WARNING LETTER

Brodt Zenatti Holdings LLC

MARCS-CMS 583679 — JUL 30, 2019

Delivery Method: Express Delivery
Product: Food & Beverages

Recipient:

Avi Snati
Owner
Brodt Zenatti Holdings LLC
19311 N Riverside Drive
Jupiter, FL 33469-2554
United States

Issuing Office:

Division of South East Imports
6751 Steger Drive
Cincinnati, OH 45237
United States

July 30, 2019

WARNING LETTER

VIA EXPRESS DELIVERY

Avi Snati, Owner
Brodt Zenatti Holdings LLC
19311 N Riverside Drive
Jupiter, FL 33469-2554

Re: CMS # 583679

Dear Mr. Avi Snati:

On May 17, 2019, the U.S Food and Drug Administration (FDA) conducted a Foreign Supplier Verification Program (FSVP) inspection at your facility, Brodt Zenatti Holdings LLC., located at 19311 N Riverside Drive, Jupiter, FL 33469-2554. This inspection was conducted to determine compliance with the requirements of section 805 of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 384a) and the Foreign Supplier Verification Program (FSVP) implementing regulation in 21 CFR part 1 subpart L.

The FSVP regulation requires that importers perform certain risk-based activities to verify that human and/or animal food they import into the United States has been produced in a manner that meets applicable U.S. food safety standards. You may find information relating to the FSVP regulation and your responsibilities to comply with the regulation through links in FDA's FSVP web page at https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm.

During our inspection, we found that you are not in compliance with the requirements of 21 CFR Part 1 subpart L for your tahini imported from Karawan Tahini and Halva, located in the West Bank (i.e., Karawan). Because of these significant violations, you are not in compliance with section 805 of the FD&C Act.

The inspection was initiated as part of a Salmonella Concord multi-state outbreak investigation. During the investigation, epidemiologic and traceback analyses of records and information supplied by firms along the distribution chain identified Karawan brand tahini as the likely source of the outbreak. Salmonella Concord was also isolated from a sample of Karawan brand tahini analyzed by New York City Department of Health during the course of the investigation. Karawan brand tahini is imported by your company.

At the conclusion of the FSVP inspection, our investigator provided you with Form FDA 483a, FSVP observations.

We acknowledge you have conducted a voluntary recall of Karawan brand and SoCo brand of tahini, and you verbally committed to cease importing the product. However, to date, we have not received your response to the Form FDA 483a for your FSVP violations, and your voluntary recall does not address your FSVP violations.

Your significant deviation is described below:

• You did not develop an FSVP as required by section 805 of the FD&C Act and 21 CFR part 1 subpart L. Specifically, your firm did not develop an FSVP for sesame paste tahini manufactured by Karawan Tahini and Halva in the West Bank.

The above violations are not intended to be an all-inclusive list of violations of the FSVP requirements. It is your responsibility to ensure that you are in compliance with section 805 of the FD&C Act and implementing regulation in 21 CFR part 1 subpart L.

You should take prompt action to correct the above violations. If you do not promptly correct them, we may take further action. For instance, we may take action under section 801(a)(3) of the FD&C Act (21 U.S.C. 381(a)(3)) to refuse admission of food that you import. Our inspection revealed that you were not familiar with FSVP requirements, and without evidence of corrective action we may conclude that you appear to be in violation of FSVP requirements for all food that you import. If you do not promptly correct the above violations, we may place food that you import on Detention Without Physical Examination (DWPE) when you import the products.

You can find DWPE information relating to FSVP in Import Alert # 99-41 at http://www.accessdata.fda.gov/cms_ia/ialist.html. In addition, the importation or offering for importation into the United States of an article of food without the importer having an FSVP that meets the requirements of section 805 of the FD&C Act or the FSVP regulation is prohibited under section 301(zz) of the FD&C Act.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should address the specific things you are doing to correct these violations. You should include in your response documentation and information that would assist us in evaluating your corrections, (e.g., documentation of changes you made, such as a copy of your revised FSVP, records to demonstrate implementation of your FSVP, and any additional information that you wish to supply relevant to your compliance with the FSVP regulation. If you cannot complete all corrections within 15 days, you should explain the reason for your delay and state when you will correct any remaining violations.

In addition, Karawan brand tahini is currently subject to DWPE per import alert 99-19, as a consequence of being found contaminated with Salmonella. You can find DWPE information relating to Import Alerts at https://www.accessdata.fda.gov/cms_ia/ialist.html.

Please send your reply to Food and Drug Administration, Attention: LCDR Krista Ferry, Compliance Officer, Division of South East Imports, 6751 Steger Drive, Cincinnati, OH 45237. If you have any questions regarding this letter, you may contact LCDR Ferry via phone at 513-679-2700 x 2158 or via email at krista.ferry@fda.hhs.gov. Please reference CMS # 583679 on any documents or records you provide to us and/or within the subject line of any email correspondence you send to us.

Sincerely,
/S/
Ruth P. Dixon
Program Division Director
Division of Southeast Imports

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)