Gmail

Admin TrueSight <admin@truesight.me>

ACTION REQUIRED: Initial Agent Assignment Notification

1 message

FDA - Food Facility Registration <CFSANFoodFacilityRegistration@fda.hhs.gov> Sun, Sep 17, 2023 at 5:40 PM
Reply-To: fis@fda.gov
To: admin@truesight.me

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
5001 Campus Drive, HFS-681
College Park, MD 20740

Date: September 17, 2023

Dear Sir/Madam,

The U.S. Food and Drug Administration (FDA) is hereby notifying you that FDA received a food facility registration listing you as the U.S. Agent for the foreign food facility identified below. The registration was submitted to FDA as required by section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 350d] and FDA's food facility registration regulation at Title 21, Code of Federal Regulations (CFR) Part 1, Subpart H. Under section 415 of the FD&C Act and 21 CFR Part 1, Subpart H, a foreign food facility engaged in manufacturing/processing, packing, or holding of food for consumption in the United States must be registered with FDA and such registration must include, among other things, the name and contact information of the U.S. Agent for the facility.

Food Facility Name:	COOPERCABRUCA
Food Facility Address:	Rua ADELINO KFOURY SILVEIRA 17 ITABUNA, BAHIA , Itabuna, Bahia, 45603-345 BRAZIL
Receipt Code:	jBJcF3
Confirmation Due Date:	Oct 17, 2023

Name of U.S. Agent:	TrueTech Inc		
Title of U.S. Agent:			
Street Address Line 1:	3041 Taraval St, San Francisco		
Street Address Line 2:			
City:	Dover	**State:**	Delaware
ZIP Code:	19901		
Country/Area:	UNITED STATES		
Phone Number of U.S. Agent:	415 3000019		
Email Address of U.S. Agent:	admin@truesight.me		

In accordance with 21 CFR 1.231(a)(5) and (b)(7), FDA will not confirm a registration or provide a registration number until the person identified as the U.S. agent for a foreign facility confirms that person has agreed to serve as the U.S. Agent. We are requiring your action within 30 calendar days of

receipt of this notification. The due date to confirm this registration is October 17, 2023. If you take no action within 30 calendar days, the registration information will be removed from our database and the facility will be required to submit another registration submission.

To confirm or decline this listing, please complete the following: (Please note that you must have an account to access the Food Facility Registration Module (FFRM).)

- Log into your account on https://www.access.fda.gov/ (If you do not have an account, please select "Create New Account".).
- Click "Food Facility Registration" on the menu.
- On the FFRM Main menu, click on "Confirm Receipt Code" located on the left column.
- When prompted, enter the receipt code listed above.
- The next screen you will be asked if you agree or disagree. Next, select the appropriate radio button to either "Agree" or "Disagree" and then click "Submit". Upon completion, a confirmation page will follow advising that you have successfully confirmed your status.

You can also visit https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm084398.htm#confirm for instructions for confirming or declining this assignment. Please note that you are required to have an account to access the Food Facility Registration Module.

If you confirm, you will assume the responsibilities of the U.S Agent and the registrant will receive their registration number if the UFI provided in Section 2 is accurate. Please note that you will need to save the above listed receipt code to maintain access to this registration in the future.

If you decline, the registrant will be notified that you have not agreed to serve as the U.S. Agent for the facility. We will then request that the facility amend its registration to designate another U.S. Agent who has affirmatively agreed to serve.

If you confirm as the U.S. Agent for the foreign food facility listed above, but your contact information is incorrect, 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 update this information within 60 calendar days of any change to the previously submitted contact information. The authorized individual may be, but is not required to be, the U.S. Agent for the facility.After January 4, 2020, you must submit updates electronically via https://www.access.fda.gov/, unless FDA has granted a waiver under 21 CFR 1.245

Section 743 of the FD&C Act [21 U.S.C. 379j-31] authorizes FDA to assess and collect fees to cover FDA's costs for certain activities, including reinspection-related costs. A reinspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the FD&C Act, specifically to determine whether compliance has been achieved. Reinspection-related costs means all expenses, including administrative expenses, incurred in connection with FDA's arranging, conducting, and evaluating the results of the reinspection and assessing and collecting the reinspection fees [21 U.S.C. 379j-31(a)(2)(B)]. For a foreign facility, FDA will assess and collect fees for reinspection-related costs from the U.S. Agent for the facility.

If you have any questions about this notification, please call this office at 1-800-216-7331 or email FURLS@fda.gov.
Thank You,

Food Facility Registration Data Management Support Services
U.S. Food and Drug Administration
E-mail: furls@fda.gov