DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	3/25/2022-4/12/2022* FEI NUMBER 3008461022
Industry Information: www.fda.gov/oc/industry	

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Andrew Franze, Owner

FIRM NAME	STREET ADDRESS
(b) (4)	3505 Rombouts Ave
CITY, STATE, ZIP CODE	E-MAIL ADDRESS
Bronx, NY 10475-1218	(b) (6), (b) (7)(C)

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

As a very small importer, you did not obtain written assurance, before importing a food, that your foreign supplier produced the food in compliance with process and procedures that provide the required level of public health protection.

This is a repeat observation from the previous inspection conducted on January 6, 2020. Specifically, you did not obtain written assurance, before importing a food, for (b) (4) from (b) (4) (b) (4) and (b) (4) and (b) (4), both from foreign supplier (b) (4) (b) (4)

***DATES OF INSPECTION**
3/25/2022(Fri), 4/12/2022(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Willy A Orantes, Investigator X Willy A Orantes Investigator Signed By: Willy A. Orantes -S Date Signed: 04-12-2022 15:03:36	4/12/2022

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.