DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003P–0313]

Canned Tuna Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Bumble Bee Seafoods, Inc., to market test a product designated as ''Bumble Bee Chunk Light Tuna 'Touch of Lemon' in water, with natural lemon flavor'' that deviates from the U.S. standard of identity for canned tuna. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

DATES: This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than Novemeber 3, 2003.

FOR FURTHER INFORMATION CONTACT: Linda McCollum, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Bumble Bee Seafoods, Inc., P.O. Box 85362, 9655 Granite Ridge Dr., suite 100, San Diego, CA 92123.

The permit covers limited interstate marketing tests of products identified as ''Bumble Bee Chunk Light Tuna 'Touch of Lemon' in water, with natural lemon flavor'' that deviate from the U.S. standard of identity for canned tuna (21 CFR 161.190) in that lemon juice and lemon oil will be used as flavoring ingredients instead of lemon oil and citric acid. Also, the product will be labeled ''in water, with natural lemon flavor'' rather than ''lemon flavored chunk light tuna.'' In all other respects, the test product will conform to the standard for canned tuna. The purpose of this permit is to test the product throughout the United States.

This permit provides for the temporary marketing of approximately 20,000 tons (20,321,200 kilograms) of product packaged in 1.9 million cases. The test product will be manufactured by Bumble Bee Seafoods, Inc., 13100 Arctic Circle, Santa Fe Springs, CA 90670; and at Bumble Bee International, Inc., Malecon Industrial Zone, Jose Gonzalez Clemente Ave., Rd. 341 Km 4.5, Mayaguez, PR 00680. The product will be distributed throughout the United States.

The information panel of the labels will bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the labels as required by the applicable sections of 21 CFR part 101. This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than November 3, 2003.

Dated: July 21, 2003.

Christine Taylor,

Director, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Peripheral and Central Nervous System Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 24 and 25, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda MD, 301–652–2000.

Contact Person: Anuja Patel, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, or e-mail: *patelA@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800-741–8138 (301–443–0572 in the Washington, DC area), code 12543. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 24, 2003, the committee will discuss new drug application (NDA) 21–487, memantine hydrochloride, Forest Laboratories, Inc., indicated for the treatment of moderate to severe dementia of the Alzheimer's type. On September 25, 2003, the committee will discuss NDA 20–717, Provigil (modafinil) Tablets, Cephalon, Inc., indicated for use to improve wakefulness in patients with excessive sleepiness associated with disorders of sleep and wakefulness.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 15, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 15, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Angie Whitacre at 301–827–7001 at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 25, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–19657 Filed 8–1–03; 8:45 am]

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