DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900	1/7/2026-5/20/2026* FEI NUMBER 3017402674
Industry Information: www.fda.gov/oc/industry	

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Martin Karaivanov, Managing Partner

FIRM NAME	STREET ADDRESS
Balkanica LLC	2 Ackerman Ave
CITY, STATE, ZIP CODE Clifton, NJ 07011-1502	E-MAIL ADDRESS martin@balkanica.us

This document lists observations made by the FDA representative(s) during the review of your Foreign Supplier Verification Program (FSVP). They are observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) including by submitting this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FOREIGN SUPPLIER VERIFICATION PROGRAM I OBSERVED:

OBSERVATION 1

You did not develop an FSVP.

Specifically, you stated that you did not have an FSVP for some of the foods you imported. The imported foods for which you confirmed that you have not developed an FSVP for include the foods from the specified foreign suppliers as identified by an "N" mark in the "No FSVP" column of the attached list. This list documents all of foods and foreign suppliers covered by FSVP you imported between January 7, 2025 and January 7, 2026.

OBSERVATION 2

Your foreign supplier verification activities did not provide assurance that the hazards requiring a control in the food you import have been significantly minimized or prevented.

Specifically, your foreign supplier verification activities did not provide assurance that the hazards requiring a control in the food you import have been significantly minimized or prevented for the food that you import:

☐ Fumonisins are a hazard identified in your hazard analysis for maize starch but were not identified by the FS and were not addressed by the supplier for the Chocolate wafers that you import from (b) (4)

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jesse N Nardone, Investigator X Jesse N Nardone Investigator Signed By: JESSE RAY N. NARDONE -S Date Signed: 05-29-2026 08:38:11	5/29/2026

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***DATES OF INSPECTION**
1/07/2026(Wed), 4/21/2026(Tue), 5/20/2026(Wed)

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jesse N Nardone, Investigator	X Jesse N Nardone Investigator Signed By: JESSE RAY N. NARDONE -S Date Signed: 05-29-2026 08:38:11	DATE ISSUED 5/29/2026

The observations of objectionable practices listed on the front of this form are reported:

1. Pursuant to Section 805 of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the laws and regulations enforced by the Food and Drug Administration.