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DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

Date: _____ (MONTH/DAY/YEAR)

Section 1 - TYPE OF REGISTRATION

1a. ❑ **DOMESTIC REGISTRATION** ❑ **FOREIGN REGISTRATION**

1b. ❑ **INITIAL REGISTRATION**

❑ **UPDATE OF REGISTRATION INFORMATION**
Provide the facility registration number: _____

Check all that apply below and further identify changes in the applicable sections.

❑ **Facility Name/Address Change**	❑ **Seasonal Facility Dates of Operation Change**
❑ **Preferred Mailing Address Change**	❑ **Establishment Type Change**
❑ **Parent Company Change**	❑ **Warehouse Storage Type Change**
❑ **Emergency Contact Change**	❑ **Human Food Product Category Change**
❑ **Trade Name Change**	❑ **Animal Food Product Category Change**
❑ **United States Agent Change - Foreign Countries only**	❑ **Owner, Operator, or Agent in Charge Change**

Section 2 - FACILITY NAME / ADDRESS INFORMATION

FACILITY NAME:	
FACILITY STREET ADDRESS:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (If a foreign facility, include Area & Country Codes):
FAX NUMBER (If available; if a foreign facility, include Area & Country Codes):	E-MAIL ADDRESS (if available):

Section 3 - OPTIONAL: PREFERRED MAILING ADDRESS INFORMATION
(only complete this section if different from Section 2, Facility Name/Address Information)

NAME:	
ADDRESS:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (If a foreign facility, include Area & Country Codes):
FAX NUMBER (If available; if a foreign facility, include Area & Country Codes):	E-MAIL ADDRESS:

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Section 4 - PARENT COMPANY NAME / ADDRESS INFORMATION (IF APPLICABLE)	
NAME OF PARENT COMPANY:	
STREET ADDRESS OF PARENT COMPANY:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (If a foreign facility, include Area & Country Codes):
FAX NUMBER (If available; if a foreign facility, include Area & Country Codes):	E-MAIL ADDRESS (if available):

Section 5 - FACILITY EMERGENCY CONTACT INFORMATION	
INDIVIDUAL'S NAME:	
TITLE:	OFFICE PHONE (If a foreign facility, include Area & Country Codes):
HOME PHONE (If a foreign facility, include Area & Country Codes):	CELL PHONE (if available; if a foreign facility, include Area & Country Codes):
E-MAIL ADDRESS (if available):	

Section 6 - TRADE NAMES (IF THIS FACILITY USES TRADE NAMES OTHER THAN THAT LISTED IN SECTION 2 ABOVE, LIST THEM BELOW (E.G., "ALSO DOING BUSINESS AS," "FACILITY ALSO KNOWN AS"):
ALTERNATE TRADE NAME #1:
ALTERNATE TRADE NAME #2:

Section 7 - UNITED STATES AGENT (TO BE COMPLETED BY FACILITIES LOCATED OUTSIDE ANY STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO.)	
NAME OF UNITED STATES AGENT:	
TITLE:	
ADDRESS:	
CITY:	STATE:
ZIP CODE:	COUNTRY:
PHONE NUMBER (include Area Code):	
FAX NUMBER (if available; include Area Code):	
E-MAIL ADDRESS (if available):	

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Section 8 - OPTIONAL: SEASONAL FACILITY DATES OF OPERATION

(GIVE THE APPROXIMATE DATES THAT YOUR FACILITY IS OPEN FOR BUSINESS, IF ITS OPERATIONS ARE ON A SEASONAL BASIS)

DATES OF OPERATION:

Section 9 - OPTIONAL: ESTABLISHMENT TYPES

(CHECK **ALL** TYPES OF OPERATIONS THAT ARE PERFORMED AT THIS FACILITY REGARDING THE MANUFACTURING, PROCESSING, PACKING OR HOLDING OF FOOD)

❑ Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)
NOTE: If the facility is a warehouse / holding facility only, ***go to Section 10 (solely warehouse / holding facility) and check all that apply.***

❑ Acidified / Low Acid Food Processor	❑ Labeler / Relabeler
❑ Interstate Conveyance Caterer/Catering Point	❑ Manufacturer / Processor
❑ Molluscan Shellfish Establishment	❑ Repacker / Packer
❑ Commissary	❑ Salvage Operator (Reconditioner)
❑ Contract Sterilizer	❑ Animal food manufacturer / processor / holder

Section 10 - OPTIONAL: IF YOUR FACILITY IS *SOLELY* A WAREHOUSE / HOLDING FACILITY, COMPLETE THIS SECTION; ALL OTHER FACILITIES, COMPLETE SECTION 11 (human or animal product categories) INSTEAD OF THIS SECTION.

❑ Ambient Storage (including heated storage)	❑ Refrigerated Storage	❑ Frozen Storage

Section 11 - GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION

To be completed by all human food facilities except those that are solely warehouses.
[Note: Categories are derived from the Product Code Builder (www.fda.gov/search/databases.html), with cross-references to the categories found under 21 CFR 170.3. Please see instructions for further examples.]

❑ 1. ALCOHOLIC BEVERAGES
[21 CFR 170.3 (n) (2)]

❑ 2. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula (Optional Selection)

❑ 3. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS
[21 CFR 170.3 (n) (1), (9)]

❑ 4. BEVERAGE BASES
[21 CFR 170.3 (n) (3), (16), (35)]

❑ 5. CANDY WITHOUT CHOCOLATE, CANDY SPECIALITIES & CHEWING GUM
[21 CFR 170.3 (n) (6), (9), (25), (38)]

❑ 6. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING/INSTANT CEREALS
[21 CFR 170.3 (n) (4)]

❑ 7. CHEESE AND CHEESE PRODUCTS
[21 CFR 170.3 (n) (5)]

❑ 8. CHOCOLATE AND COCOA PRODUCTS
[21 CFR 170.3 (n) (3), (9), (38), (43)]

❑ 9. COFFEE AND TEA
[21 CFR 170.3 (n) (3), (7)]

❑ 10. COLOR ADDITIVES FOR FOODS
[21 CFR 170.3 (o) (4)]

❑ 25. MULTIPLE FOOD DINNERS, GRAVIES, SAUCES AND SPECIALTIES [21 CFR 170.3 (n) (11), (14), (17), (18), (23), (24), (29), (34), (40)]

❑ 26. NUT AND EDIBLE SEED PRODUCTS
[21 CFR 170.3 (n) (26), (32)]

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❑ 11. DIETARY CONVENTIONAL FOODS OR MEAL REPLACEMENTS (includes Medical Foods) [21 CFR 170.3 (n) (31)]

12. DIETARY SUPPLEMENTS

❑ Proteins, Amino Acids, Fats and Lipid Substances [21 CFR 170.3 (o) (20)]
❑ Vitamins and Minerals [21 CFR 170.3 (o) (20)]
❑ Animal By-Products and Extracts (Optional Selection)
❑ Herbals and Botanicals (Optional Selection)

❑ 13. DRESSINGS AND CONDIMENTS [21 CFR 170.3 (n) (8), (12)]

❑ 14. FISHERY/SEAFOOD PRODUCTS [21 CFR 170.3 (n) (13), (15), (39), (40)]

❑ 15. SUBSTANCES THAT MIGRATE INTO FOOD FROM FOOD PACKAGING AND OTHER ARTICLES THAT CONTACT FOOD (Optional Selection)

❑ 16. FOOD ADDITIVES, GENERALLY RECOGNIZED AS SAFE (GRAS) INGREDIENTS, OR OTHER INGREDIENTS USED FOR PROCESSING [21 CFR 170.3 (n) (42); 21 CFR 170.3 (o) (1), (2), (3), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (22), (23), (24), (25), (26), (27), (28), (29), (30), (31), (32)

❑ 17. FOOD SWEETENERS (NUTRITIVE) [21 CFR 170.3 (n) (9), (41), 21 CFR 170.3 (o) (21)]

❑ 18. FRUITS AND FRUIT PRODUCTS [21 CFR 170.3 (n) (16), (27), (28), (35), (43)]

❑ 19. GELATIN, RENNET, PUDDING MIXES, OR PIE FILLINGS [21 CFR 170.3 (n) (22)]

❑ 20. ICE CREAM AND RELATED PRODUCTS [21 CFR 170.3 (n) (20), (21)]

❑ 21. IMITATION MILK PRODUCTS [21 CFR 170.3 (n) (10)]

❑ 22. MACARONI OR NOODLE PRODUCTS [21 CFR 170.3 (n) (23)]

❑ 23. MEAT, MEAT PRODUCTS AND POULTRY (FDA REGULATED) [21 CFR 170.3 (n) (17), (18), (29), (34), (39), (40)]

❑ 24. MILK, BUTTER, OR DRIED MILK PRODUCTS [21 CFR 170.3 (n) (12), (30), (31)]

❑ 28. SHELL EGG AND EGG PRODUCTS [21 CFR 170.3 (n) (11), (14)]

❑ 29. SNACK FOOD ITEMS (FLOUR, MEAL OR VEGETABLE BASE) [21 CFR 170.3 (n) (37)]

❑ 30. SPICES, FLAVORS, AND SALTS [21 CFR 170.3 (n) (26)]

❑ 31. SOUPS [21 CFR 170.3 (n) (39), (40)]

❑ 32. SOFT DRINKS AND WATERS [21 CFR 170.3 (n) (3), (35)]

❑ 33. VEGETABLES AND VEGETABLE PRODUCTS [21 CFR 170.3 (n) (19), (36)]

❑ 34. VEGETABLE OILS (INCLUDES OLIVE OIL) [21 CFR 170.3 (n) (12)]

❑ 35. VEGETABLE PROTEIN PRODUCTS (SIMULATED MEATS) [21 CFR 170.3 (n) (33)]

❑ 36. WHOLE GRAINS, MILLER GRAIN PRODUCTS (FLOURS), OR STARCH [21 CFR 170.3 (n) (1), (23)]

❑ 37. MOST/ALL HUMAN FOOD PRODUCT CATEGORIES (Optional Selection)

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Section 11a - OPTIONAL GENERAL PRODUCT CATEGORIES – FOOD FOR ANIMAL CONSUMPTION

- ❑ 1. GRAIN PRODUCTS (E.G., BARLEY, GRAIN SORGHUMS, MAIZE, OAT, RICE, RYE AND WHEAT)
- ❑ 2. OILSEED PRODUCTS (E.G., COTTONSEED, SOYBEANS, OTHER OIL SEEDS)
- ❑ 3. ALFALFA AND LESPEDEZA PRODUCTS
- ❑ 4. AMINO ACIDS
- ❑ 5. ANIMAL-DERIVED PRODUCTS
- ❑ 6. BREWER PRODUCTS
- ❑ 7. CHEMICAL PRESERVATIVES
- ❑ 8. CITRUS PRODUCTS
- ❑ 9. DISTILLERY PRODUCTS
- ❑ 10. ENZYMES
- ❑ 11. FATS AND OILS
- ❑ 12. FERMENTATION PRODUCTS
- ❑ 13. MARINE PRODUCTS
- ❑ 14. MILK PRODUCTS
- ❑ 15. MINERALS
- ❑ 16. MISCELLANEOUS AND SPECIAL PURPOSE PRODUCTS
- ❑ 17. MOLASSES
- ❑ 18. NON-PROTEIN NITROGEN PRODUCTS
- ❑ 19. PEANUT PRODUCTS
- ❑ 20. RECYCLED ANIMAL WASTE PRODUCTS
- ❑ 21. SCREENINGS
- ❑ 22. VITAMINS
- ❑ 23. YEAST PRODUCTS
- ❑ 24. MIXED FEED (POULTRY, LIVESTOCK, AND EQUINE)
- ❑ 25. PET FOOD
- ❑ 26. MOST/ALL ANIMAL FOOD PRODUCT CATEGORIES

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DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

Section 12 - CERTIFICATION STATEMENT		
The owner, operator, or agent in charge of the facility must submit this form. *By submitting this form to FDA, the owner, operator, or agent in charge certifies that the above information is true and accurate and that the facility has authorized the submitter to register on its behalf. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.*		
PRINT NAME OF PERSON SUBMITTING THE REGISTRATION FORM		
PHONE NUMBER (If a foreign facility, include Area & Country Codes):	FAX NUMBER ((If available; **if a foreign facility, include Area & Country Codes):**	E-MAIL ADDRESS (if available):

FDA USE ONLY	
DATE REGISTRATION FORM RECEIVED	**DATE NOTIFICATION SENT TO FACILITY**

Public reporting burden for this collection of information is estimated to average between 1 and 12 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CFSAN (HFS-024)
5100 Paint Branch Parkway
College Park, MD 20740

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

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DHHS/FDA - CANCELLATION OF FOOD FACILITY REGISTRATION	
PROVIDE THE FACILITY REGISTRATION NUMBER:	
☐ **DOMESTIC REGISTRATION**	☐ **FOREIGN REGISTRATION**
FACILITY NAME / ADDRESS INFORMATION	
FACILITY NAME:	
FACILITY STREET ADDRESS:	
CITY:	**STATE:**
ZIP CODE (POSTAL CODE):	**PROVINCE/TERRITORY:**
COUNTRY:	
CERTIFICATION STATEMENT	
The owner, operator, or agent in charge of the facility must submit this form. *By submitting this form to FDA, the owner, operator, or agent in charge certifies that the above information is true and accurate and that the facility has authorized the submitter to cancel the registration on its behalf. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.*	
PRINT NAME OF PERSON SUBMITTING THE CANCELLATION FORM	
ADDRESS	**E-MAIL ADDRESS (IF AVAILABLE)**
FDA USE ONLY	
DATE CANCELLATION FORM RECEIVED	**DATE CONFIRMATION SENT TO FACILITY**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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[FR Doc. 03–2443 Filed 1–29–03; 1:47 pm]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 02N–0278]

RIN 0910–AC41

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing a regulation that would require U.S. purchasers or U.S. importers or their agents to submit to FDA prior notice of the importation of food. The proposed regulation implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which requires prior notification of imported food to begin by December 12, 2003. The Bioterrorism Act requires FDA to issue final regulations that specify the period of advance notice by this date or a statutory notice provision requiring not less than 8 hours prior notice and not more than 5 days prior notice will take effect until a final rule is issued.

DATES: Submit written or electronic comments by April 4, 2003. Submit written or electronic comments on the collection of information by March 5, 2003.

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. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, ATTN: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Mary Ayling, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2428.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background and Legal Authority

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Bioterrorism Act, which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in Title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A—Protection of Food Supply, section 307, which amends the Federal Food, Drug, and Cosmetic Act (the act) by adding section 801(m) (21 U.S.C. 381(m)). This new provision changes when FDA will receive certain information about imported foods by requiring the Secretary of Health and Human Services (the Secretary), after consultation with the Secretary of the Treasury, to issue implementing regulations by December 12, 2003, mandating prior notification to FDA of food that is imported or offered for import into the United States. Functions of the U.S. Customs Service (U.S. Customs) will soon be a part of the Department of Homeland Security (DHS). Future consultations may be with DHS instead of, or in addition to, the Department of Treasury.

Section 801(a) of the act sets out procedures for imports under FDA's jurisdiction. When an FDA-regulated product is imported or offered for import, generally brokers submit entry information to the U.S. Customs on behalf of the importers of record. U.S. Customs then provides entry information and may deliver samples to FDA to enable admissibility decisions to be made. Under U.S. Customs authorities, entry of the merchandise must be made within 15 days after importation.

U.S. Customs regulations provide for different kinds of entries. Commonly, merchandise is the subject of an entry for consumption (i.e., unrestricted, general use) under a basic importation and entry bond at the first port of arrival, but U.S. Customs authorities also allow for the entry of merchandise for transportation under a custodial bond from the port of arrival to another port where the consumption entry will be made. If no entry of any kind is made within 15 days, the article cannot move and the carrier or other authorized party must notify U.S. Customs and a general order (i.e., bonded or secure) warehouse that the article remains unentered. Generally, at that point, the article is moved to the bonded warehouse (or