

115°22'00"W; to lat. 48°45'00"N, long. 115°50'00"W, to the point of beginning.

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Issued in Seattle, Washington, on July 23, 1996.

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Acting Assistant Manager, Air Traffic
Division, Northwest Mountain Region.

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Poison Prevention Packaging

CFR Correction

In Title 16 of the Code of Federal Regulations, parts 1000 to End, revised as of January 1, 1996, on page 685, in § 1700.14, paragraph (a)(25) was inadvertently omitted. The omitted text should read as follows:

§ 1700.14 Substances requiring special packaging.

(a) * * *

(25) *Naproxen*. Naproxen preparations for human use and containing the equivalent of 250 mg or more of naproxen in a single retail package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

BILLING CODE 1505-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 73 and 184

[Docket No. 93G-0017]

Direct Food Substances Affirmed as Generally Recognized as Safe; Listing of Color Additives Exempt From Certification; Ferrous Lactate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm that ferrous lactate is generally recognized as safe (GRAS) as a color fixative on ripe olives. The agency is adding this use of ferrous lactate as a color fixative on ripe olives to the other uses for ferrous lactate. The agency is also amending this regulation to permit additional methods of synthesis for ferrous lactate. This action is in response to a petition filed by

Purac America, Inc. The agency, on its own initiative, is also amending its color additive regulations to provide for the safe use of ferrous lactate for the coloring of ripe olives.

DATES: The amendments to § 184.1311 (21 CFR 184.1311) will be effective on August 2, 1996. New § 73.165 will be effective on September 4, 1996, except as to any provisions that may be stayed by the filing of proper objections; written objections by September 3, 1996. The Director of the Office of the Federal Register approves the incorporations by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications listed in § 184.1311(b), effective August 2, 1996; and in new § 73.165(b) effective September 4, 1996.

ADDRESSES: Submit written objections to new § 73.165 to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3074.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the procedures described in 21 CFR 170.35, Purac America, Inc., c/o 700 13th St. NW., suite 1200, Washington, DC 20005, submitted a petition (GRASP 3G0396) requesting that the regulations in § 184.1311 be amended to affirm that ferrous lactate is GRAS as a color fixative in black olives.

FDA published a notice of filing of this petition in the Federal Register of December 27, 1993 (58 FR 68437), and gave interested parties an opportunity to submit comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Also, in this notice, FDA announced that, on its own initiative, the agency would amend the color additive regulations to provide for the safe use of ferrous lactate as a color additive for the coloring of ripe olives. No comments were received in response to this notice of filing.

Since the filing of this petition, the agency has come to recognize that ferrous lactate is being used as a color fixative in ripe, rather than black, olives. The Agricultural Marketing Service of the U. S. Department of Agriculture defines "ripe type" olives as "* * * those which have been treated and oxidized in processing to produce a

typical dark brown to black color" (7 CFR 52.3752(a)). Also, in 21 CFR 73.160, the use of ferrous gluconate is approved for the coloring of ripe olives. Ferrous lactate is a potential substitute for ferrous gluconate. Therefore, to maintain consistency, the agency will refer to ripe olives instead of black olives.

II. Standards for GRAS Affirmation

Under § 170.30 (21 CFR 170.30), general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances added to food. 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, experience based on common use in food (§ 170.30(a)). 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 in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation but ordinarily is to be based upon generally available data and information concerning the pre-1958 history of use of the food ingredient (§ 170.30(c)). In its petition, Purac America, Inc., relied on the scientific procedures that have been used to support the regulated uses of ferrous lactate in § 184.1311, and on additional submitted published and unpublished data, to establish that ferrous lactate is GRAS for use as a color fixative on ripe olives.

III. Use, Estimated Exposure Levels, and Synthesis of Ferrous Lactate

Ferrous lactate is currently affirmed as GRAS for use as a nutrient supplement under § 184.1311. Because ferrous lactate is used interchangeably with several other iron salts that also may be used as nutrient supplements, FDA considered the exposure to ferrous lactate resulting from its use on ripe olives in relation to total exposure from iron.

Based on information supplied in the petition, FDA has estimated that the exposure to iron from the consumption of ferrous lactate-treated olives would be no greater than 0.14 milligrams per person per day (mg/person/day) (Ref. 1).