

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 02N-0276]

[RIN 0910-AC40]

FMB

Display Date 3-5-03

Publication Date 3-6-03

Certifier R. LEDESMA

**Registration of Food Facilities Under the Public Health Security and  
Bioterrorism Preparedness and Response Act of 2002; Correction**

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

**ACTION:** Notice of proposed rulemaking; correction.

---

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice of proposed rulemaking that appeared in the **Federal Register** of February 3, 2003 (68 FR 5378). The document proposed a regulation that would require domestic and foreign facilities that manufacture, process, pack, or hold food for human and animal consumption in the United States to register with FDA by December 12, 2003. Due to a printing error, the document was published with inadvertent errors in the appendix. This document corrects those errors.

**FOR FURTHER INFORMATION CONTACT:** Joyce Strong, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 03-2443, <sup>on page 5378,</sup> appearing at page 5423 <sup>1</sup> in <sup>ms</sup> the Federal Register of Monday, February 3, 2003, the appendix, which is a draft food facility registration form, has several errors. For the convenience of the reader, we are republishing the appendix.

Dated: February 21, 2003  
February 21, 2003.



William K. Hubbard,  
Associate Commissioner for Policy and Planning.

Note: The following appendix will not appear in the Code of Federal Regulations.

[INSERT GLOSSY]

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S

VERIFIED TO BE A TRUE  
COPY OF THE ORIGINAL



## DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

Date: _____ (MONTH/DAY/YEAR)	
<b>Section 1 - TYPE OF REGISTRATION</b>	
1a. <input type="checkbox"/> DOMESTIC REGISTRATION	<input type="checkbox"/> FOREIGN REGISTRATION
1b. <input type="checkbox"/> INITIAL REGISTRATION	
<input type="checkbox"/> UPDATE OF REGISTRATION INFORMATION Provide the facility registration number: _____	
Check all that apply below and further identify changes in the applicable sections.	
<input type="checkbox"/> Facility Name/Address Change	<input type="checkbox"/> Seasonal Facility Dates of Operation Change
<input type="checkbox"/> Preferred Mailing Address Change	<input type="checkbox"/> Establishment Type Change
<input type="checkbox"/> Parent Company Change	<input type="checkbox"/> Warehouse Storage Type Change
<input type="checkbox"/> Emergency Contact Change	<input type="checkbox"/> Human Food Product Category Change
<input type="checkbox"/> Trade Name Change	<input type="checkbox"/> Animal Food Product Category Change
<input type="checkbox"/> United States Agent Change - Foreign Countries only	<input type="checkbox"/> Owner, Operator, or Agent in Charge Change
<b>Section 2 - FACILITY NAME / ADDRESS INFORMATION</b>	
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):
<b>Section 3 - OPTIONAL: PREFERRED MAILING ADDRESS INFORMATION</b> (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:

## DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

<b>Section 4 - PARENT COMPANY NAME / ADDRESS INFORMATION (IF APPLICABLE)</b>	
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):
<b>Section 5 - FACILITY EMERGENCY CONTACT INFORMATION</b>	
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):	
<b>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")):</b>	
ALTERNATE TRADE NAME #1:	
ALTERNATE TRADE NAME #2:	
<b>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.)</b>	
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):	

## DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

<b>Section 8 - OPTIONAL: SEASONAL FACILITY DATES OF OPERATION</b> (GIVE THE APPROXIMATE DATES THAT YOUR FACILITY IS OPEN FOR BUSINESS, IF ITS OPERATIONS ARE ON A SEASONAL BASIS)		
DATES OF OPERATION:		
<b>Section 9 - OPTIONAL: ESTABLISHMENT TYPES</b> (CHECK <b>ALL</b> TYPES OF OPERATIONS THAT ARE PERFORMED AT THIS FACILITY REGARDING THE MANUFACTURING, PROCESSING, PACKING OR HOLDING OF FOOD)		
<input type="checkbox"/> Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators) <b>NOTE:</b> If the facility is a warehouse / holding facility only, <b>go to Section 10 (solely warehouse / holding facility) and check all that apply.</b>		
<input type="checkbox"/> Acidified / Low Acid Food Processor	<input type="checkbox"/> Labeler / Relabeler	
<input type="checkbox"/> Interstate Conveyance Caterer/Catering Point	<input type="checkbox"/> Manufacturer / Processor	
<input type="checkbox"/> Molluscan Shellfish Establishment	<input type="checkbox"/> Repacker / Packer	
<input type="checkbox"/> Commissary	<input type="checkbox"/> Salvage Operator (Reconditioner)	
<input type="checkbox"/> Contract Sterilizer	<input type="checkbox"/> Animal food manufacturer / processor / holder	
<b>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.</b>		
<input type="checkbox"/> Ambient Storage ( including heated storage)	<input type="checkbox"/> Refrigerated Storage	<input type="checkbox"/> Frozen Storage
<b>Section 11 - GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION</b> To be <b>completed by all human food facilities</b> except those that are solely warehouses. <b>[Note: Categories are derived from the Product Code Builder (<a href="http://www.fda.gov/search/databases.html">www.fda.gov/search/databases.html</a>), with cross-references to the categories found under 21 CFR 170.3. Please see instructions for further examples.]</b>		
<input type="checkbox"/> 1. ALCOHOLIC BEVERAGES [21 CFR 170.3 (n) (2)]	<input type="checkbox"/> 6. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING/INSTANT CEREALS [21 CFR 170.3 (n) (4)]	
<input type="checkbox"/> 2. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula (Optional Selection)	<input type="checkbox"/> 7. CHEESE AND CHEESE PRODUCTS [21 CFR 170.3 (n) (5)]	
<input type="checkbox"/> 3. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS [21 CFR 170.3 (n) (1), (9)]	<input type="checkbox"/> 8. CHOCOLATE AND COCOA PRODUCTS [21 CFR 170.3 (n) (3), (9), (38), (43)]	
<input type="checkbox"/> 4. BEVERAGE BASES [21 CFR 170.3 (n) (3), (16), (35)]	<input type="checkbox"/> 9. COFFEE AND TEA [21 CFR 170.3 (n) (3), (7)]	
<input type="checkbox"/> 5. CANDY WITHOUT CHOCOLATE, CANDY SPECIALITIES & CHEWING GUM [21 CFR 170.3 (n) (6), (9), (25), (38)]	<input type="checkbox"/> 10. COLOR ADDITIVES FOR FOODS [21 CFR 170.3 (o) (4)]	

## DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

- |   |   |
|---|---|
| <input type="checkbox"/> 11. DIETARY CONVENTIONAL FOODS OR MEAL REPLACEMENTS (includes Medical Foods) [21 CFR 170.3 (n) (31)]   | <input type="checkbox"/> 25. MULTIPLE FOOD DINNERS, GRAVIES, SAUCES AND SPECIALTIES [21 CFR 170.3 (n) (11), (14), (17), (18), (23), (24), (29), (34), (40)] |
| <input type="checkbox"/> 12. DIETARY SUPPLEMENTS  | <input type="checkbox"/> 26. NUT AND EDIBLE SEED PRODUCTS [21 CFR 170.3 (n) (26), (32)]   |
| <input type="checkbox"/> Proteins, Amino Acids, Fats and Lipid Substances [21 CFR 170.3 (o) (20)]   | <input type="checkbox"/> 27. PREPARED SALAD PRODUCTS [21 CFR 170.3 (n) (11), (17), (18), (22), (29), (34), (35)]  |
| <input type="checkbox"/> Vitamins and Minerals [21 CFR 170.3 (o) (20)]  | <input type="checkbox"/> 28. SHELL EGG AND EGG PRODUCTS [21 CFR 170.3 (n) (11), (14)]   |
| <input type="checkbox"/> Animal By-Products and Extracts (Optional Selection)   | <input type="checkbox"/> 29. SNACK FOOD ITEMS (FLOUR, MEAL OR VEGETABLE BASE) [21 CFR 170.3 (n) (37)]   |
| <input type="checkbox"/> Herbals and Botanicals (Optional Selection)  | <input type="checkbox"/> 30. SPICES, FLAVORS, AND SALTS [21 CFR 170.3 (n) (26)]   |
| <input type="checkbox"/> 13. DRESSINGS AND CONDIMENTS [21 CFR 170.3 (n) (8), (12)]  | <input type="checkbox"/> 31. SOUPS [21 CFR 170.3 (n) (39), (40)]  |
| <input type="checkbox"/> 14. FISHERY/SEAFOOD PRODUCTS [21 CFR 170.3 (n) (13), (15), (39), (40)]   | <input type="checkbox"/> 32. SOFT DRINKS AND WATERS [21 CFR 170.3 (n) (3), (35)]  |
| <input type="checkbox"/> 15. SUBSTANCES THAT MIGRATE INTO FOOD FROM FOOD PACKAGING AND OTHER ARTICLES THAT CONTACT FOOD (Optional Selection)  | <input type="checkbox"/> 33. VEGETABLES AND VEGETABLE PRODUCTS [21 CFR 170.3 (n) (19), (36)]  |
| <input type="checkbox"/> 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)] | <input type="checkbox"/> 34. VEGETABLE OILS (INCLUDES OLIVE OIL) [21 CFR 170.3 (n) (12)]  |
| <input type="checkbox"/> 17. FOOD SWEETENERS (NUTRITIVE) [21 CFR 170.3 (n) (9), (41), 21 CFR 170.3 (o) (21)]  | <input type="checkbox"/> 35. VEGETABLE PROTEIN PRODUCTS (SIMULATED MEATS) [21 CFR 170.3 (n) (33)]   |
| <input type="checkbox"/> 18. FRUITS AND FRUIT PRODUCTS [21 CFR 170.3 (n) (16), (27), (28), (35), (43)]  | <input type="checkbox"/> 36. WHOLE GRAINS, MILLER GRAIN PRODUCTS (FLOURS), OR STARCH [21 CFR 170.3 (n) (1), (23)]   |
| <input type="checkbox"/> 19. GELATIN, RENNIN, PUDDING MIXES, OR PIE FILLINGS [21 CFR 170.3 (n) (22)]  | <input type="checkbox"/> 37. MOST/ALL HUMAN FOOD PRODUCT CATEGORIES (Optional Selection)  |
| <input type="checkbox"/> 20. ICE CREAM AND RELATED PRODUCTS [21 CFR 170.3 (n) (20), (21)]   |   |
| <input type="checkbox"/> 21. IMITATION MILK PRODUCTS [21 CFR 170.3 (n) (10)]  |   |
| <input type="checkbox"/> 22. MACARONI OR NOODLE PRODUCTS [21 CFR 170.3 (n) (23)]  |   |
| <input type="checkbox"/> 23. MEAT, MEAT PRODUCTS AND POULTRY (FDA REGULATED) [21 CFR 170.3 (n) (17), (18), (29), (34), (39), (40)]  |   |
| <input type="checkbox"/> 24. MILK, BUTTER, OR DRIED MILK PRODUCTS [21 CFR 170.3 (n) (12), (30), (31)]   |   |

## DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

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

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

## DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

Section 12 - CERTIFICATION STATEMENT		
<p><i>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.</i></p>		
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.