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

* * * * *

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

Richard E. Prang,

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

[FR Doc. 96–19674 Filed 8–1–96; 8:45 am]

BILLING CODE 4910–13–M

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).

This represents a small contribution to the reference daily intake (RDI) of 18 mg/day for iron (21 CFR 104.20(d)(3)). As ferrous lactate can replace ferrous gluconate for coloring or fixing color in ripe olives, no actual increase in exposure to iron is expected.

Lactic acid is GRAS (21 CFR 184.1061) and is a ubiquitous component of the human body. FDA has estimated that exposure to lactate from the petitioned use would not contribute significantly to the overall dietary exposure to lactate (Ref. 1).

Section 184.1311(a) describes ferrous lactate as a greenish-white powder prepared by reacting calcium lactate or sodium lactate with ferrous sulfate or by direct reaction of lactic acid with iron filings. The petitioner described two additional methods for preparing ferrous lactate: (1) Reaction of ferrous chloride with sodium lactate and (2) reaction of ferrous sulfate with ammonium lactate.

The petitioner also submitted a draft copy of specifications for ferrous lactate that has been incorporated into the 4th edition of the Food Chemicals Codex recently published by the National Academy of Sciences. The agency has reviewed these additional methods of synthesis and specifications for ferrous lactate and has concluded that they are acceptable (Ref. 1).

IV. Safety

FDA discussed the safety of ferrous lactate in a proposal that published in the Federal Register on April 21, 1987 (52 FR 13086). As noted above, ferrous lactate is affirmed as GRAS for use as a nutrient in food under § 184.1311. Ferrous lactate is also recognized as a coloring adjunct and nutrient by the Food and Agriculture Organization/ World Health Organization and the Joint Expert Committee on Food Additives. Ferrous lactate is listed as a color retention agent in the Registry of Food Additives of the European Communities. Ferrous lactate is also listed by the Spanish Ministry of Health for color fixation of black olives. The petitioner has relied primarily on the above data to support its proposed use of ferrous lactate as a color fixative for ripe olives.

FDA has considered the information in the petition, along with other available information, concerning ferrous lactate and other iron salts and has concluded that ferrous lactate is safe for use as a color fixative for ripe olives (Ref. 2). This determination is based on the fact that lactate is a normal constituent of food and a normal intermediary metabolite in humans. Ferrous salts are present in many foods, particularly meats and poultry and are used as nutrients in food processing. The exposure to iron from the consumption of ferrous lactate-treated olives represents only a small contribution to the RDI of 18 mg/day for iron.

V. Conclusions on Use of Ferrous Lactate as a Color Fixative on Ripe Olives

FDA has evaluated all of the available information on ferrous lactate. Based on its review, the agency concludes that the data are adequate to demonstrate the safety of ferrous lactate for the petitioned use. Therefore, the agency concludes, based upon scientific procedures, that ferrous lactate is GRAS for use as a color fixative on ripe olives at levels consistent with current good manufacturing practice. The agency is therefore amending § 184.1311 to provide for this use.

The agency is also amending § 184.1311 to provide for the additional methods of synthesis for ferrous lactate that were discussed above. Additionally, the agency is amending § 184.1311 to require that the ingredient meets the specifications listed in the Food Chemicals Codex. In the existing GRAS regulation for food use of ferrous lactate (§ 184.1311), the agency indicated that it was developing specifications for ferrous lactate in cooperation with the National Academy of Sciences. The agency, as noted above, has reviewed the specifications for ferrous lactate that published in the 4th edition of the Food Chemicals Codex and has found them acceptable. Therefore, the agency is amending § 184.1311 to require that ferrous lactate meet the specifications in the Food Chemicals Codex, 4th edition, pages 154 and 155.

VI. Use of Ferrous Lactate as a Color Additive

In the document announcing the filing of Purac America, Inc.'s, GRAS affirmation petition for ferrous lactate, FDA proposed, on its own initiative, to amend the color additive regulations in part 73 (21 CFR part 73) to provide for the safe use of ferrous lactate as a color additive for the coloring of ripe olives. The agency undertook this action because of questions as to whether ferrous lactate, when used for the petitioned purpose, is functioning as a color fixative or as a color additive. Section 721(b)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e(b)(4), provides that ''* * * a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).'' Therefore, to eliminate any questions with respect to the use of ferrous lactate on ripe olives, the agency proposed to amend part 73 to provide for the safe use of ferrous lactate for the coloring of ripe olives.

Having concluded that ferrous lactate is GRAS for use as a color fixative on ripe olives, the agency is amending part 73 to provide for the use of ferrous lactate as a color additive for the coloring of ripe olives.

The agency has also determined that the Food Chemicals Codex specifications for ferrous lactate are acceptable for the color additive use of ferrous lactate in coloring ripe olives, and in the regulation, the agency is requiring that the substance conform to these specifications. Section 721(c) of the act provides that GRAS substances when listed as color additives are exempt from certification. Therefore, ferrous lactate, when used as a color additive for coloring ripe olives, is exempt from certification.

In accordance with § 71.15 (21 CFR 71.15), 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 Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 71.15, the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VII. Environmental Effect

The agency has carefully considered the potential environmental effects of this action. FDA 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, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Economic Effects of GRAS Affirmation

FDA has examined the economic implications of this final rule affirming that the use of ferrous lactate is GRAS as a color fixative on ripe olives and of amending § 184.1311 to permit

additional methods of synthesis for ferrous lactate 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 effects; distributive impacts; and equity). The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses.

FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. The compliance costs to firms are zero because no current activity is prohibited by affirming the GRAS status of ferrous lactate as a color fixative for ripe olives, or by amending the regulations to permit additional methods of synthesis for ferrous lactate. Because this final rule will not increase the health risks faced by consumers, total health costs are also zero. Potential benefits include the ability to use additional methods to synthesize ferrous lactate and any resources saved by eliminating the need to prepare further petitions to affirm the GRAS status of this substance.

Affirming that ferrous lactate is GRAS as a color fixative for ripe olives under conditions of current good manufacturing practice and permitting additional methods of synthesis for ferrous lactate will expand the formulation possibilities for food manufacturers, including small businesses. Therefore, in accordance with the Regulatory Flexibility Act, FDA has also determined that this rule will have a positive impact on small businesses.

IX. References

The following references have 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. Memoranda from Chemistry Review Branch, HFS–247, to Direct Additives Branch, HFS–217, dated December 19, 1994, July 28, 1995, and November 21, 1995.

2. Memorandum from Additives Evaluation Branch no. 1, HFS–226, to Direct Additives Branch, HFS–217, dated September 9, 1993.

X. Objections to § 73.165

Any person who will be adversely affected by new § 73.165 may at any time on or before September 3, 1996, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. 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 document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the Federal Register.

List of Subjects

21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

21 CFR Part 184

Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drug and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR parts 73 and 184 are amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: Secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e).

2. New § 73.165 is added to subpart A to read as follows:

§ 73.165 Ferrous lactate.

(a) *Identity.* The color additive ferrous lactate is the ferrous lactate defined in § 184.1311 of this chapter.

(b) *Specifications.* Ferrous lactate shall meet the specifications given in the Food Chemicals Codex, 4th ed. (1996), pp. 154 to 155, which is 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 Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) *Uses and restrictions.* Ferrous lactate may be safely used in amounts consistent with good manufacturing practice for the coloring of ripe olives.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act (the act).

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

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

3. Section 184.1311 is amended by revising paragraphs (a), (b), and (c) to read as follows:

§ 184.1311 Ferrous lactate.

(a) Ferrous lactate (iron (II) lactate, $C_6H_{10}FeO_6$, CAS Reg. No. 5905–52–2) in the trihydrate form is a greenish-white powder or crystalline mass. It is prepared by reacting calcium lactate or sodium lactate with ferrous sulfate, direct reaction of lactic acid with iron filings, reaction of ferrous chloride with sodium lactate, or reaction of ferrous sulfate with ammonium lactate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 4th ed. (1996), pp. 154 to 155, which is 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 Center for Food Safety and Applied Nutrition's library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food as a nutrient supplement as defined in

§ 170.3(o)(20) of this chapter and as a color fixative for ripe olives, with no other limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

* * * * *

Dated: July 19, 1996.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–19305 Filed 8–1–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 101

[Docket No. 93N–0153]

RIN 0910–AA19

Food Labeling; Nutrient Content Claims and Health Claims; Restaurant Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food labeling regulations to remove the provisions that exempt restaurant menus from the requirements for how nutrient content claims and health claims are to be made and from the requirements for the provision of nutrition information with respect to the nutrients that are the basis for the claim, when claims are made. Because a significant number of meals are consumed outside of the home, the extension of these requirements to menus will help to increase the awareness of the American consumer to the relationships between diet and health. FDA is issuing this final rule at this time in response to a decision by the United States District Court for the District of Columbia.

DATES: This regulation is effective May 2, 1997. Written comments on the information collection requirements should be submitted by October 1, 1996.

ADDRESSES: Submit written comments on the information collection requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document. Persons who believe it would be useful for the agency to hold a public meeting on what is required by this rule should also send their letters to the Dockets Management Branch.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

I. Background

A. Requirements for Nutrition Labeling and Nutrient Content Claims and Health Claims

The Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and the final regulations that implement the 1990 amendments (58 FR 2066, January 6, 1993, as modified at 58 FR 44020, August 18, 1993) provide for a number of fundamental changes in how food is labeled, including mandatory nutrition labeling on most foods, uniform definitions for terms that characterize the level of nutrients in a food, and the use of claims about the relationship between nutrients and diseases or health-related conditions. These changes apply to virtually all foods in the food supply, including foods sold in restaurants.

The provision on nutrition labeling that was added to the Federal Food, Drug, and Cosmetic Act (the act) by the 1990 amendments, section 403(q) (21 U.S.C. 343(q)), includes an exemption for foods that are served or sold in restaurants or other establishments in which food is served for immediate human consumption (section 403(q)(5)(A)(i)). This exemption, however, is contingent on there being no claims or other nutrition information on the label or labeling, or in the advertising, for the food. The use of nutrient content claims, health claims, or other nutrition information on the label or labeling of a food sold in a restaurant or other establishment in which food is served for immediate consumption will subject that food to the nutrition labeling provisions of the act (see sections 403 (q) and (r) of the act and § 101.9 (j)(2)(i) through (j)(2)(iii) (21 CFR 101.9 (j)(2)(i) through (j)(2)(iii))). Consistent with these provisions, in this discussion the term ''restaurant foods'' refers to foods served in restaurants and in other establishments in which food that is ready for human consumption is sold (e.g., institutional food service, delicatessens, catering) or sold only in such establishments. Firms selling such foods will be referred to as ''restaurants,'' and responsible individuals in these firms will be referred to as ''restaurateurs.''

In the January 6, 1993, final rules on nutrient content claims and health claims (entitled ''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food'' (58 FR 2302); and ''Food Labeling; General Requirements for Health Claims for Food'' (58 FR 2478), respectively (hereinafter referred to as the ''nutrient content claims final rule'' and the ''health claims final rule,'' and collectively, as the ''claims final rules'')), the agency concluded that if claims on restaurant foods are to be useful to consumers, they must be valid. Thus, FDA stated that the same standards will apply to restaurant foods as to other foods with respect to basic definitions for nutrient content claims. FDA also stated that when a restaurant makes explicit or implied reference to a food or substance in food, and directly or indirectly links that substance to an effect on a disease or health-related condition (i.e., when both basic elements of a health claim are present), the restaurant must comply with the health claims regime (58 FR 2478 at 2516). At the same time, FDA acknowledged that how a restaurant demonstrates compliance with these requirements is a difficult matter. FDA pointed out, in the claims final rules (58 FR 2302 at 2386 and 58 FR 2478 at 2515), that it is not obligated under the act to regulate claims on restaurant foods in a manner identical to that in which it regulates claims on packaged foods. In the nutrient content claims final rule (58 FR 2302), the agency amended § 101.10 *Nutrition labeling of restaurant foods* (21 CFR 101.10) to provide flexibility for restaurants in determining compliance with FDA's requirements for the claims regime and in providing nutrition labeling for foods that bear a claim.

Consequently, although restaurant food must comply with the same standards as other foods to bear a claim, the way in which a restaurant determines the nutrient content of a food or meal, and the way in which nutrition information is communicated to consumers, may be different for restaurant foods than for foods from other sources. For example, § 101.10 provides that nutrient levels in restaurant foods may be determined through the use of nutrient data bases, cookbooks, or other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. For compliance purposes,