

airspace necessary for that mission. There is no change to the lateral boundaries, times of use, or activities conducted in R-3702A and R-3702B. R-3702C, which overlies R-3702B, is unaffected by this amendment. This amendment affects only the internal subdivision of existing restricted areas and enhances efficient airspace utilization. Therefore, I find that notice and public procedure under 5 U.S.C. 553(b) are unnecessary because this action is a minor amendment in which the public would not be particularly interested. Section 73.37 of part 73 of the Federal Aviation Regulations was republished in FAA Order 7400.8C dated June 29, 1995.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This action amends the internal subdivision of existing restricted airspace and does not affect the lateral boundaries, times of use, or activities conducted within the restricted airspace. As a result, there are no changes to air traffic control procedures or routes. Therefore, this action is not subject to environmental assessments and procedures under FAA Order 1050.1D, "Policies and Procedures for Considering Environmental Impacts," and the National Environmental Policy Act.

List of Subjects in 14 CFR Part 73

Airspace, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 14 CFR 11.69.

§ 73.37 [Amended]

2. R-3702A Fort Campbell, KY [Amended].

By removing the current "Designated altitudes. Surface to 16,000 feet MSL" and substituting the following:

"Designated altitudes. Surface to 6,000 feet MSL."

3. R-3702B Fort Campbell, KY [Amended].

By removing the current "Designated altitudes. 16,000 feet MSL and including FL 220" and substituting the following:

"Designated altitudes. 6,000 feet MSL to FL 220."

Issued in Washington, DC, on September 8, 1995.

Harold W. Becker,

Manager, Airspace—Rules and Aeronautical Information Division.

[FR Doc. 95-23429 Filed 9-20-95; 8:45 am]

BILLING CODE 4910-13-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Requirements for the Special Packaging of Household Substances; Correction

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule; correction.

SUMMARY: The CPSC corrects the amendments to its requirements under the Poison Prevention Packaging Act of 1970 ("PPPA") for child-resistant packaging which appeared in the Federal Register on July 21, 1995 (60 FR 37710). The correction specifies the effective date for the amendment to 16 CFR 1700.14 (see 60 FR at 37739, col. 2).

DATES: The amendment to 16 CFR 1700.14 will become effective July 22, 1996.

FOR FURTHER INFORMATION CONTACT: Michael Bogumill, Division of Regulatory Management, Directorate for Compliance, Consumer Product Safety Commission, Washington, DC 20207; telephone (301)504-0400, ext. 1368.

Dated: September 15, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 95-23351 Filed 9-20-95; 8:45 am]

BILLING CODE 6355-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 89G-0316]

Maltodextrin Derived From Potato Starch; Affirmation of GRAS Status as Direct Human Food Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that maltodextrin derived from potato starch is generally recognized as safe (GRAS) for use as a direct human food ingredient. This action is in response to a petition filed by AVEBE America, Inc. **DATES:** Effective September 21, 1995. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication listed in 21 CFR 184.1444, effective September 21, 1995.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3071.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the procedures described in § 170.35 (21 CFR 170.35), AVEBE America, Inc., Princeton Corporate Center, 4 Independence Way, Princeton, NJ 08450, submitted a petition (GRASP 9G0353) proposing that maltodextrin derived from potato starch be affirmed as GRAS for use as a direct food ingredient.

FDA published a notice of filing of this petition in the Federal Register of August 31, 1989 (54 FR 36053), and gave interested parties an opportunity to submit comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. FDA received no comments in response to that notice.

II. Standards for GRAS Affirmation

Pursuant to § 170.30 (21 CFR 170.30), general recognition of safety of food ingredients may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of food substances. The basis of such views may be either: (1) Scientific procedures, or (2) in the case of a substance used in food prior to January

1, 1958, through experience based on common use in food. General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation, and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)). General recognition of safety through experience based on common use of a substance in food prior to January 1, 1958, may be determined without the quantity or quality of scientific evidence required for approval of a food additive regulation, and ordinarily is to be based upon generally available data and information (§ 170.30(c)(1)).

III. Safety Evaluation

The petition by AVEBE America, Inc., argues that experience based on common use in food prior to 1958 establishes that maltodextrin derived from potato starch is GRAS. The petition contains documentation that maltodextrin derived from potato starch was used in infant formula prior to 1958. However, based upon an evaluation of the evidence presented, the agency does not agree that the information in the petition establishes that maltodextrin derived from potato starch was in common use in food as defined in § 170.3(f) (21 CFR 170.3(f)), before 1958. However, the agency does conclude that the information presented in the petition, together with other available information, supports a determination that use of maltodextrin derived from potato starch is GRAS based upon scientific procedures. Data in the petition, along with other information in the agency's files, demonstrate that potato starch is chemically equivalent to corn starch. Additionally, the hydrolysis products made from these starch sources, including maltodextrins, are essentially equivalent. Thus, maltodextrin derived from potato starch is equivalent in all material respects to maltodextrin derived from corn starch, which has been affirmed as GRAS (§ 184.1444 (21 CFR 184.1444)).

1. Evidence of Uses in Food Prior to 1958

The agency has reviewed the information submitted by the petitioner to support its assertion that maltodextrin derived from potato starch was in common use in food prior to 1958 in Europe. "Common use in food" means a substantial history of consumption of a substance for food use

by a significant number of consumers (§ 170.3(f)).

Information included in the petition documents that maltodextrin derived from potato starch was first sold for use by infants and children in Europe in 1935 (Ref. 1). One such product was produced by enzyme hydrolysis of potato starch as described by a 1951 brochure (Ref. 2), which is included in the petition. Additionally, in 1935, a British patent specification was issued entitled "Improved Process for the Production of a Sugar Preparation from Starch, and for Manufacturing a Milk Suitable for Infants" (Ref. 3). The patent specifically mentions potato starch as one of the alternate starting materials (the others being starch from wheat, oats, or other cereals). The benefits of maltodextrin and its uses as an ingredient in milk fed to infants were also described in an article printed in Holland in 1942 (Ref. 4). In 1947, Campagne (Ref. 5) published a scientific explanation of the function of maltodextrin-based products in the infant diet. The diet described contained maltodextrin derived from potato starch.

The agency concludes that information presented in the petition demonstrates that maltodextrin derived from potato starch was used in infant formula prior to 1958. The agency does not agree, however, that the evidence supports a finding of "common" use in food because the totality of information shows that maltodextrin was used solely as an ingredient in infant formulas. No evidence was presented to show that the population at large used maltodextrin derived from potato starch in the food supply. While the agency does not believe that maltodextrin derived from potato starch was commonly used in food prior to 1958, its historical use in infant formulas is evidence of general recognition of safety because it represents documented experience in a particularly sensitive segment of the population, namely, human infants.

2. Evidence of Chemical Equivalency of Potato Starch to Corn Starch

Starch is the reserve carbohydrate in tubers, such as potatoes; in grains, such as rice, corn, or barley; in seeds; and in many fruits. As early as 1811, scientists had determined that food starches from various plant sources were essentially equivalent (Ref. 6). All food starches, regardless of the plant source, are composed of chemically equivalent polymeric forms of alpha-bond-linked glucose units (Ref. 7). Starch consists of polymers of amylose and amylopectin polysaccharides (Refs. 6 and 8). The relative proportions of amylose and

amylopectin are characteristic of the plant species from which the starch is derived. Corn starch, for example, typically contains about 27 percent by weight of amylose and 73 percent by weight of amylopectin, whereas potato starch typically contains 22 percent amylose by weight and 78 percent amylopectin by weight (Refs. 8 and 9).

Because food starches derived from different plant sources are equivalent in all material respects, FDA's food additive regulation for modified food starch (21 CFR 172.892) does not specify that any particular source of food starch be used to manufacture the additive. (According to the petitioner, potato starch is being used to make modified food starch.) In the Federal Register of April 1, 1985 (50 FR 12821) (Ref. 10), FDA published a proposal to find that the use of potato starch (as well as several other starches) in food is GRAS. FDA has not issued a final rule in that rulemaking. In addition, the Committee on Food Chemicals Codex of the National Academy of Sciences has published a monograph on maltodextrin stating that it may be obtained from any edible starch (Ref. 11). Like FDA's food additive regulation for modified food starch, the monograph does not require that the starch be derived from any particular plant source.

Producing maltodextrin by the degradation of starch requires the formation of intermediate breakdown products called dextrins, which result from the partial hydrolysis of starch with mineral acids or amylase. Further hydrolysis of the starch dextrins yields maltodextrins.

Dextrins are affirmed as GRAS under 21 CFR 184.1277 and can be prepared by partially hydrolyzing the starch in corn, potato, arrowroot, wheat, rice, or other starch sources. It has been common industrial practice to use a wide variety of starch sources in manufacturing commercial dextrin products (Refs. 7 and 12). During digestion, acid and enzymatic processes in the stomach convert the starch macromolecules to smaller molecules such as maltodextrin, and eventually to glucose. This digestion process is similar to the commercial process used to produce glucose and fructose, which are GRAS starch-based sweeteners presently used in foods (Ref. 7). (See corn sugar, 21 CFR 184.1857; corn syrup, 21 CFR 184.1865; and high fructose corn syrup, 21 CFR 182.1866.)

Starch hydrolysates below 20 dextrose equivalents (D.E.) are classified as maltodextrins (Refs. 13 and 14). Specifications for maltodextrins are listed in the Food Chemicals Codex, 3d ed., 3d supp. (1992) (Ref. 11).

Equivalent maltodextrin products result from equivalent hydrolysis of edible starch sources (Ref. 15). Since corn starch and potato starch are essentially equivalent, the products of hydrolysis, from simple glucose molecules to more complex starch hydrolysates, such as dextrans and maltodextrins, are essentially equivalent in terms of chemical, physical, and organoleptic properties.

3. Corroborative Evidence of Chemical Equivalency

The petitioner has submitted data to demonstrate the equivalency of maltodextrin derived from corn and potato starches, based upon their dextrose equivalents (D.E.) (Refs. 16, 17, and 18). Hydrolysis of corn starch or potato starch under similar conditions produces a maltodextrin product with a D.E. of less than 20. The range of carbohydrate composition (glucose, maltose, maltotriose, and polysaccharides larger than maltotriose) in maltodextrins derived from potato starch (Ref. 16) is virtually identical to that for maltodextrins derived from corn starch (Refs. 15, and 16) at a D.E. of less than 20. Also, based upon information submitted by the petitioner and on information available in current scientific literature, FDA believes that potato starch may be considered chemically similar to corn starch in regard to amylose and amylopectin content (Refs. 6, 8, 9, 19, and 20).

4. Proposed Use in Food

Information supplied by the petitioner evidences that maltodextrin derived from potato starch will be used as a replacement for maltodextrin derived from corn starch in the same foods, at essentially the same levels, and for the same technical effects that maltodextrin derived from corn starch is now used (Ref. 21). The petitioner states that maltodextrins are currently used in a wide range of processed and convenience foods, principally as a filler or carrier for flavorings and intensive sweeteners and as a sweetness reducer or texture modifier. Because maltodextrin derived from potato starch will be used as a replacement for maltodextrin derived from corn starch, the consumer exposure to maltodextrin is not expected to increase.

5. General Recognition of Safety

The agency has determined, based on the published literature, that the safety of maltodextrin derived from potato starch is generally recognized by food safety experts. Foremost in the support of safety is published information that shows that corn starch and potato starch

are essentially equivalent, and therefore maltodextrin derived from potato starch is equivalent to the maltodextrin derived from corn starch. Thus, maltodextrin derived from potato starch presents no more of a safety concern than maltodextrin derived from corn starch, which has been affirmed as GRAS.

Additionally, based on published information in the petition, maltodextrin derived from potato starch was extensively used in infant formulas for over 20 years prior to 1958 (Refs. 1, 2, 3, 4, and 5), and the agency is not aware of any reports of injuries or health risks resulting from such use.

As a consequence of conclusions regarding safety, many countries, including those represented by the European Starch Association (Ref. 14), recognize "food starches," including potato starch, as a suitable raw material for maltodextrin production. Furthermore, the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Committee on Food Additives (JECFA) (Refs. 22 and 23) recognizes maltodextrin as an intermediate product in the production of enzyme-treated starches, a process that JECFA has stated results in the production of normal (meaning safe) food constituents. JECFA does not restrict the sources of food starches used in the production of products such as maltodextrins. JECFA also does not require toxicological testing of products such as maltodextrins that are produced from enzyme-treated starches. Finally, as noted previously, the agency has proposed to find that potato starch is GRAS.

The agency concurs that maltodextrin derived from potato starch is chemically and functionally equivalent to maltodextrin derived from corn starch (Ref. 15). No increase in exposure to maltodextrin would be expected due to the substitution of one source for the other. Because potato starch is already a significant constituent of the typical diet (Ref. 24), the agency does not believe that there will be any impurities in potato-derived maltodextrin that would cause a safety concern (Refs. 15 and 25).

6. Specifications

The agency has reviewed the specifications for maltodextrin published in the Food Chemicals Codex, 3d ed., 3d supp., p. 125, and finds that they are acceptable for maltodextrin derived from edible starches. Therefore, the agency is adopting the specifications for maltodextrin derived from edible starches for maltodextrin derived from

potato starch. Published elsewhere in this issue of the Federal Register is a notice of proposed rulemaking to adopt these specifications for maltodextrin derived from corn starch.

IV. Conclusions

The agency has evaluated the information in the petition, along with other available data, and has reached the following conclusions:

(1) Potato starch is chemically equivalent to corn starch.

(2) Maltodextrin derived from potato starch is chemically equivalent to maltodextrin derived from corn starch, which is currently affirmed as GRAS for food use without restriction under § 184.1444.

(3) Maltodextrin derived from potato starch has been used in infant formula prior to 1958 with no reported adverse effects.

(4) When maltodextrin derived from potato starch is manufactured as specified in § 184.1444, there is general recognition among qualified experts that its use in food is safe.

Based upon the evaluation of published information, corroborated by unpublished data and information, i.e., based upon scientific procedures (§ 170.30(b)), the agency also concludes that maltodextrin derived from potato starch is GRAS for use as a replacement for maltodextrin derived from corn starch. Therefore, the agency is affirming that maltodextrin derived from potato starch is GRAS when used in accordance with good manufacturing practice (21 CFR 184.1(b)(1)).

V. Environmental Impact

The agency has determined under 21 CFR 25.24(b)(7) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive

Order. In addition, because the final rule is not a significant regulatory action as defined by the Executive Order and therefore is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule requires no change in the current industry practice concerning the manufacture and use of this ingredient, the cost of compliance with this regulation is zero, and the potential benefits of the rule include the wider use of this substance to achieve the intended technical effects, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. References

The following references have been placed on display at the Dockets Management Branch (address above) and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

1. "Potato-Derived Maltodextrins for Infants and Toddlers," W. A. Scholten's Chemical Factories' Brochure, Avebe Foxhol, 1941.
2. "The Double Triangle," 3d Annual, no. 36, W. A. Scholten's Chemical and Potato Starch Factories and Meihuizen Boon's Factories, Holland, pp. 1-10, June 21, 1951.
3. Patent Specification no. 435,034, "Improved Process for the Production of a Sugar Preparation from Starch, and for Manufacturing a Milk Suitable for Infants," United Kingdom, 1935.
4. Kuyk, P. G., and K. Schots, "For Infant and Toddler," in "The Book of Foods and Allied Products and of Substitutes During Wartime," 1942.
5. Campagne, J. vL., "Feeding and Nutritional Derangements of Infants," Scientific Publisher of the Amsterdam Book and Newspaper Society, pp. 33, and 126-127, 1947.
6. Wolfram, M. L., and H. El Khadem, "Chemical Evidence for the Structure of Starch" in "Starch: Chemistry and Technology," R. L. Whistler, and E. F. Paschall, eds. Academic Press, Inc., New York, pp. 251-278, 1965.
7. Schenck, F. W., and R. E. Hebeda, "Starch Hydrolysis Products: An Introduction and History" in *Starch Hydrolysis Products, Worldwide Technology, Production, and Applications*, F. W. Schenck, and R. E. Hebeda, eds., VCH Publishers, Inc., New York, pp. 1-21, 1992.
8. "Evaluation of the Health Aspects of Starches and Modified Starches as Food Ingredients," Life Sciences Research Office, Federation of American Societies for Experimental Biology, 1979.
9. Young, A. H., "Fractionation of Starch" in "Starch," 2d ed., R. L. Whistler, and E. F. Paschall, eds., Academic Press, Inc., New York, pp. 249-283, 1984.

10. "Unmodified Food Starches and Acid-Modified Starches; Proposed Affirmation of GRAS Status as Direct and Indirect Human Food Ingredients," 50 FR 12821, April 1, 1985.

11. Food Chemicals Codex, 3d ed., 3d supp., p. 125, 1992.

12. Evans, R. B., and O. B. Wurzburg, "Production and Use of Starch Dextrins" in *Starch: Chemistry and Technology*, vol. 2, R. L. Whistler and E. F. Paschall, eds., Academic Press, Inc., New York, pp. 253-278, 1967.

13. "Food Additives and Contaminants Committee Report on Modified Starches," United Kingdom Ministry of Agriculture, Fisheries and Food, FAC/REP/31, Her Majesty's Stationery Office, London, p. 5, 1980.

14. "Definition of Maltodextrin," European Starch Associations, Circular Letter Stex 4/88, February 1988.

15. Memorandum dated September 11, 1989, from the Food and Color Additives Review Section, FDA to the Direct Additives Branch, FDA, "Maltodextrin from Potatoes."

16. "Maltodextrins," Technical Bulletin No. 5.10.20.119EF, AVEBE Veenddam-Holland, April 1987.

17. Letter plus attachments, in response to a letter of July 13, 1978, from George W. Irving of the Select Committee on GRAS Substances, Federation of American Societies for Experimental Biology, Bethesda, MD, to Corbin Miles, Food and Drug Administration, Washington, DC, pp. 1-4, 1978.

18. "Maltodextrins and Corn Syrup Solids," Technical Bulletin, A. E. Staley Manufacturing Co., Decatur, IL, Bulletin, July 1987.

19. Zuber, M. S., "Genic Control of Starch Development" in "Starch: Chemistry and Technology," R. L. Whistler, and E. F. Paschall, eds., Academic Press, Inc., New York, pp. 43-62, 1965.

20. Whistler, R. L., and J. R. Daniel, "Starch," in *Kirk-Othmer's Encyclopedia of Chemical Technology*, 3d ed., vol. 21, J. Brown, C. I. Eastman, C. Galojuch, A. Klingsberg, and M. Wainwright, eds., pp. 492-496, 1983.

21. "Maltodextrin; Proposed Affirmation of GRAS Status as Direct Human Food Ingredient," 47 FR 36443, August 20, 1982.

22. "Specifications for the Identity and Purity of Food Additives and Their Toxicological Evaluation," FAO Nutrition Meetings Report Series, no. 46 and WHO Technical Report Series, no. 445, pp. 13-14, 1970.

23. "Toxicological Evaluation of Some Food Colours, Emulsifiers, Stabilizers, Anti-Caking Agents, and Certain Other Substances," FAO Nutrition Meetings Report Series, no. 46A, p. 62 and WHO/FOOD ADD./70.36, 1970.

24. "Potato Facts," Economics Research Service, U.S. Department of Agriculture, Fall/Winter, 1988/89.

25. Memorandum dated October 17, 1989, from the Additives Evaluation Branch, FDA, to the Direct Additives Branch, FDA, "Maltodextrin derived from potatoes."

List of Subjects in 21 CFR Part 184

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 and redelegated to the Director of the Center for Food Safety and Applied Nutrition, 21 CFR part 184 is amended as follows:

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

1. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. Section 184.1444 is amended by revising the second sentence in paragraph (a) and by revising paragraph (b) to read as follows:

§ 184.1444 Maltodextrin.

(a) * * *. It is prepared as a white powder or concentrated solution by partial hydrolysis of corn starch or potato starch with safe and suitable acids and enzymes.

(b)(1) Maltodextrin derived from corn starch must be of a purity suitable for its intended use.

(2) Maltodextrin derived from potato starch meets the specifications of the Food Chemicals Codex, 3d ed., 3d supp. (1992), p. 125, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capital St. NW., suite 700, Washington, DC 20408, or at the Division of Petition Control (HFS-217), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

* * * * *

Dated: September 6, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95-23352 Filed 9-20-95; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Gentamicin Sulfate Intrauterine Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the