

(2) Remove bus power control unit 20PC and replace it with a new improved unit having part number 106-000-3.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM-113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM-113.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The removals and replacements shall be done in accordance with Dornier Service Bulletin SB-328-24-061, Revision 1, dated November 3, 1994, which contains the following effective pages:

Page No.	Revision level shown on page	Date shown on page
1, 3	1	Nov. 3, 1994.
2	Original	Oct. 14, 1994.

This incorporation by reference is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Dornier Luftfahrt GmbH, P.O. Box 1103, D-82230 Wessling, Germany. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on August 8, 1996.

Issued in Renton, Washington, on June 19, 1996.

Darrell M. Pederson,
Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 96-16245 Filed 6-27-96; 8:45 am]
BILLING CODE 4910-13-P

FEDERAL TRADE COMMISSION

16 CFR Part 305

Rule Concerning Disclosures Regarding Energy Consumption and Water use of Certain Home Appliances and Other Products Required Under the Energy Policy and Conservation Act ("Appliance Labeling Rule")

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission ("Commission") issues final amendments to the Appliance Labeling Rule ("the Rule") to permit the placement of energy use labels required by the Canadian and Mexican governments in a location "directly adjoining" the Rule's required "EnergyGuide" label. Previously the Rule prohibited the affixation of non-required information "on or directly adjoining" the EnergyGuide. The relaxation of this prohibition will further the goal of the North American Free Trade Agreement ("NAFTA") to make compatible the standards-related measures of the signatories to facilitate trade in a good or service among the parties. Moreover, the amendment will result in considerable savings for the appliance manufacturing industry.

EFFECTIVE DATE: June 28, 1996.

FOR FURTHER INFORMATION CONTACT: James G. Mills, Attorney, Division of Enforcement, Federal Trade Commission, Washington, D.C. 20580 (202-326-3035).

SUPPLEMENTARY INFORMATION:

I. Background

A. The Request by Whirlpool

In July, 1995, the Whirlpool Corporation ("Whirlpool") requested permission to use hang tag EnergyGuide labels that have the corresponding Canadian "EnerGuide" appliance energy use label printed on the reverse side, and/or permission to use a single stick-on or hang tag label consisting of the Commission's EnergyGuide immediately next to (or above) the appropriately corresponding Canadian EnerGuide. Whirlpool also asked for permission to label in the same manner using the appliance energy use label required by Mexico, or using all three labels.

In support of its request, Whirlpool stated that the continued existence of separate appliance labeling requirements among the United States, Canada, and Mexico represents an obstacle to free trade among the signatories to NAFTA. Whirlpool contended that the ability to print the labels required by the three countries next to each other on a single piece of label stock would mitigate the impact of that obstacle. Whirlpool also stated that using such labels would save Whirlpool significant resources—by reducing the number of separate U.S. and Canadian models of appliances that Whirlpool produces and by reducing labeling expenses.

B. Applicable Sections of the Appliance Labeling Rule

Section 305.11(a)(5)(i)(K) of the Rule, 16 CFR 305.11(a)(5)(i)(K), states that: No marks or information other than that specified in this Part shall appear on or directly adjoining [the EnergyGuide] label except for a part or publication number identification, as desired by the manufacturer. * * * [emphasis added]

The language in this section pertains to labels for refrigerators, refrigerator-freezers, freezers, dishwashers, clothes washers, water heaters, and room air conditioners. Identical language appears in two other sections relating to labels for furnaces and pool heaters (16 CFR 305.11(a)(5)(ii)(I)) and central air conditioners (16 CFR 305.11(a)(5)(iii)(H)(1)). The purpose of this prohibition was to avoid having other information detract from the Energy Guide label.

C. The Notice of Proposed Rulemaking

The Commission agreed that permitting manufacturers to use side-by-side or back-to-back labeling that included the energy use labels of the three NAFTA signatories could further the goals of NAFTA and could reduce the cost of compliance with the Rule. The Commission, therefore, on February 22, 1996, issued a Notice of Proposed Rulemaking ("NPR") proposing amendments to the above-referenced sections of the Rule.¹

In the NPR, the Commission addressed whether permitting this type of labeling would result in consumer confusion. The Commission reasoned that, because the EnergyGuide is the only one of the three labels that is exclusively in English, and because there are two disclosures on it stating that the information is derived from U.S. government tests and utility costs, U.S. consumers may realize that only one label is pertinent to them. Further, the United States and Canada, and, to a slightly lesser extent, Mexico, use compatible test procedures for identifying energy use, and require information to be reported in terms of kilowatt-hour use per year. Thus, the Commission concluded preliminarily that the similarity of the information being disclosed on each country's label may make the possibility of confusion less likely. Moreover, U.S. consumers are already seeing Canadian labels on some appliances (especially in the northern states), and possibly Mexican labels, although not directly adjoining the EnergyGuide. Finally, the Commission pointed out that, on many

¹ 61 FR 6801.

packages, instruction manuals, and labels that accompany products destined for multiple countries, consumers are presented with information in more than one language. Thus, the Commission tentatively determined that consumers are not likely to be confused or misled by the presence of multiple appliance energy use labels, as long as they can clearly distinguish which is intended for the U.S. audience.

The Commission noted in the NPR that it has worked closely with representatives of the Canadian EnerGuide program over the past two years to explore regulatory harmonization under NAFTA. This work has centered around each country's recent review of its respective appliance labeling rule, with both considering each other's research and proposed changes. More recently, representatives of the Mexican government have joined in this dialogue. The Commission stated its intention to continue this cooperative pursuit of tri-lateral harmonization to determine whether a single label can be designed that effectively fulfills the requirements of all three countries, and characterized the proposed amendments as an interim measure to provide manufacturers greater labeling flexibility to facilitate trade.

To obtain more information regarding its proposal, the Commission posed the following questions in the NPR:

1. Would allowing energy use labels required by the Canadian or Mexican governments to be placed next to the U.S. EnergyGuide be likely to detract from the effectiveness of the EnergyGuide or cause consumer confusion?

2. Should the Commission limit the information that the amendments would permit to be placed "directly adjoining" the EnergyGuide only to *energy use disclosures* required by the governments of Canada and Mexico? For example, should the amendments permit additional information required by the governments of Canada and Mexico, such as environmental or safety-related information, also to be placed "directly adjoining" the EnergyGuide?

3. Should the Commission limit the amendments to apply to energy use (or other) information required only by the governments of Canada and Mexico, or should the amendments permit energy use (or other) information required by the governments of all other nations?

II. Discussion of Comments

The Commission received four comments in response to the NPR.² Three comments were from manufacturers of major household appliances,³ and one was from a trade association representing manufacturers.⁴ All the comments supported the proposed amendments.

A. Amending the Rule To Permit Placement of Canadian and Mexican Energy Use Labels in Close Proximity to the EnergyGuide

AHAM and Whirlpool agreed with the Commission that the proposed amendments would promote the intent of NAFTA to facilitate the free flow of commerce across North American international boundaries.⁵ AHAM, White, and Wood agreed that the proposed amendments would benefit appliance manufacturers until the Commission's Rule could be harmonized with the energy use regulations of Canada and Mexico.⁶ These comments commended the Commission for its continuing efforts at harmonization and its goal of developing a single energy use label that meets the requirements of all three NAFTA signatories.⁷

AHAM, Whirlpool, and Wood stated that the proposed amendments would enable manufacturers to comply with the Rule more efficiently and economically.⁸ Wood explained:

Allowing the placement of any two or all three of the energy labels on applicable models side by side, above and below or on a single label or hang tag will allow our company to reduce the number of [stock-keeping units] required to be built and tracked. The reason for this is that a great many of the appliances going to Canada and Mexico are identical to that produced for the domestic market, with the only difference being the energy' label. In order to build this change on the production line and keep track

²The comments are found on the Public Record at the Federal Trade Commission in Washington, D.C., under Rulemaking Record Number R611004 (Appliance Labeling Rule). They are numbered B19229500001-B19229500004. The numerical prefix "B192295" identifies the comments as being in response to the NPR. In this notice, the comments are cited by an identification of the commentor, the last two digits of the comment number, and the relevant page number(s), e.g., "Whirlpool, 02, 2-3." The four comments were from: The Association of Home Appliance Manufacturers ("AHAM, 01"); The Whirlpool Corporation ("Whirlpool, 02"); White Consolidated Industries, Inc. ("White, 03"); and, W.C. Wood Company, Inc. ("Wood, 04").

³Wood, 04; Whirlpool, 02; White, 03.

⁴AHAM, 01.

⁵AHAM, 01, 2; Whirlpool, 02, 1.

⁶AHAM, 01, 2; White, 03, 1; Wood, 04, 2.

⁷*Id.*

⁸AHAM, 01, 1-2; Whirlpool, 02, 1, 3; Wood, 04, 1.

of the 'energy' label through the warehouse and distribution chain, a separate and unique model is built.

The appliance industry is a very competitive market and with NAFTA it is a very competitive North American market. A relaxation in the current labeling rules will provide our company with real economic benefits.⁹

B. Would the Proposed Amendments Be Likely To Result in Consumer Confusion or Detraction From the EnergyGuide?

The comments unanimously concluded that placement of Canadian and/or Mexican energy use labels next to the EnergyGuide would not detract from the Commission's label and would not confuse consumers.¹⁰ Whirlpool's reasoning was representative of all the comments:

The primary energy descriptors are identical for all three nations and the U.S. label is the only one written entirely in English. Also, the FTC label notes that energy consumption estimates are based on U.S. government standard tests. Furthermore, we submit that consumers are becoming more and more sophisticated in quickly identifying the differences in instructional and point of purchase labels since an increasing number of such materials are being written in multilingual script to accommodate world marketing trends.¹¹

C. Should the Proposed Amendments Be Limited To Apply Only to Energy Use Labels? Should the Proposed Amendments Be Limited To Apply Only to Information Required by the Canadian and Mexican Governments?

All four comments agreed that the proposed amendments should apply only to energy use disclosure labels.¹² They reasoned that too many unrelated labels next to the EnergyGuide would detract from its message and cause information overload and confusion. As suggested by White, other information may be more appropriate communicated in care and use manuals:

[We] urge that the content remain energy information only, consistent with the familiar Energy Guide. Diverse information detracts from the important energy information and the industry guards against the appliance becoming a "billboard." Literature included with the appliance and intended as a continuous guide for safe use and maintenance is more appropriate for including other information.¹³

Moreover, as AHAM pointed out, some safety and environmental disclosures are voluntary in some of the

⁹Wood, 04, 1.

¹⁰AHAM, 01, 3, 4; Whirlpool, 02, 2; White, 03, 1; Wood, 04, 2.

¹¹Whirlpool, 02, 2.

¹²AHAM, 01, 3-4; Whirlpool, 02, 1-2; White, 03, 1; Wood, 04, 2.

¹³White, 03, 1.

countries, and mandatory in others, while energy use information is required by law in all three.¹⁴

Whirlpool suggested that the proposed amendments be expanded to apply to the energy use labels required by countries in Europe, Latin America, and Asia, in addition to Canada and Mexico, even though total harmonization of labels of all the countries in these areas may be decades away. In support of this proposal, Whirlpool stated that the Commission should take the lead in permitting multinational labeling to avoid future conflicts as the appliance industry markets its products worldwide. Whirlpool provided regulatory language with its comment that would accomplish this end.¹⁵

AHAM, advocated a more conservative approach, stating:

There will likely come a time when a common international "energy use disclosure" is appropriate and desired, as U.S. product exports increase to countries throughout the world. However, at this time, AHAM does not recommend other countries' information be permitted in conjunction with the EnergyGuide label.¹⁶

The Commission agrees with AHAM in this regard. While there may be sufficient similarity between the Commission's Rule and the labeling requirements of other nations at some future time to justify including them in this section of the Rule, the present record does not contain evidence to justify an expansion of the proposed amendments as Whirlpool has suggested.

III. Conclusion

The record contains unanimous support for the proposed amendments. Moreover, with the exception of Whirlpool's suggestion to allow the placement of the energy use labels of other countries, in addition to those of Canada and Mexico, "on or directly adjoining" the EnergyGuide, the record also supports the form and language of the proposed amendments as they appear in the NPR. The Commission, therefore, amends the Appliance Labeling Rule as proposed in the NPR. Manufacturers are still prohibited from placing other information on or directly adjoining the EnergyGuide.

Section A—Regulatory Flexibility Act

In the NPR, the Commission concluded, on a preliminary basis, that the provisions of the Regulatory Flexibility Act relating to an initial

Regulatory Flexibility Act analysis (5 U.S.C. 603–604) were not applicable to this proceeding because the amendments, if promulgated, would not have a "significant economic impact on a substantial number of small entities" (5 U.S.C. 605). The Commission concluded, therefore, that a regulatory flexibility analysis was not necessary.

To determine whether a final regulatory flexibility analysis would be necessary, however, in the NPR the Commission requested information on whether the proposed amendments would have a significant impact on a substantial number of small entities. No comments were received on this issue.

In light of the above, and because the amendments do not impose any new obligations on entities regulated by the Appliance Labeling Rule, the Commission certifies, under Section 605 of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that the amendments announced today will not have a significant impact on a substantial number of small entities.

Section B—Paperwork Reduction Act

In the NPR, the Commission stated that the amendments would not expand the Appliance Labeling Rule's existing recordkeeping and reporting requirements, and that the Commission, therefore, was not requesting that the Office of Management and Budget adjust the existing clearance for the Appliance Labeling Rule (OMB No. 3084–0069) under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). To substantiate the accuracy of its reporting burden estimate, however, the Commission requested comment on the extent of the reporting and recordkeeping burden associated with the amendments.

The Commission received one comment on this issue. Whirlpool agreed with the Commission's conclusion that the amendments would not expand existing recordkeeping and reporting requirements. Whirlpool stated, "In fact, granting of this proposal would reduce recordkeeping and reporting among the regulated community."¹⁷

Accordingly, the Commission reaffirms its prior determination that the amendments do not alter the Rule's recordkeeping or reporting requirements and that they do not, therefore, require OMB clearance.

Text of Amendments

For the reasons discussed above, the Commission amends 16 CFR Part 305 to permit (but not require) appliance manufacturers to place the energy use

disclosure labels required by the governments of Canada and Mexico in a location directly adjoining the Commission's EnergyGuide, as follows below:

List of Subjects in 16 CFR Part 305

Advertising, Energy conservation, Household appliances, Labeling, Reporting and recordkeeping requirements.

PART 305—[AMENDED]

1. The authority citation for Part 305 continues to read as follows:

Authority: 42 U.S.C. 6294.

2. Section 305.11(a)(5)(i)(K), (a)(5)(ii)(I), and (a)(5)(iii)(H)(I) are revised to read as follows:

§ 305.11 Labeling for covered products.

- (a) * * *
- (5) * * *
- (i) * * *

(K) No marks or information other than that specified in this Part shall appear on or directly adjoining this label, except a part or publication number identification may be included on this label, as desired by the manufacturer, and the energy use disclosure labels required by the governments of Canada or Mexico may appear directly adjoining this label, as desired by the manufacturer. If a manufacturer elects to use a part or publication number, it must appear in the lower right-hand corner of the label and be set in 6-point type or smaller.

- (ii) * * *

(I) No marks or information other than that specified in this Part shall appear on or directly adjoining this label, except a part or publication number identification may be included on this label, as desired by the manufacturer, and the energy use disclosure labels required by the governments of Canada or Mexico may appear directly adjoining this label, as desired by the manufacturer. If a manufacturer elects to use a part or publication number, it must appear in the lower right-hand corner of the label and be set in 6-point type or smaller.

* * * * *

- (iii) * * *

- (H) * * *

(I) No marks or information other than that specified in this Part shall appear on or directly adjoining this label, except a part or publication number identification may be included on this label, as desired by the manufacturer, and the energy use disclosure labels required by the governments of Canada or Mexico may appear directly adjoining this label, as

¹⁴ AHAM, 01, 4.

¹⁵ Whirlpool, 02, 2.

¹⁶ AHAM, 01, 4.

¹⁷ Whirlpool, 02, 3.

desired by the manufacturer. If a manufacturer elects to use a part or publication number, it must appear in the lower right-hand corner of the label and be set in 6-point type or smaller.

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

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

BILLING CODE 6750-01-M

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