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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier A. Corbin

Food and Drug Administration

[Docket No. 02P-0462]

Food Labeling: Nutrient Content Claims; Implied Nutrient Content Claim in the Brand Name CARBOLITE; Availability of Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a petition submitted by Carbolite Foods, Inc. (the petitioner), for the use of an implied nutrient content claim in their brand name CARBOLITE.

DATES: Submit written or electronic comments on the petition by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. The petition is available for review at the Dockets Management Branch or electronically on the agency's Web site at <http://www.fda.gov/ohrms/dockets>. You also may request a copy of the petition from the Dockets Management Branch.

FOR FURTHER INFORMATION CONTACT: Constance Henry, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD, 20740-3835, 301-436-1450.

SUPPLEMENTARY INFORMATION:**I. Background**

Section 403(r)(4)(A)(iii) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)(A)(iii)), provides that any person may petition the Secretary of Health and Human Services (and by delegation FDA) for permission to use an implied claim characterizing the level of a nutrient (nutrient content claim) in a brand name. Under § 101.69(o)(3) (21 CFR 101.69(o)(3)), FDA will publish a notice of the petition in the **Federal Register** announcing its availability to the public and seeking comment on the petition. Within 100 days of the date of receipt of a petition accepted for review, FDA will notify the petitioner by letter of its decision to: (1) Grant the petitioner permission to use the proposed brand name, if such use is not misleading, specifying any conditions or limitations on such use, or (2) deny the petition, stating the reasons for the denial.

FDA must grant the petition if it finds that the petitioned claim is not misleading and is consistent with terms defined by regulation under section 403(r)(2)(A)(i) of the act. If FDA fails to notify the petitioner of its decision to grant or deny the petition within the 100-day period, the petition shall be considered to be granted. We have determined this 100-day deadline to be January 15, 2003.

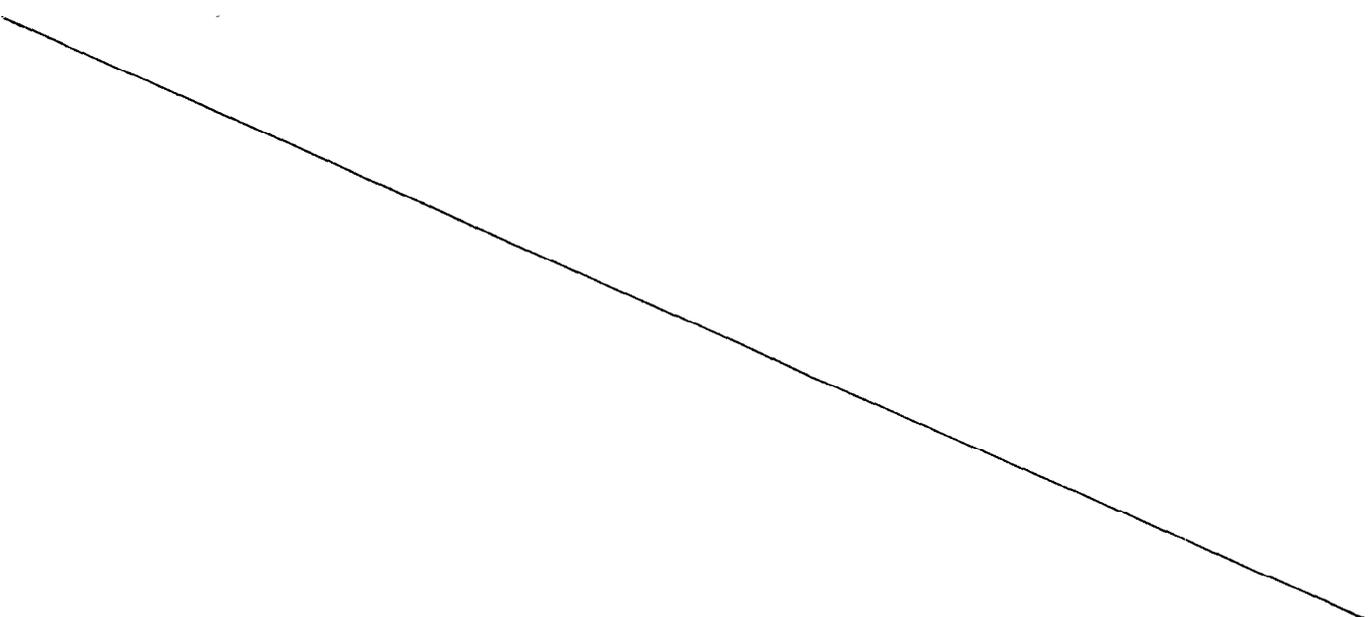
II. Nutrient Content Claim in a Brand Name Petition

Carbolite Foods, Inc., submitted a petition to FDA on October 7, 2002, under section 403(r)(4)(A)(iii) of the act (§ 101.69(o)) seeking permission to use its brand name CARBOLITE as an implied nutrient content claim in a brand name.

In accordance with § 101.69(o), Carbolite’s petition for a nutrient content claim in a brand name must identify the implied nutrient content claim for CARBOLITE, the nutrient the claim is intended to characterize (sugar), the corresponding term for characterizing the level of such nutrient as defined by a regulation under section 403(r)(2)(A)(i) of the act (“zero sugar” (also referred to as “sugar free” and defined in 21 CFR 101.60(c)(1)) and “reduced sugar” (defined in 21 CFR 101.60(c)(5))), and the brand name of which the implied claim is intended to be a part—CARBOLITE. The petition states that the petitioner seeks permission “to use the company brand name ‘CARBOLITE’ for its line of ‘zero sugar’ and ‘reduced sugar’ food products.”

III. Comments

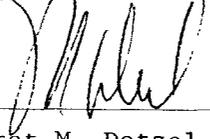
You may submit written or electronic comments to the Dockets Management Branch (see **ADDRESSES**). Groups or organizations must submit two copies of any mailed comments. Individuals may submit one copy of their comments. Submit only one copy of your comment if submitting an electronic comment. Identify your written or electronic comments with the docket



number found in brackets in the heading of this document. The petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 12/3/02

December 3, 2002.



Margaret M. Dotzel,
Assistant Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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