propionate, and sodium propionate, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient uses for these substances, 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 the prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of these propionates 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 to any future time.

No reports of prior-sanctioned uses for propionic acid, calcium propionate, or sodium propionate were submitted in response to the proposal. Therefore, in accordance with that proposal, any right to assert a prior sanction for uses of these substances under conditions different from those set forth in this final rule has been waived.

Five comments were received in response to the proposal. A summary of these comments and the agency's responses follow:

1. Three comments stated that the proposed regulations for calcium propionate and sodium propionate did not include the use of these ingredients in jams and jellies, preserves, fruit, butter, and sweet spreads. The comments requested that the final regulations for calcium propionate and sodium propionate include the food category jams and jellies as defined by § 170.3(n) (28) (21 CFR 170.3(n)(28)). One of these comments from a trade association provided information on the permitted use of calcium propionate and sodium propionate as preservatives in the standards of identity for artificially sweetened fruit jelly (21 CFR 150.141(a)(6)) and artifically sweetened fruit preserves and jams (21 CFR 150.161(a)(6)). The comment further stated that the standards of identity for conventional jams and jellies provide for the optional use of "safe and suitable" preservatives, and the comment questioned whether this term would permit the use of calcium propionate and sodium propionate in these foods.

FDA acknowledges that calcium propionate and sodium propionate may be used as optional ingredients in jams or jellies because FDA considers these ingredients to be safe and suitable preservatives. FDA also acknowledges that these substances may be used as preservatives in artificially sweetened fruit jelly, preserves, or jams when they are listed for this use in the standards of identity for these foods. Because the agency failed to include the use of calcium propionate and sodium propionate in jams and jellies in the proposed GRAS affirmation regulations for these ingredients, in response to the comments, FDA is amending those regulations (21 CFR 184.1221(c)(2) and 184.1784(c)(2)) in this final rule to include the food category jams and jellies. This change affirms as GRAS the use of calcium propionate and of sodium propionate as ingredients in jams or jellies or in artificially sweetened fruit jelly, jams, or preserves as described in the standards of identity for these foods.

2. Three comments asserted that it was not clear whether the use of sodium propionate or calcium propionate in jams and jellies used as fillings in a variety of baked goods was included in the proposal. One comment requested that an appropriate food category be established for jam- or jelly-filled baked goods because these products could be categorized either as baked goods (§ 170.3(n)(1)) or as jams and jellies (§ 170.3(n)(28)).

As described in comment 1 above, FDA has modified the regulations for calcium propionate and sodium propionate to affirm as GRAS the use of these ingredients in jams and jellies as well as in baked goods. FDA believes that this change adequately provides for the use of these ingredients in jam- or jelly-filled baked goods.

The agency has carefully considered the request that it establish a new category for jam- and jelly-filled baked goods. FDA has reviewed the definitions of the food categories established in § 170.3(n) and finds that this section incorporates by reference exhibit 33B to the report of the National Academy of Sciences/National Research Council (NAS/NRC), entitled "A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe" (September 1972). This exhibit lists the foods included in each food category and shows that jam- or jelly-filled baked goods are listed as a subcategory of both the baked goods category on page 267 and the jams and jellies category on page 247. Thus, jam- or jelly-filled baked goods are already provided for in § 170.3(n) (1) and (28). The agency thus concludes that it is not necessary to create a new food category for these foods. The agency further advises that an ingredient may be used in the jam or jelly portion of a jam- or jelly-filled baked good when the ingredient is affirmed as GRAS for use in either baked goods or in jams or jellies.

3. Two comments requested that the baked goods category listed in the final regulations for calcium propionate and sodium propionate be modified to include fried foods such as doughnuts, waffles, and pancakes or that a new food category be added to § 170.3(n) to provide for such fried dough foods. One comment asserted that doughnuts, as well as some other dough products, are regarded as baked goods although they are not produced in ovens.

The agency has considered the need to create a new category in § 170.3(n) to include doughnuts and other fried dough products. It finds that dough products are listed in exhibit 33B of the NAS/NRC survey as a subcategory of baked goods, and that therefore, because this exhibit is incorporated by reference in § 170.3(n), dough products specified in the comment are provided for in § 170.3(n)(1). The agency believes that establishing a new category called "fried foods," which would include doughnuts as well as other dough products, would not be helpful because a wide variety of foods other than dough foods can be fried. A fried foods category could, if established, cover all existing food categories. For these reasons, the agency concludes that the use of propionates in dough products are covered by the proposed regulation, and modification of the regulation is not necessary.

4. One comment from a food manufacturer stated that calcium propionate is currently used as a substitute for sodium propionate as an antimicrobial agent in baked and certain fried foods and in various components of these foods, such as frostings. The comment specifically questioned whether the proposed regulation would permit the substitution of calcium for sodium propionate in frostings and fillings that are components of baked goods. The comment also noted that substituting the calcium salt for the

sodium salt will reduce the sodium ion intake for the consumer.

The agency finds no basis to deny the substitution of calcium for sodium salt under certain conditions of use. In fact, substitution for sodium salt is encouraged because of the agency's stated concern about sodium consumption (see the **Federal Register** of June 18, 1982; 47 FR 26590). The agency advises that it was the intent of the proposed regulations for calcium and sodium propionate to affirm as GRAS the use of both ingredients in baked goods. The agency advises further that the intent also was to permit the use of either salt in components of baked goods, such as fillings and frostings. To make clear, however, that calcium and sodium propionates may be used as antimicrobial agents in baked goods and fillings and frostings used in baked goods as well as in confections and frostings and gelatins and fillings when they are sold as separate products, the agency is modifying the regulation for calcium propionate to include two new food categories, confections and frostings (21 CFR 170.3 (n)(9)) and gelatins, puddings, and fillings (21 CFR 170.3(n)(22)). The agency cautions, however, that for any food product in which the calcium salt of propionic acid is used as a substitute for the sodium salt, the labeling must name the ingredient that is actually present.

5. Two comments expressed a concern that the listing of food categories in the proposed regulations for calcium propionate and sodium propionate has the effect of excluding their use in other foods categories.

The agency advises that the food categories listed in the proposed regulations for calcium and sodium propionate were the uses reported in the NAS/NRC survey. They are not intended to be specific limitations and do not preclude the use of these ingredients in any food category. Persons who desire to use these substances in other food categories may make independent GRAS determinations on their own responsibility. Alternatively, persons seeking FDA approval of any new uses of these ingredients may submit a food additive or GRAS petition in accordance with § 171.1 or § 170.35 (21 CFR 171.1 or 170.35).

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 had 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, the agency has previously considered 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 that Order. FDA has not received any new information or comments that would alter its previous determination.

The agency's finding of no 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

Indirect 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 listing for "Propionic acid."

§ 182.3081 [Removed]

b. By removing § 182.3081 *Propionic acid.*

§ 182.3221 [Removed]

c. By removing § 182.3221 *Calcium propionate.*

§ 182.3784 [Removed]

d. By removing § 182.3784 *Sodium propionate.*

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

2. Part 184 is amended:

a. By adding new § 184.1081 to read as follows:

§ 184.1081 Propionic acid.

(a) Propionic acid ($C_3H_6O_2$, CAS Reg. No. 79–09–4) is an oily liquid having a slightly pungent, rancid odor. It is manufactured by chemical synthesis or by bacterial fermentation.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 254, 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 antimicrobial agent as defined in § 170.3(o)(2) of this chapter and a flavoring agent as defined in § 170.3(o)(12) 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 § 184.1221 to read as follows:

§ 184.1221 Calcium propionate.

(a) Calcium propionate ($C_6H_{10}CaO_4$, CAS Reg. No. 4075–81–4) is the calcium salt of propionic acid. It occurs as white crystals or a crystalline solid, possessing not more than a faint odor of propionic acid. It is prepared by neutralizing propionic acid with calcium hydroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 60, 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 antimicrobial agent as defined in § 170.3(o)(2) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; cheeses as defined in § 170.3(n)(5) of this chapter; confections and frostings as defined in § 170.3(n)(9) of this chapter; gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter; and jams and jellies as defined in § 170.3(n)(28) of this chapter.

(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 § 184.1784 to read as follows:

§ 184.1784 Sodium propionate.

(a) Sodium propionate ($C_3H_5NaO_2$, CAS Reg. No. 137-40-6) is the sodium salt of propionic acid. It occurs as colorless, transparent crystals or a granular crystalline powder. It is odorless, or has a faint acetic-butyric acid odor, and is deliquescent. It is prepared by neutralizing propionic acid with sodium hydroxide.

(b) The ingredients meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 296, which is incorporated by reference. Copies are available from the 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 antimicrobial agent as defined in § 170.3(o)(2) of this chapter and a flavoring agent as defined in § 170.3(o)(12) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter; cheeses as defined in § 170.3(n)(5) of this chapter; confections and frostings as defined in § 170.3(n)(9) of this chapter; gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter; jams and jellies as defined in § 170.3(n)(28) of this chapter; meat products as defined in § 170.3(n)(29) of this chapter; and soft candy as defined in § 170.3(n)(38) of this chapter.

(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 May 3, 1984.

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

Dated: March 5, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84-8770 Filed 4-2-84; 8:45 am]

BILLING CODE 4160-01-M

---

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lincomycin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by the Upjohn Co., requesting waiver of the requirements of section 512(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(m)) to manufacture finished feeds for chickens and swine from premixes containing not more than 50 grams of lincomycin per pound.

EFFECTIVE DATE: April 3, 1984.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Bureau of Veterinary Medicine (HFV-128), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4317.

SUPPLEMENTARY INFORMATION: The Upjohn Co., Kalamazoo, MI 49001, is sponsor of NADA 97-505 providing for use of Lincomix® 20 and 50 (20-and 50-gram-per-pound lincomycin premixes) for manufacturing broiler and swine feeds. In the **Federal Register** of April 8, 1983 (48 FR 15246), FDA approved supplemental NADA 97-505 providing that intermediate premixes and finished poultry and swine feeds manufactured from premixes containing no more than 20 grams of lincomycin per pound are not required to comply with the provisions of section 512(m) of the act. The Upjohn Co. has filed an additional supplement to NADA 97-505 providing that finished poultry and swine feeds manufactured from premixes containing no more than 50 grams of lincomycin per pound are not required to comply with the provisions of section 512(m) of the act. The supplemental NADA is approved and the regulations are amended accordingly.

Lincomix® 50 meets the uniform criteria set forth in the 1971 Bureau of Veterinary Medicine memorandum for administrative waiver of the requirements of section 512(m) of the act. The pertinent provisions of the memorandum indicate that the waiver is appropriate if:

1. The feeding of 1.5X to 2X level of the product in the finished feed does not have an impact on the tissue residue picture, i.e., an impact on an existing withdrawal period or tolerance.

2. The product is not a known carcinogen or is not classed with a family of known carcinogens.

3. Appropriate documentation covering animal safety is on file. This will not require additional data since the documentation is by definition a part of the NADA.

4. The margin of safety to the animal and the consumer is such that the product label does not have to contain a statement such as "Use as the sole source of * * *."

5. Data are on file to demonstrate that the product is effective over the approved range. This data should generally satisfy current standards for the demonstration of effectiveness.

6. Except under special circumstances, the product has been used at least 3 years in the target species without significant complaints related to or associated with it. Applications of this criterion require a review of available drug experience reports.

Although Lincomix® 50 has not been used for 3 years in both target species, the sponsor has held approvals for use of other concentrations of lincomycin premix for over 3 years (broilers—35 FR 7300, May 9, 1970; swine—41 FR 26855, June 30, 1976). The agency concluded that this requirement could be satisfied on the basis of use of those premixes without significant complaints.

The 1971 memorandum explains that waiver of the ministerial requirements of section 512(m) of the act is permitted only for specific effectiveness claims or at specific levels of the drug, and that distinct products with corresponding labeling for those claims or levels