TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

| 21 CFR Section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeper | Total hours |
|---|---|---|---|---|---|
| 226.102 | 65 | 260 | 16,900 | 1.75 | 29,575 |
| 226.110 | 65 | 260 | 16,900 | 0.25 (15 minutes) | 4,225 |
| 226.115 | 65 | 10 | 650 | 0.5 (30 minutes) | 325 |
| Total | | | | | 89,050 |

[1] There are no capital costs or operating and maintenance costs associated with this collection.

The estimate of time required for record preparation and maintenance is based on previous Agency communications with industry. Other information needed to calculate the total burden hours (i.e., manufacturing sites, number of Type A medicated articles being manufactured, etc.) are derived from Agency records and experience.

Dated: June 16, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–14471 Filed 6–19–14; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–D–0663]**

### Draft Guidance for Industry: Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products'' dated June 2014. The draft guidance document provides investigational new drug application (IND) sponsors and applicants for a biologics license application (BLA), or a supplement to a BLA, with recommendations on considerations when assessing whether to submit an Environmental Assessment (EA) for gene therapies, vectored vaccines, and related recombinant viral or microbial products (GTVVs). The guidance also contains recommendations as to what information should be included in an EA and what sponsors and applicants can expect once an EA is filed. The guidance, when finalized, will supplement the guidance entitled ''Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications,'' dated July 1998 (1998 Guidance) and will also supersede those recommendations for GTVVs in section IV.B.1 Assessing Toxicity to Environmental Organisms'' of the guidance.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 18, 2014.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products'' dated June 2014. The draft guidance document provides IND sponsors and applicants for a BLA, or a supplement to a BLA, with recommendations on considerations when assessing whether to submit an EA for GTVVs. The guidance also contains recommendations as to what information should be included in an EA and what sponsors and applicants can expect once an EA is filed. Products addressed in the guidance include all GTVVs, but not live-attenuated viral or microbial vaccines created by traditional methods such as serial passaging or recombinant protein-based vaccines. The guidance, when finalized, will supplement the 1998 Guidance, and will also supersede those recommendations for GTVVs in section IV.B.1 entitled ''Assessing Toxicity to Environmental Organisms'' of the guidance.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

#### II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 25 have been approved under OMB control number 0910–0322; the collections of

information in 21 CFR part 312 have been approved under OMB control number 0910–0014; and the collections of information for 21 CFR part 601 have been approved under OMB control number 0910–0338.

### III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

### IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: June 16, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–14470 Filed 6–19–14; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–P–1189]**

### 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 or we) received applications for temporary permits from Bumble Bee Foods, LLC; Chicken of the Sea International; and StarKist Seafood Company (the applicants). We are announcing that we have issued temporary permits to the applicants to market test products (designated as ''canned tuna'' products) that deviate from the U.S. standard of identity for canned tuna. The purpose of the temporary permits is to market test the product throughout the United States and the Commonwealth of Puerto Rico. The permits will allow the applicants to measure consumer acceptance of the products and assess the commercial feasibility of the products.

**DATES:** These permits are effective for 15 months, beginning on the date each applicant introduces or causes the introduction of the test products into interstate commerce, but not later than September 18, 2014.

**FOR FURTHER INFORMATION CONTACT:** Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371.

**SUPPLEMENTARY INFORMATION:** We have issued a temporary permit to each of the following applicants: Bumble Bee Foods, LLC; Chicken of the Sea International; and StarKist Seafood Company. We are issuing these temporary permits in accordance with 21 CFR 130.17, which addresses temporary permits for interstate shipment of experimental packs of food varying from the requirements of standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

These permits cover limited interstate marketing tests of products identified as ''canned tuna.'' These test products deviate from the U.S. standard of identity for canned tuna (21 CFR 161.190) in that they are labeled without the statement ''Below Standard in Fill'' as required in § 161.190(c)(4) and 21 CFR 130.14(b). The test products meet all the requirements of the standard with the exception of this deviation.

The purpose of these temporary permits is to market test the product throughout the United States and the Commonwealth of Puerto Rico. These permits will allow the applicants to measure customer acceptance of the products and assess commercial feasibility of the products.

Table 1 lists the amount of product for distribution and the manufacturers of the products for each of the applicants. The retail cans for the products are of various sizes.

TABLE 1—AMOUNT, MANUFACTURER, AND LOCATION BY APPLICANT

| Applicant | Amount of canned tuna for distribution | Manufacturer and location |
|---|---|---|
| Bumble Bee Foods, LLC, 9655 Granite Ridge Dr., San Diego, CA 92123. | 141,000,000 pounds (lbs) (63,800,905 kilograms (kgs)). | Asian Alliance, 8/8 Moo 3, Rama 2 Rd., Bunbor, Muang, Samutsakorn 74000, Thailand.<br>Chicken of the Sea Georgia Canning, 129 North Commerce Dr., Lyons, GA 30436.<br>Bumble Bee Seafoods, Inc., 13100 Arctic Circle, Santa Fe Springs, CA 90670.<br>Chotiwat Manufacturing Co., 84/22 Moo 7, Asia Highway Rd. #43, P.O. Box 37, T. Korhong, Hatyai Songkhla, Thailand 90110.<br>Gentuna (GTC/Century), P.O. Tambler, General Santos City, South Cotabato, Philippines 9500.<br>I.S.A. Value Co., Ltd. (Narong), 101/6 Mu 6, Soi Muangsakul Road, Samaedam, Bangkhutien, Bangkok 10150, Thailand.<br>Pataya Foods, 90/6 Tambol Tarsai, Muang, Samutprakarn, Pataya, Thailand.<br>PT Aneka Tuna, Jalan Raya Surabaya-Malang Km. 38, Gempol, Pasuruan 67155 Jawa Timur.<br>R.S. Cannery Co., Ltd., 255/1 Industrial Soi 3, Industrial Estate, Samutprakarn 10280, Thailand. |