Instructions for Filling Out DHHS/FDA Forms 3537 and 3537a
Food Facility Registration and Registration Cancellation

Instructions for Form 3537
Food Facility Registration Form

NOTE: Form 3537 is used to register a food facility or to provide an update to an existing registration. If you wish to cancel a food facility registration, you must use Form 3537a. The owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must fill out, sign, and submit this form.

An individual (other than the owner, operator, or agent in charge of the facility) who submits this form to FDA must, in section 13 of the form (certification statement), identify by name the individual who authorized submission of the registration. Form 3537 must be signed and printed or typed with black or dark blue ink. If there is no information available for a specific block in a mandatory section, enter the words "Not Available," "N/A," or "None" in that block unless specified otherwise in these instructions. Do not make any entries or marks in the parts of the form designated "FDA USE ONLY". Some sections of the form contain a circle for making a selection. Check the circle when making a selection. All sections on these forms are mandatory unless described otherwise. Forms that are incomplete or illegible will not be processed and may considerably delay a requested action (such as issuance of a Food Facility Registration Number).

Date: Enter the date in the format MM/DD/YYYY. Example: 10/31/2003

Section 1 – TYPE OF REGISTRATION
Subsection 1a. Check the circle for only one of the two choices. Domestic means that the facility is located in any State or Territory of the U.S., in the District of Columbia, or in the Commonwealth of Puerto Rico. Foreign means all others.

Subsection 1b. -- INITIAL REGISTRATION
Check the circle for Initial Registration only if this is the first time you have registered this facility with FDA under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Subsection 1b. -- UPDATE OF REGISTRATION INFORMATION
If you are updating information for a Food Facility Registration, please provide the current Registration Number in the space provided. Enter the Personal Identification Number (PIN) that was provided upon receipt of the Food Facility Registration Number in the space marked PIN. A form submitting an update will not be processed without the appropriate Registration Number and PIN.

Subsection 1b. -- Update Information
Check the circle for each update that applies. If this is a new registration, leave this section blank.

Subsection 1c. -- NEW OWNER INFORMATION
If you are a new owner of a previously registered facility, you must re-register. Please provide the previous owner's name and registration number, if known.

Section 2 – FACILITY NAME/ADDRESS INFORMATION
Provide the requested information in the blocks provided. If the facility and address are already listed with the FDA for some other purpose, be sure to use the exact same facility name and address for Section 2.

Section 3 – PREFERRED MAILING ADDRESS INFORMATION (OPTIONAL)

If you prefer to be contacted at an address other than that of the facility, please print or type the requested information in the blocks provided in this section of the form.

Section 4 – PARENT COMPANY NAME/ADDRESS INFORMATION (IF APPLICABLE AND IF DIFFERENT FROM SECTIONS 2 AND 3)
Complete this section only if the food facility is owned by a parent company.

Section 5 – FACILITY EMERGENCY CONTACT INFORMATION (OPTIONAL FOR FOREIGN FACILITIES)
Domestic facilities must provide the information requested in this section. You must supply at least one telephone number. Providing an individual's name, title, and e-mail address is optional. For foreign facilities, FDA will assume that your U.S. agent is your emergency contact unless you provide alternative information in this section.

Section 6 – TRADE NAMES

"Trade name" is the name or names under which the facility conducts business, or additional names by which the facility is known. If your food facility uses a trade name other than the one listed in Section 2, please print or type the additional trade name(s) in this section. If your food facility does not have any other trade name, enter the word "None" in the appropriate blocks.

Section 7 – UNITED STATES AGENT
Foreign food facilities must have a U.S. Agent. The U.S. Agent must reside or maintain a place of business in the U.S. and be physically present in the U.S. Please print or type the information requested in this section. The U.S. agent's fax number and e-mail address are optional. A U.S. agent's emergency contact phone number must be provided unless the facility has designated an alternate emergency contact in section 5.

Section 8 – SEASONAL FACILITY DATES OF OPERATION (OPTIONAL)
If your food facility operates only during parts of the year, such as during the harvest season, you may enter the date ranges when the facility operates. Example: "Open June 1st through August 31st and October 1st through December 20th."

Section 9 – TYPE OF ACTIVITY CONDUCTED AT THE FACILITY (OPTIONAL)
You may fill in all of the circles that apply to your facility.

Section 10 – TYPE OF STORAGE (OPTIONAL)
This section applies to facilities that are primarily holders (facilities used for storage). You may check all of the circles that apply. If your facility is strictly a refrigerated, frozen, or ambient (neither frozen nor refrigerated) storage facility, you should check the appropriate circle. If more than one choice applies, you should check all that apply.

Section 11a – GENERAL PRODUCT CATEGORIES – FOOD FOR HUMAN CONSUMPTION
All food facilities must complete this section. Check all of the circles that apply to your facility. If you manufacture/process, pack, or hold food that fits into one or more of these categories, check the circle for each category of food manufactured/processed, packed or held at your facility. If none of these categories applies to your facility, select Item 37 (NONE OF THE ABOVE MANDATORY CATEGORIES). If your facility manufactures/processes, packs, or holds food in most or all of the categories in section 11a, you may select Item 36 "MOST/ALL HUMAN FOOD PRODUCT CATEGORIES" instead of selecting all applicable categories. Additional information and cross references can be found at http://www.fda.gov/search/databases.html#pcb (Product Code Builder).

Section 11b – GENERAL PRODUCT CATEGORIES – FOOD FOR ANIMAL CONSUMPTION (OPTIONAL) This section only applies to food for animals. You may check the circle for each category of animal food manufactured/processed, packed or held at your facility. If your facility manufactures/processes, packs, or holds food in most or all of the categories in section 11b, you may select Item 26, "MOST/ALL ANIMAL FOOD PRODUCT CATEGORIES" instead of selecting all applicable categories

Section 12 –OWNER, OPERATOR, OR AGENT IN CHARGE INFORMATION
If the contact information for the owner, operator, or agent in charge is the same as that in another section of the form, check the circle corresponding to that section; otherwise enter the information as requested. The fax number and e-mail address for the owner, operator, or agent in charge are optional.

Section 13 --CERTIFICATION STATEMENT
Either the owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must submit this form. By submitting the form to FDA, or by authorizing an individual to submit the form to FDA, the owner, operator, or agent in charge of the facility is certifying that the information contained in the form is true and accurate. If an individual authorized by the owner, operator, or agent in charge of the facility submits the form to FDA, that individual also certifies that the information contained in the form is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent in charge of the facility must identify in this section the name and contact information for the individual who authorized submission of the registration. Anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. government is subject to criminal penalties under 18 U.S.C 1001.

SIGNATURE: The submitter is required to sign this form in black or dark blue ink.

NAME OF PERSON SUBMITTING THE REGISTRATION FORM: Print or type the name of the submitter in this space.

CHECK ONE BOX: If the submitter is the owner, operator, or agent in charge, check circle A, "OWNER, OPERATOR, OR AGENT IN CHARGE." If the submitter is an individual authorized by the owner, operator, or agent in charge (such as an administrative employee), check circle B, "INDIVIDUAL AUTHORIZED TO SUBMIT THE REGISTRATION."

If you checked circle B, check either the circle, "Owner, operator, or agent in charge" if the owner, operator, or agent in charge authorized you to submit the registration, or the circle, "_____(name of individual who authorized registration on behalf of the owner, operator, or agent in charge)," if someone other than the owner, operator, or agent in charge authorized you to submit the registration. If you checked, "owner, operator, or agent in charge," you are finished with the form. If you checked, "_____(name of individual who authorized registration on behalf of the owner, operator, or agent in charge), complete the name and address information for the individual who authorized you to submit the registration on behalf of the owner, operator, or agent in charge. The fax number and e-mail address for that individual are optional.

Do not mail these instructions back to the FDA with your form. Keep them with your records.

Mail completed Form 3537 to U.S. Food and Drug Administration, HFS-681, 5600 Fishers Lane, Rockville, MD 20857, or FAX it to (301) 210-0247.

Instructions for Form 3537a
Cancellation of Food Facility Registration Form

NOTE: You must use Form 3537a to cancel a food facility registration. If you wish to submit a registration or provide an update to an existing registration, you must use Form 3537. The owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must fill out, sign, and submit this form.

An individual (other than the owner, operator, or agent in charge of the facility) who submits this form to FDA must complete the certification statement. The certification statement section requires the name of the individual who authorized submission of the cancellation. This form must be signed and printed or typed with black or dark blue ink. Do not make any entries or marks in the parts of the form designated "FDA USE ONLY". If there is no information available for a specific block in a mandatory section, enter the words "Not Available", "N/A", or "None" in that block unless specified otherwise in these instructions. Some sections of the form contain a circle for making a choice or selection. Check the circle when making a choice or selection. All sections on these forms are mandatory unless described otherwise.

REGISTRATION NUMBER: The first entry on Form 3537a is the Facility Registration Number. Print or type it in the appropriate block.

PIN NUMBER: Provide the PIN number that you obtained when you registered.

FACILITY NAME/ADDRESS INFORMATION: Print or type this information in the blocks provided on the form. Be sure to use exactly the same facility name and address that was used on Form 3537 in Section 2.

CERTIFICATION STATEMENT
Either the owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must submit this form. By submitting the form to FDA, or by authorizing an individual to submit the form to FDA, the owner, operator, or agent in charge of the facility is certifying that the information contained in the form is true and accurate. If an individual authorized by the owner, operator, or agent in charge of the facility submits the form to FDA, that individual also certifies that the information contained in the form is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent in charge of the facility must identify in this section the name and contact information for the individual who authorized submission of the registration. Anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. government is subject to criminal penalties under 18 U.S.C 1001.

SIGNATURE: The submitter is required to sign this form in black or dark blue ink.

NAME OF PERSON SUBMITTING THE REGISTRATION FORM: Print or type the name of the submitter in this space.

CHECK ONE BOX: If the submitter is the owner, operator, or agent in charge, check circle A, "OWNER, OPERATOR, OR AGENT IN CHARGE." The form is now complete. If the submitter is an individual authorized by the owner, operator, or agent in charge (such as an administrative employee), check circle B, "INDIVIDUAL AUTHORIZED TO SUBMIT THE REGISTRATION."

If you checked circle B, check either the circle, "Owner, operator, or agent in charge" if the owner, operator, or agent in charge authorized you to submit the cancellation, or the circle, "_____(name of individual who authorized registration on behalf of the owner, operator, or agent in charge)," if someone other than the owner,

operator, or agent in charge authorized you to submit the cancellation. If you checked, "owner, operator, or agent in charge," the form is complete. If you checked the circle, "_____(name of individual who authorized registration on behalf of the owner, operator, or agent in charge), complete the name and address information for the individual who authorized you to submit the cancellation of registration on behalf of the owner, operator, or agent in charge. The fax number and e-mail address for that individual are optional.

Do not mail these instructions back to the FDA with your form. Keep them with your records.

Mail completed Form 3537a to U.S. Food and Drug Administration, HFS-681, 5600 Fishers Lane, Rockville, MD 20857 or FAX it to (301) 210-0247.