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By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 96-16476 Filed 6-27-96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 94F-0405]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Aspartame

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of aspartame as a general purpose sweetener. This action is in response to a petition by the NutraSweet Co., and will simplify the existing regulation by replacing most of the 23 currently listed uses of aspartame with a single use category for food.

DATES: The regulation is effective June 28, 1996. Submit written objections and requests for a hearing by July 29, 1996. 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 in 21 CFR 172.804(c)(2), effective June 28, 1996.

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

FOR FURTHER INFORMATION CONTACT: Blondell Anderson, Center for Food Safety and Applied Nutrition (HFS-207), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3106.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of December 8, 1994 (59 FR 63368), FDA announced that a food additive petition (FAP 5A4439) had been filed by the NutraSweet Co., 1751 Lake Cook Rd., Deerfield, IL 60015-5239, proposing that the food additive regulations be

amended in § 172.804 *Aspartame* (21 CFR 172.804) to provide for the safe use of aspartame as a general purpose sweetener.

I. Background

Aspartame is currently approved for use in a large number of processed foods under § 172.804 (21 CFR 172.804) (20 permitted uses as a sweetener and 3 permitted uses as a flavor enhancer). The regulation has resulted from the approval of 27 separate food additive petitions (FAP's).

The acceptable daily intake (ADI) of 50 milligrams per kilogram body weight per day (mg/kg/day) was established for aspartame as a result of the agency's review of FAP 2A3661, which requested use of aspartame in carbonated beverages (48 FR 31376, July 8, 1983). The ADI is the level of consumption that has been determined to be safe for human consumption every day over an entire lifetime. The agency's review of all petitions submitted subsequent to aspartame's approval in carbonated beverages involved primarily: (1) An assessment of the estimated exposure from each additional use; and (2) a determination of whether the cumulative estimated exposure, including the newly requested use, would cause the acceptable daily intakes for aspartame and for its major breakdown product, diketopiperazine (DKP), to be exceeded over a lifetime by individuals consuming aspartame at the 90th percentile level. The 90th percentile intake (which represents high exposure) is the level of consumption at which 90 percent of the population (a selected population subgroup) consumes the ingredient at or below the indicated value.

NutraSweet is now requesting that the aspartame regulation be amended to allow its use as a general purpose sweetener at levels determined by current good manufacturing practice (CGMP). FDA's CGMP regulation for food additives requires, among other things, that the level of an additive used in food not be higher than that level required to accomplish the intended functional effect (21 CFR 172.5(a)(1)). This level has not, in general, been set by the agency except when there appears to be a specific need to do so. In the case of the agency's review of FAP 7A4044, which requested the use of aspartame in baked goods and baking mixes, the maximum level of use of aspartame that would be consistent with CGMP was set at 0.5 percent by weight of ready-to-bake products or of finished formulations prior to baking. In that decision, the agency imposed a use limit that can be verified by an analytical

method that is incorporated by reference into the regulation. That requirement is maintained in this regulation. For all other uses of aspartame the agency has determined that CGMP levels of use need not be specified.

The practical effect of the amendment requested in the current petition would be to simplify the existing regulation in § 172.804 by replacing most of the 23 currently listed uses of aspartame with a single use category for food. As discussed below, the permitted uses of aspartame are sufficiently broad that including any additional category not allowed by the current regulation will not cause human exposure to change significantly.

II. Petition for Use of Aspartame as a General Purpose Sweetener

To support the proposed amendment, NutraSweet has submitted a summary of postmarket aspartame intake surveys performed by the Market Research Corp. of America (MRCA) between 1984 and 1992. These surveys (which measure the actual amount of aspartame consumed by individuals) track the quantity of aspartame-sweetened foods that are consumed over a 2-week period. According to the July 1991 to June 1992 survey, the intake of aspartame for individuals who consume aspartame at the 90th percentile ("eaters only") is 3.0 mg/kg/day (6 percent of the ADI) for the "all ages" population group and is 5.2 mg/kg/day (10.4 percent of the ADI) for children in the 0-month to 5-year-old subgroups (the groups that consume the highest amounts of aspartame per kg of body weight). NutraSweet states in the petition that aspartame intake from the potential new uses is not expected to significantly increase aspartame consumption above current levels. This is because: (1) Its intake from the major use category (e.g., beverages) has stabilized and the potential new uses will have, at most, a minor effect on total consumption; and (2) the permitted uses of competing high-intensity sweeteners continue to be broadened.

III. Exposure Estimates

The agency focused its safety evaluation on whether human exposure to aspartame as a general purpose sweetener would exceed the ADI of 50 mg/kg/day; and whether human exposure to DKP, the aspartame decomposition product, would exceed the ADI of 30 mg/kg/day (Ref. 1).

A. Aspartame

In the Commissioner's 1981 decision to approve aspartame (46 FR 38285, July 24, 1981), several methods were described for projecting the level of

aspartame consumption. In one method the agency estimated that if aspartame replaced all sucrose in the diet of an average 60 kg individual, the aspartame consumption would be approximately 8.3 mg/kg/day. In the petition, Nutrasweet projects an aspartame intake of 8.1 mg/kg/day for all age groups when used as a general purpose sweetener.

The agency has reassessed the anticipated exposure to aspartame in light of all the evidence gained since the earlier approval. Assuming that all sucrose added to food would be replaced by aspartame, the agency estimates that the daily intake would be 8.7 mg/kg/day. Use of other approaches to estimate consumption also results in consistent intake estimates that are far below the ADI (Ref. 1). This shows that high levels of aspartame intake derived for different age groups are unlikely to exceed the ADI if used in food with no limitations other than CGMP.

B. DKP

Aspartame can partially decompose to yield DKP in certain food products when they are heated or stored for prolonged periods of time. FDA has previously set an ADI for DKP of 30 mg/kg/day (48 FR 31376, July 8, 1983). In order to derive a conservative exposure to DKP, FDA used the highest exposure estimate derived for aspartame (based on the assumption that all sugars added to food would be replaced with aspartame). This DKP exposure estimate does not exceed 10 percent of the ADI for all age groups and does not exceed 16 percent for the 0- to 5-year-old age group (Ref. 1). These estimates show that the ADI for DKP will not be exceeded when aspartame is used as a general purpose sweetener.

IV. Comment

The agency received one comment in response to the filing notice of December 8, 1994, from the McNeil Specialty Products Co. (Ref. 2). This comment raised two points, each of which is addressed below.

The first point raised by the comment was that the filing notice failed to specify that the agency was soliciting comments on the entire petition, not just on the environmental assessment. The comment suggested that the entire petition should be made available at the Dockets Management Branch and that a separate notice should be published in the Federal Register explicitly requesting comments on all aspects of the petition.

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(b)(5)), FDA is required to

announce the filing of a food additive petition. Although public notice of a petition is required, the act is silent with respect to public comment on a petition.

Historically, FDA has not placed food additive petitions on public display when a notice of filing is published and knows of no reason why such public display should be required. The agency considers comments received consistent with their relevance to the petitioned action. Information from the petition can be obtained through a request made under the Freedom of Information Act consistent with 21 CFR part 20.

The second point raised by the comment was that the petition lacks information required under § 171.1(c) (21 CFR 171.1(c)) on the amount of the additive proposed for use, appropriate functionality data to support the additional use categories requested, and methods to determine the level of the additive in food. It is further noted in the comment that if such information exists in other petitions, § 171.1(b) allows the petitioner to reference, rather than resubmit, such information. The comment points to: (1) Data establishing functionality and appropriate use levels and analytical techniques for the newly-requested approvals are not present in the current petition and (2) the petitioner had not specifically referenced such data; thus, the petition does not comply with the requirements found in § 171.1(c). Therefore, the comment contends that the petition is deficient and should not have been accepted for filing, and should be amended accordingly prior to the agency taking final action.

The agency disagrees with the contention that the petition lacks information required under § 171.1(c). As stated above in section I. of this document, aspartame has been previously approved for use as a sweetener in a large number of processed foods. These various approvals have resulted from the agency's consideration of 27 separate food additive petitions. The approved uses of aspartame span a wide range of food matrices and include products which are stored under a wide variety of conditions. Data establishing the functionality and stability of aspartame, and descriptions of methods for detecting aspartame in a wide variety of food products, are contained in either the 27 petitions or in several Food Master Files established for aspartame by the agency. Much of this information has been discussed in previous Federal Register documents.

Further, all of these petitions are specifically referenced in FAP 5A4439.

Therefore, the statement made in the comment that these petitions are not specifically referenced in the subject petition is factually incorrect.

V. Conclusions

FDA has calculated exposure estimates to aspartame under the assumption that the sweetener would be used in food with no limits other than CGMP. Having considered the results of these exposure estimates, which were made using extremely conservative assumptions (such as, that aspartame would replace all sugars added to food), the agency concludes that the use of aspartame as a general purpose sweetener will not cause the ADI for aspartame to be exceeded. The agency has estimated exposure to DKP (the major decomposition product of aspartame) and concludes that the ADI for DKP will also not be exceeded by its use as a general purpose sweetener. Based on these evaluations, the agency further concludes that the use of aspartame as a general purpose sweetener, subject only to CGMP conditions of use (including a specific CGMP level of use of 0.5 percent in baked goods and baking mixes), is safe and that the regulation for aspartame should be amended in § 172.804(c) as set forth below. In addition, § 172.804(b) is amended to conform to the requirement of providing three addresses for methods that are incorporated by reference, one where the method may be obtained and two where it may be examined by the public.

In accordance with § 171.1(h) (21 CFR 171.1(h)), 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 § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

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.

Any person who will be adversely affected by this regulation may at any time on or before July 29, 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.

VI. 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. Memorandum from the Chemistry Review Branch, FDA, to the Novel Ingredients Branch, FDA; March 8, 1994.
2. Comment from the McNeil Specialty Products Co., January 6, 1995.

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

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, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 379e).

2. Section 172.804 is amended by revising the introductory text, the second sentence of paragraph (b), and paragraph c; by removing paragraph (d) and redesignating paragraphs (e) and (f) as paragraphs (d) and (e) to read as follows:

§ 172.804 Aspartame.

The food additive aspartame may be safely used in food in accordance with good manufacturing practice as a sweetening agent and a flavor enhancer in foods for which standards of identity established under section 401 of the act do not preclude such use under the following conditions:

* * * * *

(b) * * * 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, Food And Drug Administration, 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)(1) When aspartame is used as a sugar substitute tablet for sweetening hot beverages, including coffee and tea, L-leucine may be used as a lubricant in the manufacture of such tablets at a level not to exceed 3.5 percent of the weight of the tablet.

(2) When aspartame is used in baked goods and baking mixes, the amount of the additive is not to exceed 0.5 percent by weight of ready-to-bake products or of finished formulations prior to baking. Generally recognized as safe (GRAS) ingredients or food additives approved for use in baked goods shall be used in combination with aspartame to ensure its functionality as a sweetener in the final baked product. The level of aspartame used in these products is determined by an analytical method entitled "Analytical Method for the Determination of Aspartame and Diketopiperazine in Baked Goods and Baking Mixes," October 8, 1992, which was developed by the Nutrasweet Co. Copies are available from the Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, or are available for inspection at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC 20204, and the Office of the Federal Register, 800 North

Capitol St. NW., suite 700, Washington, DC.

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Dated: June 18, 1996.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 96-16522 Filed 6-27-96; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8670]

RIN 1545-AU20

Revision of Section 482 Cost Sharing Regulations; Correction

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to final regulations (TD 8670), which were published in the Federal Register on Monday, May 13, 1996 (61 FR 21955) relating to qualified cost sharing arrangements.

EFFECTIVE DATE: May 13, 1996.

FOR FURTHER INFORMATION CONTACT: Lisa Sams, (202) 622-3840 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections are under section 482 of the Internal Revenue Code.

Need for Correction

As published, the final regulations contain errors which may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the final regulations (TD 8670), which are the subject of FR Doc. 96-11781, is corrected as follows:

§ 1.482-7 [Corrected]

On page 21956, column 2, instructional "Par. 3.", is corrected by revising item g. to read as follows:

g. By redesignating the introductory text of paragraph (j)(2) following the heading and paragraphs (j)(2)(i) through (j)(2)(v) as the introductory text of paragraph (j)(2)(i) and paragraphs (j)(2)(i)(A) through (j)(2)(i)(E),