

Substances	Limitations
	2. At levels not to exceed 0.3 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.3, and 3.1, whose specific gravity is less than 0.94, and of olefin polymers complying with items 3.3, 3.4, 3.5, and 4.0. The finished polymers are to contact food in articles having a volume of at least 18.9 liters (5 gallons) only under conditions of use D, E, F, and G described in Table 2 of § 178.170(c) of this chapter.

Dated: July 16, 1985.

John M. Taylor,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-17528 Filed 7-23-85; 8:45 am]

BILLING CODE 4180-01-M

21 CFR Parts 182 and 184

[Docket No. 82N-0089]

Vitamin D; Affirmation of GRAS Status With Specific Limitations as a Direct Human Food Ingredient

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that vitamin D (when added to food as crystalline vitamin D₂, crystalline vitamin D₃, vitamin D₂ resin, and vitamin D₃ resin) is generally recognized as safe (GRAS) with specific limitations as a direct human food ingredient. The safety of this ingredient as a food nutrient has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective August 23, 1985. The Director of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 184.1950 effective on August 23, 1985.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lin, Center for Food Safety and Applied Nutrition (HFF-385), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 19, 1983 (48 FR 16695), FDA published a proposal to affirm that two forms of vitamin D, ergocalciferol (crystalline vitamin D₂) and cholecalciferol (crystalline vitamin D₃), are generally recognized as safe (GRAS) with specific limitations for use as direct human food ingredients in

conventional food¹ and infant formula. FDA published the proposal in accordance with the announced 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, mutagenic evaluations, and the report of the Select Committee on GRAS Substances (the Select Committee) on vitamin D₂ and vitamin D₃ are available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-82, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents also are available for public purchase from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status of the crystalline forms of vitamin D₂ and vitamin D₃, FDA gave public notice that it was unaware of any prior-sanctioned food uses for these ingredients other than for the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions, so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of these ingredients recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181), or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate. FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

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

In the proposal, FDA expressed concern about the fact that the 1971 National Academy of Sciences/National Research Council (NAS/NRC) food ingredient survey reported that the total amount (poundage) of vitamin D₂ and vitamin D₃ available for use in food in 1970 was far in excess of the amount needed to fortify foods. Although NAS/NRC additionally reported that its survey on vitamin D₂ and vitamin D₃ did

not differentiate between use in human food, in animal feed, or in dietary supplements, and probably contained inaccuracies such as failure to account for dilution of multiple strength solutions, FDA was concerned that extreme overages of this vitamin may be used in food. The agency was also concerned that impure vitamin D resins may be used in food and that there may be insufficient safety data available to support their use. The agency therefore requested specific comments on whether resinous forms of vitamin D are used in food and on the magnitude of any overages of the vitamin that are used.

Fourteen comments were received in response to the proposal. Nine comments were from manufacturers of food or food ingredients, two comments were from trade associations, two comments were from universities, and one comment was from a consulting food chemist. A summary of these comments and the agency's responses to them follow:

1. Seven comments responded to the request in the proposal for information on the use of vitamin D resins in food. One comment from a food company stated that it uses only crystalline vitamin D that meets the specifications of the Food Chemicals Codex, 3d Ed. (1981). The six remaining comments indicated that vitamin D resins are currently used in food and requested that the proposal be modified to permit their continued use. These comments stated that vitamin D resins have been used in food since the 1940's, and that no safety problems have been associated with their use. The comments provided information on the methods of manufacture of vitamin D resins and information on their inactive vitamin D isomers and other impurities. One comment claimed that some of the animal studies included in the Select Committee's report were actually conducted on vitamin D resins.

FDA has reviewed the information submitted by these comments and agrees that vitamin D resins may safely be used as alternative sources of vitamin D in food. The comments have provided information demonstrating that the vitamin D resins are manufactured by the same methods that are used to synthesize the crystalline forms of the vitamin, except that the resins are not purified to their crystalline forms. The major impurities found in the resins are unreacted provitamins (ergosterol and 7-dehydrocholesterol), lumisterol, and tachysterol, with minor amounts of other photochemical products. FDA finds that the presence of these impurities in the resins is not harmful. These impurities

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)).

are the same products that are formed in animals when animals are exposed to sunlight (Ref. 1), and at the levels at which vitamin D is added to food, the impurities will be present in food in amounts that are extremely small, much lower even than the amounts that occur naturally in animals. The agency is therefore modifying the proposal to permit vitamin D₂ and vitamin D₃ resins to be added to foods as alternatives to the crystalline forms of these vitamins.

2. One comment responded to the agency's request for information about the amounts of vitamin D that are being added to foods. The comment did not provide any specific information but acknowledged that it is often necessary to add 25 percent or more vitamin D than is declared on the label to offset losses of the vitamin that may occur during the processing or the storage of food. The comment also acknowledged that overages that are added may result in a higher amount of vitamin D in food products than is declared on the label. The comment, however, did not favor establishment of an upper limit for either the amount of vitamin D added to food or the amount actually remaining in the food. The comment stated that there are many technological problems associated with the use of vitamin D in foods, and it therefore recommended that the agency allow food processors to determine the appropriate amount of overage for each food product.

As indicated in the proposal, FDA is aware that overages of vitamin D are added to foods to offset losses of the vitamin that may occur during processing or storage. The agency is also aware that vitamin D will be more stable in some foods than others, and that there is considerable variation in the expected shelf life of vitamin D in foods. The agency further recognizes that food manufacturers and processors face technical problems in mixing small amounts of vitamin D in foods (usually 0.1 part per million or less) and assaying for these small amounts of the vitamin. Finally, the agency is aware that these problems vary depending upon such factors as whether the food product is a liquid or solid.

Based on these factors, FDA concludes that it cannot establish an upper limit on the amount of vitamin D that can be added in the processing of a particular food. Food manufacturers must determine for their own products, on a case-by-case basis, the amount of vitamin D that will be lost in the processing and in the storage of a particular food before it is delivered for consumer purchase. For the use of vitamin D to be GRAS under the

regulation that FDA is adopting, however, the amount of the vitamin that remains in the food at the time it is available for consumer purchase must be within the specific limitation that FDA has established for the applicable food category.

FDA is therefore not making any change in the regulation based upon this issue.

3. Four comments requested that the proposed regulations be modified to permit the interchangeable use of vitamin D₂ and vitamin D₃ in the food categories listed for each of these ingredients. The comments stated that it has been common industry practice to use either vitamin D₂ or vitamin D₃ as a source of vitamin D in foods, and that there is no safety reason to permit only vitamin D₂ for use in breakfast cereals and grain products, as provided in the proposal.

FDA agrees that at current consumption levels, there is no significant difference in the safety of vitamin D₂ and vitamin D₃, and that in most food applications, these substances may be used interchangeably as sources of vitamin D. The agency has therefore modified § 184.1950 (21 CFR 184.1950) to permit the interchangeable use of vitamin D₂ and vitamin D₃ under the specific conditions established in this regulation.

To make clear that crystalline vitamin D₂, crystalline vitamin D₃, and the less pure resinous forms of these vitamins may be used interchangeably in food, the agency has decided not to issue separate regulations affirming the GRAS status of vitamin D₂ and vitamin D₃. Instead, the agency is issuing a single regulation that affirms the GRAS status of vitamin D and that makes clear that crystalline vitamin D₂, crystalline vitamin D₃, vitamin D₂ resin, or vitamin D₃ resin may all be used as a food source of the vitamin within the specific conditions of use established in the regulation.

4. Two comments asserted that the proposal was incomplete regarding the processing and method of manufacture for vitamin D₃. The comments stated that vitamin D₃ is not only obtained from fish liver oil but is also produced from cholesterol obtained from fish oils, wool grease, lanolin, and the brains and spinal cords of animals. According to the comments, the cholesterol is chemically converted to 7-dehydrocholesterol, which in turn is irradiated with ultraviolet light to produce vitamin D₃ (cholecalciferol). One of these comments objected to the inclusion of any methods of manufacture for either vitamin D₂ or vitamin D₃ in the

GRAS affirmation regulation. The comment argued that the inclusion of manufacturing methods in the regulation will inhibit development of new methods.

FDA agrees that vitamin D₃ may be safely produced by the method of manufacture described in these comments, and the agency has therefore modified the regulation to incorporate this method. However, the agency does not agree that the regulation should not contain a description of any methods of manufacture. FDA has historically included methods of manufacture in its GRAS affirmation regulations.

In the Federal Register of December 7, 1976 (41 FR 53600), the agency made clear that the descriptions of methods of manufacture included in GRAS affirmation regulations are not intended to inhibit the development of new methods or to inhibit modifications in the methods of manufacture that are included in the regulations. FDA includes methods of manufacture in GRAS affirmation regulations to define as thoroughly as possible the composition of the ingredient that has been evaluated and affirmed as GRAS (21 CFR 184.1(a)) and to differentiate it from other possible versions of the ingredient that the agency has not affirmed as GRAS.

Manufacturers who modify a method or develop a new method of manufacture will be able to determine, by comparing the new method with the methods set forth in the regulation, whether the new method introduces impurities that may require a new evaluation of the safety of the substance. Methods of manufacture also supplement the food-grade specifications for an ingredient because inclusion of these methods helps to identify potential impurities in GRAS ingredients that may not be included in their food-grade specifications.

A description of manufacturing methods is necessary in this regulation because specifications have not yet been established for the resin forms of vitamin D₂ and vitamin D₃.

5. Two comments objected to the adoption of specific limitations on the use of vitamin D in foods. The comments stated that food manufacturers have acted responsibly in adding vitamin D to foods, and that FDA should continue to grant flexibility to food manufacturers in using vitamin D in foods. One of the comments also stated that it is unnecessarily burdensome to petition FDA to adopt new food uses for vitamin D.

FDA disagrees with these comments. The agency's GRAS affirmation

proposal on vitamin D stated that both FDA and the Select Committee have concluded that " * * * it is not possible to determine, without additional data, whether a significant increase in consumption of vitamin D2 and vitamin D3 would constitute a dietary hazard." This conclusion makes clear the agency's and the Select Committee's concern about expanded food uses of vitamin D. The basis for this concern is the small margin of safety between the total amount of vitamin D that is added to food and the amount of the vitamin that can produce toxic effects in humans.

FDA finds that specific limitations on the use of vitamin D in food are necessary to assure that total dietary exposure to this ingredient does not increase significantly. In addition, the agency concludes that the concern about the margin of safety for this ingredient establishes an appropriate basis for requiring food manufacturers to petition the agency for GRAS affirmation or food additive approval for new food uses of this vitamin, and that adoption of such uses should not be left only to the judgment of individual food manufacturers. FDA also points out that its decision to adopt specific limitations for the use of vitamin D in food is consistent with its adoption of specific limitations for other GRAS ingredients about which the agency has had similar concerns.

FDA also does not agree that petitioning the agency for new uses of vitamin D is unnecessarily burdensome. As indicated above, the agency concludes that a petition for new food uses of vitamin D is necessary so that the agency can assure that total dietary exposure will not increase significantly, and that any increase in exposure is safe.

6. One comment, from a company that manufactures breakfast cereals, requested that FDA affirm the GRAS status of breakfast cereals that contain 100 percent of the U.S. Recommended Daily Allowance (U.S. RDA) per 1 ounce serving (1,410 International Units (IU) per 100 grams (g)). The comment stated that there is no evidence that vitamin D is unsafe when used at this level. The comment also stated that in 1981, the company reduced the amount of vitamin D in two of its breakfast cereals from 100 percent of the U.S. RDA to 50 percent of the U.S. RDA per ounce.

FDA is not affirming that the use of vitamin D at the suggested levels in breakfast cereals is GRAS. As indicated in the proposal, FDA estimates that average lifetime exposure to vitamin D, based upon those uses included in the proposal, is 200 to 300 IU per day for

individuals between the ages of 2 and 65 years. This average lifetime estimate includes 25 IU per day for breakfast cereals. On the other hand, it is apparent that many individuals consume multiple servings of breakfast cereal fortified with vitamin D, and that their consumption exceeds the average intake to a significant degree. Data from the Nationwide Food Consumption Survey (Ref. 2) demonstrate that some individuals in all age groups beginning at 9 years of age or older consume more than 100 g of ready-to-eat cereal per day. For these individuals, the risk posed by increases in vitamin D levels in breakfast cereals to 705 or 1,410 IU per 100 g, as requested in this comment, is unknown. The agency therefore concludes that it cannot affirm the GRAS status of these levels of use of vitamin D without additional data demonstrating that such uses are safe.

The agency further concludes that it is the responsibility of this cereal manufacturer to demonstrate the safety of its products, and that the comment is in error in its assertion that FDA should affirm the GRAS status of these uses of vitamin D because there is no evidence to demonstrate that they are unsafe. For these reasons, the agency is maintaining the limitation of 350 IU per 100 g as the maximum level of use for vitamin D in breakfast cereals.

The agency also points out in response to the comment that cereal products that contain 705 IU vitamin D per 100 g (equivalent to 50 percent of the U.S. RDA) are foods for special dietary use, as defined in 21 CFR 101.9(a)(2). FDA does not consider these products to be conventional foods, and therefore they are not covered by this regulation.

7. Five comments requested that the proposal be modified to include certain special dietary foods and enteral formulas. The comments urged that the proposal be expanded to include such products as formulated liquid diets, meal replacements, dry diet mixes, fortified drinks and mixes, and diet bars. Two of these comments requested that the maximum level for vitamin D in these special dietary foods and enteral formulas be set at 250 IU per 100 grams, as served. One of these comments submitted food labels from some of the products.

FDA has inspected the food labels that were submitted and has carefully considered whether it has sufficient information on these products to evaluate the safety of these uses of vitamin D. The agency finds that many of the products referred to in the comments, such as weight control milk beverages and flavorings for milk, were included in the proposal under the food

category milk products, as described in 21 CFR 170.3(n)(31). The level of use of vitamin D in these products is within the maximum level of use included in § 184.1450(c)(1).

However, the agency finds that enteral formulas and the other products discussed in these comments are not included in the 43 food categories identified as conventional foods in 21 CFR 170.3(n), and that the use of vitamin D in these types of products was not evaluated by the Select Committee. The agency further finds that the comments do not provide appropriate information on the amount of vitamin D contained in these products, dietary serving (portion) size for these products, or the amount of these products that will be ingested daily. The agency cannot evaluate the safety of the use of vitamin D in these products without this information. FDA is, therefore, not including these uses in this final rule.

If manufacturers of special dietary foods and enteral formulas wish to have the GRAS affirmation regulation for vitamin D amended to include use of vitamin D in their products, they should submit, in accordance with 21 CFR 170.30, a GRAS affirmation petition providing specific information on the amount of vitamin D that is contained in their products and the amount of the product that will be ingested daily.

Because no food-grade specifications exist for vitamin D₂ and vitamin D₃ resins at the present time, the agency will work with the Committee on Food Chemicals Codex of the National Academy of Sciences to develop acceptable specifications for these resins. If acceptable specifications are developed, the agency will incorporate them into this regulation at a later date. Until specifications are developed, FDA has determined that the public health will be adequately protected if vitamin D resins comply with their descriptions in the regulation and are of a purity suitable for their intended use in food (21 CFR 184.1(b)).

The agency has made editorial changes in § 184.1950(a) (1) and (2) to reflect the fact that vitamin D₂ and vitamin D₃ are made by ultraviolet irradiation of provitamin D₂ and provitamin D₃.

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 findings 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).

References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Hirsh, A.L., "Vitamin D," In "Encyclopedia of Chemical Technology," Kirk-Othmer, 3d ed., John Wiley and Sons, Inc., New York, 1984, Vol. 24, pp. 186-216.
2. "Foods Commonly Eaten by Individuals: Amount per Day and per Eating Occasion," E.M. Pao, K.H. Fleming, P.M. Guenther, S.J. Mickle, p. 200, March 1982. (Available from Superintendent of Documents, Government Printing Office, Washington, DC 20402, as S/N 001-000-04267-0.)

List of Subjects

21 CFR Part 182

Generally recognized as safe (GRAS) food ingredients; Spices and flavorings.

21 CFR Part 184

Direct food ingredients; Food ingredients; Generally recognized as safe (GRAS) food ingredients; Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for Part 182 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10.

2. Part 182 is amended:

§ 182.8950 [Removed]

a. By removing § 182.8950 Vitamin D₂.

§ 182.8953 [Removed]

b. By removing § 182.8953 Vitamin D₃.

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

3. The authority citation for Part 184 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10.

4. Part 184 is amended by adding new § 184.1950 to read as follows:

§ 184.1950 Vitamin D.

(a) Vitamin D is added to food as the following food ingredients:

(1) Crystalline vitamin D₂ (C₂₈H₄₄O, CAS Reg. No. 50-14-6), also known as ergocalciferol, is the chemical 9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatrien-3-ol. The ingredient is produced by ultraviolet irradiation of ergosterol isolated from yeast and related fungi and is purified by crystallization.

(2) Crystalline vitamin D₃ (C₂₇H₄₄O, CAS Reg. No. 67-97-0), also known as cholecalciferol, is the chemical 9,10-seco(5Z,7E)-5,7,10(19)-cholestatrien-3-ol. Vitamin D₃ occurs in, and is isolated from, fish liver oils. It is also manufactured by ultraviolet irradiation of 7-dehydrocholesterol produced from cholesterol. It is purified by crystallization. Vitamin D₃ is the vitamin D form that is produced endogenously in humans through sunlight activation of 7-dehydrocholesterol in the skin.

3. Vitamin D₂ resin and vitamin D₃ resin are the concentrated forms of irradiated ergosterol (D₂) and irradiated 7-dehydrocholesterol (D₃) that are separated from the reacting materials in paragraphs (a) (1) and (2) of this section. The resulting products are sold as food sources of vitamin D without further purification.

(b) Vitamin D₂ and vitamin D₃ as crystals meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 344 and 345, 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. FDA is developing food-grade specifications for vitamin D₂ resin and vitamin D₃ resin in cooperation with the National Academy of Sciences. In the interim, these resins must be of a purity suitable for their intended use.

(c)(1) In accordance with § 184.1(b)(2), the ingredients are used in food as the sole source of added vitamin D only within the following specific limitations:

Category of food	Maximum levels in food (as served)	Functional use
Breakfast cereals, § 170.3(n)(4) of this chapter.	350 (IU/100 grams).	Nutrient supplement, § 170.3(c)(20) of this chapter.
Grain products and pastas, § 170.3(n)(23) of this chapter.	90 (IU/100 grams).	Do.
Milk, § 170.3(n)(30) of this chapter.	42 (IU/100 grams).	Do.
Milk products, § 170.3(n)(31) of this chapter.	89 (IU/100 grams).	Do.

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

(3) Vitamin D may be used in margarine in accordance with § 166.110 of this chapter.

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

Effective date. This regulation is effective August 23, 1985.

Dated: July 2, 1985.

Joseph P. Hile,

Acting Commissioner of Food and Drugs.

[FR Doc. 85-17525 Filed 7-23-85; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs Not Subject to Certification; Furazolidone Aerosol Powder

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

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the correct specifications for a previously approved furazolidone aerosol powder product.

EFFECTIVE DATE: July 24, 1985.

FOR FURTHER INFORMATION CONTACT:

Frank G. Pugliese, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4500.

SUPPLEMENTARY INFORMATION: On February 3, 1986, FDA approved, by letter, Norwich-Eaton's NADA 32-319 for a 4 percent furazolidone aerosol spray for cattle for treating bacterial eye infections and for dogs and horses for preventing or treating bacterial infections of superficial wounds. By letter of October 31, 1979, FDA approved a 10 percent formulation to replace the 4 percent formulation. FDA codified the approval in 21 CFR 524.1005 in the Federal Register of July 25, 1980 (45 FR 49543). However, the regulation failed to reflect the amended specification for the Norwich-Eaton product. The sponsorship of NADA 32-319 was subsequently transferred to SmithKline Animal Health Products (see 48 FR 28983; June 24, 1983). This document revises 21 CFR 524.1005 to reflect the currently approved specifications for that products.

List of Subjects in 21 CFR Part 524

Animal drugs, topical.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR Part 524 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

2. Section 524.1005 is amended by revising paragraphs (a) and (b) to read as follows:

§ 524.1005 Furazolidone aerosol powder.

(a) *Specifications.* The product contains either 4 or 10 percent furazolidone in inert dispersing agent and propellant.

(b) *Sponsors.* (1) See No. 000007 in § 510.600(c) of this chapter for use of the 10 percent product as in paragraph (c)(2) (i) through (iii) of this section.

(2) See No. 017135 for use of the 4 percent product as in paragraph (c)(2)(iv) of this section.

Dated: July 18, 1985.

Marvin A. Norcross,

Acting Associate Director for Scientific Evaluation.

[FR Doc. 85-17534 Filed 7-23-85; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 801

[Docket No. 84N-0148]

Medical Devices; Hearing Aids; Technical Data Amendments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the technical data sections of the agency's regulation on hearing aid devices' professional and patient labeling to incorporate by reference an updated standard.

DATES: Effective January 20, 1986. The Director of the Office of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 801.420 on January 20, 1986.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 14, 1984 (49 FR 32402), FDA proposed to amend its hearing aid regulation (21 CFR 801.420) to refer to the American National Standards Institute's (ANSI) updated ANSI S3.22-1982 (ASA 7-1982), "American National Standard Specification of Hearing Aid Characteristics." This updated standard is a modified version of ANSI S3.22-1976 (ASA 7-1976) which is incorporated by reference into § 801.420(c)(4) (approved by the Office of Management and Budget under control number 0910-0171).

The final rule amends § 801.420(c)(4) by incorporating by reference into the regulation the updated standard, ANSI S3.22-1982 (ASA 7-1982). The final rule also requires that the User Instructional Brochure or other labeling accompanying the hearing aid include, as a minimum, the appropriate values or information for the technical data specified in § 801.420(c)(4)(i) through (xii), as those elements are defined or used in ANSI S3.22-1982 (ASA 7-1982). The final rule does not affect any other provision of § 801.420.

Comments

FDA received two comments on the proposed rule. One comment supported FDA's updating of § 801.420(c), stating that the revisions reflect timely and important scientific advances in the measurement and fitting of hearing aids. Another comment supported the proposed revisions, but argued that FDA's assessment of the economic effects of the proposed rule underestimated the cost of complying with the revisions. In the proposed rule, the agency determined that maximum cost of meeting the revised regulation for a manufacturer or distributor would be \$1,000 (see 49 FR 32402). The comment claimed that \$2,600 is a more realistic cost of compliance. The comment argued that compliance with the revision would require purchasing new program modules and reprogramming presently utilized testing equipment. The comment also argued that incorporating the revised technical test data into the hearing aid labeling would require costly, burdensome reprinting of labeling. For these reasons, the comment suggested that FDA could better ensure an inexpensive transition by providing a 360-day delayed effective date for the final rule, rather than the 180-day delayed effective date prescribed by FDA in the preamble to the proposed rule.

FDA disagrees with the latter comment. FDA has carefully reevaluated its assessment of the economic effect of the rule but continues to believe that only minor changes in testing procedures will be necessary. Essentially, all testing changes can be accomplished satisfactorily with existing equipment. Only § 801.420(c)(4)(ix), which establishes a tolerance level to minimize errors in measuring battery current drain in the hearing aid, might obligate persons that develop the brochure or labeling to purchase new testing equipment. As ANSI S3.22-1982 applies this section, a worst-case condition would require the developer to purchase a millimeter, an inexpensive accessory costing about \$50. Because manufacturers will perform the testing and develop the user instructional brochures, FDA believes that it is highly unlikely that any distributor will need to purchase new equipment.

Additionally, FDA disagrees that any costly revisions of the User Instructional Brochure or of other labeling are necessary. Therefore, FDA concludes that a 6-month delayed effective date is adequate time for manufacturers to revise the User Instructional Brochure,