(iii) An ''American family member'' or ''part-time intermittent temporary (PIT)'' appointment in U.S. diplomatic establishments;

(iv) 50 U.S.C. 403j; Public Law 86–36 (50 U.S.C. 402, note); the Berlin Tariff Agreement; or as a local national employee paid from appropriated funds; or

(v) Any other nonpermanent appointment in the competitive or excepted service approved by OPM.

(5) *Overseas.* A location outside the 50 States of the United States, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 164

[Docket No. 93N–0473]

Peanut Butter; Amendment of Standard of Identity

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standard of identity for peanut butter to remove the specific reference to the addition of vitamins, so that modified peanut butter products with added vitamins can be made in accordance with the agency's general definition and standard of identity for food named by the use of a nutrient content claim (such as ''reduced fat'' or ''reduced calorie'') in conjunction with the standardized term, peanut butter. This action will assist consumers in maintaining healthy dietary practices by providing for modified forms of peanut butter. This action will also promote honesty and fair dealing in the interest of consumers.

DATES: Effective March 8, 1996.

FOR FURTHER INFORMATION CONTACT: Felicia Satchell, 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

In the Federal Register of February 3, 1994 (59 FR 5153), FDA published a proposal to amend the standard of identity for peanut butter in § 164.150 (21 CFR 164.150) to remove the specific prohibition against added vitamins. The proposal was based on comments the agency received in response to a final rule that was published in the Federal Register of January 6, 1993 (58 FR 2066). The comments noted that the requirements of the general definition and standard of identity in § 130.10 (21 CFR 130.10) create a problem for firms interested in producing modified (e.g., ''reduced fat'') peanut butter products. They pointed out that § 130.10(b) requires that the modified food may not be nutritionally inferior to the traditional standardized food, and that § 130.10(d)(3) prohibits the addition of ingredients that are specifically prohibited by the standard for the traditional food. Because there is a specific prohibition against the addition of vitamins to peanut butter in § 164.150(c), modified peanut butter products that are not nutritionally inferior to peanut butter could not be made under § 130.10.

To eliminate this problem, FDA proposed to remove the specific prohibition against the addition of vitamins in the peanut butter standard. The agency stated in that proposal that removal of the term ''added vitamins'' from § 164.150(c) would allow the addition of vitamins to modified peanut butter products made to comply with § 130.10, but that the agency still felt that added vitamins are not suitable ingredients for peanut butter when the food is used in a balanced diet. Interested persons were given until April 4, 1994, to submit comments.

II. Comments

The agency received 12 letters, each containing one or more comments, from a manufacturer, several trade associations, and food processors. Seven letters supported the proposal, and five opposed it. One comment that expressed support for the proposed change suggested an additional change in the standard of identity for peanut butter, and others requested clarification of the nutrient requirements for modified peanut butter. Most of the comments that opposed amendment of the peanut butter standard cited, as grounds for their opposition, issues that are outside the scope of this rulemaking (e.g., whether a modified peanut butter product under the general definition and standard of identity could or should be made with 90 percent of peanuts, as required by the standard of identity for peanut butter, and whether FDA is enforcing its regulations with respect to modified peanut butter products in the marketplace) and they need not be addressed here. A summary of the relevant comments and the agency's responses follow.

1. A comment from a trade association that opposed the proposal stated that its membership believes it would be misleading if the standard of identity for peanut butter were changed. It expressed the opinion that peanut butter is nutritionally sound without vitamin additives.

The agency agrees that peanut butter is nutritionally sound without added vitamins. The removal of the specific prohibition against added vitamins in the peanut butter standard is only to permit their addition, as necessary, to modified peanut butter products made under the general definition and standard of identity in § 130.10. FDA clearly stated in the proposed rule that the removal of this prohibition would not change the agency's position that added vitamins are not suitable ingredients in peanut butter when it is not being modified to reduce, for example, its fat content. Thus, in this final rule, the agency is merely removing the prohibition on the addition of vitamins to peanut butter in the standard of identity in § 164.150. It is not making any provision for the addition of these ingredients to this food under § 164.150. If vitamins are added to peanut butter, it would have to be labeled in compliance with § 130.10, i.e., ''peanut butter with added vitamins.'' Any such addition of vitamins to the food would have to be consistent with the provisions of the fortification policy in 21 CFR 104.20, or be otherwise rational.

2. One comment stated that it supported the proposal to remove the phrase ''added vitamins'' in § 164.150(c), but that the proposal did not go far enough. It stated that the agency should remove the entire statement contained in paragraph § 164.150(c), i.e., ''except that artificial flavorings, artificial sweeteners, chemical preservatives, added vitamins, and color additives are not suitable ingredients of peanut butter.'' The comment stated that none of these ingredients would be permitted in peanut butter notwithstanding the above language because the only optional ingredients permitted in peanut butter under the standard are ''safe and suitable seasoning and stabilizing ingredients.'' The comment contended that few would argue that these ''prohibited'' ingredients (artificial flavorings, artificial sweeteners, chemical preservatives, vitamins, and color additives) qualify as seasoning or stabilizing ingredients. The comment further contended that if the agency has a concern in this regard, it could state for the record that stabilizing and seasoning ingredients, as used in the

peanut butter standard, do not include these categories of ingredients.

The comment also noted that many peanut butters include a sweetener seasoning, and that there might be an opportunity to use an approved high intensity artificial sweetener to replace sugar or corn syrup in the formulation of a modified peanut butter. Likewise, the comment stated, if someone wanted to use a safe and suitable artificial flavor in a modified peanut butter product (the inclusion of which would be required to be adequately communicated via the labeling requirements contained in 21 CFR 101.22), there is no reason to prohibit its use. Thus, the comment urged the agency to fix the entire problem presented in the language of the peanut butter standard coupled with the requirement in § 130.10(d)(3) that specifically prohibits the use in the modified food of any ingredient whose use is specifically prohibited by the standard of identity for that food.

FDA is not making the requested change. The suggested removal of the prohibition against the addition of artificial flavorings, artificial sweeteners, chemical preservatives, and color additives from § 164.150(c) was not foreshadowed in the proposed rule. Further, there is no compelling reason, such as a conflict with the provisions of the general definition and standard of identity, to make the change at this time. When FDA developed the general definition and standard of identity, it specifically included a provision in § 130.10(d)(3) to prohibit the use of ingredients that were explicitly prohibited by the standard of identity for the traditional food. The purpose of the provision was to ensure that the modified food would resemble the traditional food in as many ways as possible. One way to ensure such resemblance was to require the use of similar ingredients in the new food and to exclude those ingredients that were prohibited in the traditional food.

The agency notes that if the manufacturers of modified peanut butter products find that these remaining prohibitions in § 164.150(c) represent significant barriers to the development of peanut butter products modified to meet a nutrition goal, such as ''reduced calorie'' or ''reduced fat'' products, they may submit a petition to further amend the peanut butter standard of identity.

3. One comment noted that the agency's proposal only deals with added vitamins in modified peanut butter products and questioned whether added minerals were also of concern to the agency.

Depending on the degree of modification of the peanut butter, manufacturers may need to add minerals to the modified peanut butter product to ensure that the food will not be nutritionally inferior to peanut butter. There is, however, no specific prohibition in the standard of identity for peanut butter that would preclude the addition of minerals to a modified peanut butter. FDA notes that the general definition and standard of identity in § 130.10(b) states that nutrients shall be added to the modified food to restore nutrient levels, so that the product will not be nutritionally inferior, as defined in § 101.3(e)(4) (21 CFR 101.3(e)(4)), to the traditional standardized food. Nutritional equivalence of modified peanut butter products to peanut butter is defined in the common or usual name regulation for peanut spreads in § 102.23 (21 CFR 102.23). Section 102.23(b) includes a nutrient profile based on the levels of nutrients found in peanut butter that may be used as guidance by manufacturers in determining whether nutrients need to be added to a modified peanut butter product. This nutrient profile includes requirements for protein content and quality, as well as minimum levels of niacin, vitamin B_6, folic acid, iron, zinc, magnesium, and copper that must be present in the food.

4. One comment requested that FDA clarify how the equivalent micronutrient levels for modified peanut butter products are to be determined. It noted that the nutrient levels vary from product to product. The comment suggested the use of U.S. Department of Agriculture Handbook data or an industry generated data base for nutrient data on peanut butter and requested that the agency state in the final rule what source is appropriate. The comment included a copy of data on the vitamin E content of peanut butter from its submission that it made to the agency in the rulemaking to establish a common or usual name regulation for peanut spreads in § 102.23 (see 40 FR 51052, November 3, 1975, and 42 FR 36452, July 15, 1977).

As noted above in the response to comment 3, FDA has established requirements for nutrient levels in spreadable peanut products in the common or usual name regulation on peanut spreads in § 102.23. These levels may be used by manufacturers as guidance in determining nutritional equivalency to peanut butter. However, manufacturers may make comparisons to their own traditional peanut butter formulation. The types and levels of nutrient additions will depend on the types of modifications that need to be made in formulating the modified peanut butter product and the effects of such modifications on the composition of the finished food.

With respect to the comment's resubmission of data on vitamin E, FDA addressed that data in the final rule establishing § 102.23 (see 42 FR 36452 at 36454). At that time, the agency stated that the values submitted by the comment were consistent with published literature values and suggested that 10 international units per 100 grams of peanut butter would approximate the average content of vitamin E in peanut butter. However, because the vitamin E content of peanut butter is subject to variation, additional data would be necessary before the agency could establish a value for nutritional equivalence in peanut spreads. Therefore, the agency stated that no peanut spread would be considered to be an imitation of peanut butter solely because it contains less vitamin E than peanut butter. The agency has not received any information to change that position. Thus, modified peanut products that comply with the minimum requirements for nutrient levels specified for peanut spreads (§ 102.23) will not be considered to be nutritionally inferior to peanut butter under the provisions in § 101.3(e)(4).

After considering the comments received and the other relevant factors that the agency discussed in the proposal, FDA concludes that it will promote honesty and fair dealing in the interest of consumers to amend the standard of identity for peanut butter in the manner proposed. Accordingly, FDA is revising § 164.150(c) by removing the specific reference to ''added vitamins.'' This change will allow the replacement of nutrients normally present in peanut butter that may be lost in formulating and manufacturing modified peanut butter products, thereby ensuring that the modified version of the food will not be nutritionally inferior to peanut butter.

III. Economic Impacts

FDA has examined the impact of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs Federal agencies to assess the 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). According to Executive Order 12866, a regulatory action is ''economically significant'' if it meets any one of a number of specified conditions, including having an annual

effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation is considered ''significant'' under Executive Order 12866 if it raises novel legal or policy issues. The Regulatory Flexibility Act requires Federal agencies to minimize the economic impact of their regulations on small business.

There are no compliance costs associated with this final rule because this final rule will not prohibit any current activity. The benefit of this final rule is that it allows modified peanut butter products to be labeled with a nutrient content claim and the standardized term ''peanut butter.'' This labeling may reduce the cost of identifying these products for some consumers. Therefore, FDA finds that this final rule is neither an economically significant nor significant regulatory action as defined by Executive Order 12866. In compliance with the Regulatory Flexibility Act, FDA certifies that this final rule, if promulgated, will not have a significant impact on a substantial number of small businesses.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) 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.

List of Subjects in 21 CFR Part 164

Food grades and standards, Nuts, Peanuts.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 164 is amended as follows:

PART 164—TREE NUT AND PEANUT PRODUCTS

1. The authority citation for 21 CFR part 164 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

2. Section 164.150 is amended by revising paragraph (c) to read as follows:

§ 164.150 Peanut butter.

* * * * *

(c) The seasoning and stabilizing ingredients referred to in paragraph (a) of this section are suitable substances which are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act), or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act. Seasoning and stabilizing ingredients that perform a useful function are regarded as suitable, except that artificial flavorings, artificial sweeteners, chemical preservatives, and color additives are not suitable ingredients in peanut butter. Oil products used as optional stabilizing ingredients shall be hydrogenated vegetable oils. For the purposes of this section, hydrogenated vegetable oil shall be considered to include partially hydrogenated vegetable oil.

* * * * *

Dated: February 29, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–5493 Filed 3–7–96; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Part 40

[Public Notice 2345]

Bureau of Consular Affairs; Regulations Pertaining to Both Nonimmigrants and Immigrants Under the Immigration and Nationality Act, as Amended; Failure To Comply With INA

AGENCY: Bureau of Consular Affairs, DOS.

ACTION: Final rule.

SUMMARY: The Department is finalizing the interim rule [59 FR 51367] published on October 11, 1994. The regulation implements 212(o) of the Immigration and Nationality Act (INA), which prohibits the issuance of an immigrant visa to an alien for ninety days following an alien's departure from the U.S. unless the alien was maintaining a lawful nonimmigrant status at the time of departure, or unless the alien is the spouse or unmarried child of certain individuals who obtained temporary or permanent resident status under INA 210 or 245A or section 202 of the Immigration Reform and Control Act of 1986 (IRCA).

EFFECTIVE DATE: The effective date of this final rule is October 1, 1994.

FOR FURTHER INFORMATION CONTACT: Stephen K. Fischel, Chief, Legislation and Regulations Division, 202–663–1204.

SUPPLEMENTARY INFORMATION:

Expansion of INA 245 Adjustment of Status and Companion Provision

On August 26, 1994 the President signed into law the appropriations bill for the Department of State, Pub. L. 103–317. Section 506(b) thereof amends INA 245 to permit qualified immigrants to acquire permanent residence through adjustment of status in the United States even though they entered the United States without inspection or violated their nonimmigrant status after entry.

This Act further amends the INA at section 212 by adding subsection ''(o)'', which encourages aliens who can benefit from the broadened INA 245 adjustment of status provisions to take advantage of them by discouraging them from seeking immigrant visa issuance from a U.S. consular post abroad. To induce such aliens to seek INA 245 adjustment of status, Congress imposed a requirement that an immigrant visa applicant be physically absent from the United States for ninety days since the last departure before an immigrant visa can be issued. Under this amendment, an alien who departs from the United States would be eligible to receive an immigrant visa on the 91st day following the departure. Two classes of aliens are exempted from this provision. The first class consists of aliens maintaining lawful nonimmigrant status at the time of departure. The second class consists of the spouses and children of certain aliens who benefited from the special agricultural worker program, the legalization program, and the Cuban—Haitian adjustment provisions of IRCA, and who sought benefits under the family unity provisions of the Immigration Act of 1990.

Final Rule

Interim rule 2092, published on October 11, 1994 at 59 FR 51367, invited interested persons to submit comments concerning the amendments. No comments were received.

PART 40—[AMENDED]

1. The authority citation for Part 40 continues to read as follows:

Authority: 8 U.S.C. 1104; sec. 506(a), Pub. L. 103–317, 108 Stat. 1724.

2. Accordingly, the interim rule's regulations and the October 1, 1994 effective date published at 59 FR 51358 are adopted without change.

Dated: February 15, 1996.

Mary A. Ryan,

Assistant Secretary for Consular Affairs.

[FR Doc. 96–5442 Filed 3–7–96; 8:45 am]

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