DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	2/6/2026-2/9/2026*
	FEI NUMBER 3001739169

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mrs. Laurie A. Braden, President

FIRM NAME	STREET ADDRESS
Global TV Concepts, Ltd.	6441 Lyons Rd
CITY, STATE, ZIP CODE, COUNTRY Coconut Creek, FL 33073-3602	TYPE ESTABLISHMENT INSPECTED Distributor

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional 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) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

A risk-based approach to the control of the appropriate processes needed for the quality management system has not been applied.

Specifically, there are no risk management procedures nor activity occurring pertaining to areas of the quality system for which your firm is responsible, such as shipping and distribution related risks.

OBSERVATION 2

Criteria for the evaluation and selection of suppliers were not established.

Specifically, your firm has not established any documented criteria for the selection or evaluation of suppliers, such as warehousing and distribution third-party contractors.

*DATES OF INSPECTION

2/06/2026(Fri), 2/09/2026(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Matthew T Sanchez, Investigator	X Matthew T Sanchez Investigator Signed By: MATTHEW T. SANCHEZ -S Date Signed: 02-09-2026 13:51:05	2/9/2026

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Matthew T Sanchez, Investigator	X Matthew T Sanchez Investigator Signed By: MATTHEW T. SANCHEZ -S Date Signed: 02-09-2026 13:51:05	DATE ISSUED 2/9/2026

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

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."