DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	12/11/2024-12/12/2024 FEI NUMBER 3010056143

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John P. Brandt, Owner

FIRM NAME	STREET ADDRESS
IndeCon, Inc.	8330 Lbj Fwy Ste B629
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dallas, TX 75243-1166	HCT/P 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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Records were not maintained concurrently with the performance of each step.

Specifically, you failed to document the evaluation of incoming (b)(4) product for damage and contamination. Your firm's standard operating procedures states to record observations of the product on the (b)(4). Your firm has (b)(4) products to one (b)(4). Your last (b)(4) that was received on (b)(4) contained - units of (b)(4) products.

OBSERVATION 2

Storage temperatures of HCT/Ps were not recorded.

Specifically, you failed to record storage temperatures of (b)(4). You have stated that your (b)(4) product is (b)(4) temperature but you failed to record the temperature in the area in which you store the (b)(4) products. Your standard operating procedure states that storage temperature should be (b)(4). Your firm has been actively storing (b)(4) products at this location for distribution to one (b)(4) -. Currently, you have - units on hand since (b)(4).

OBSERVATION 3

Records pertaining to HCT/Ps were not retained at (b)(4) the date of administration.

Specifically, you failed to provide all records related to the storage and (b)(4) of your (b)(4) (b)(4) products since the last inspection conducted on (b)(4). During the inspection, you only

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Nerming V Briones, Investigator Elisa M Fleming, Investigator	X Elisa M Fleming Investigator Signed By: Elisa M. Fleming -S Date Signed: 12-12-2024 10:46:57	12/12/2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	12/11/2024-12/12/2024 FEI NUMBER 3010056143

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John P. Brandt, Owner

FIRM NAME	STREET ADDRESS
IndeCon, Inc.	8330 Lbj Fwy Ste B629
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dallas, TX 75243-1166	HCT/P Distributor

provided (b)(4) records related to the current inventory. Your firm has been actively (b)(4) (b)(4) products to one (b)(4). You stated you received (b)(4) (b)(4). Your last (b)(4) that was received on (b)(4) contained - units of (b)(4) (b)(4) products.

Nerming V Briones
Investigator
Signed By: Nerming Briones -S
Date Signed: 12-12-2024 10:47:18
X

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Nerming V Briones, Investigator
Elisa M Fleming, Investigator

Elisa M Fleming
Investigator
Signed By: Elisa M. Fleming -S
Date Signed: 12-12-2024
10:46:57
X

DATE ISSUED
12/12/2024

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."