DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	11/6/2023-11/10/2023
	FEI NUMBER 3012668529

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Tae Woo Ahn, CEO

FIRM NAME	STREET ADDRESS
C&T Dream Co., Ltd.	60 Baekseokgongdan-7-Ro, Seobuk
CITY, STATE, ZIP CODE, COUNTRY Cheonan, Chungcheongnam, 31094 Korea (the Republic of)	TYPE ESTABLISHMENT INSPECTED Pharmaceutical Manufacturer

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 I OBSERVED:

OBSERVATION 1

Laboratory records are deficient in that they do not include a complete record of all data obtained during testing.

Specifically,

The firm was unable to produce data that supports the (b) (4) microbiological testing for the (b) (4) (b) (4) System. For example, the firm had conducted (b) (4) microbiological testing of Use Points (b) (4) (b) (4) from the (b) (4) System located in the (b) (4) Building between 1/2023 and 10/2023 with passing result; however, the firm was unable to provide the actual data supporting the reported results during the inspection. The (b) (4) System was used in the cleaning of (b) (4) Tank 05 prior to the manufacturing of the bulk for OTC drug product "Walgreens, Dry Skin Healing Ointment" lot number WDT23108.

"Walgreens Dry Skin Healing Ointment" Lot Number WDT23108 was distributed to the US Market in (b) (4)

OBSERVATION 2

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Robert J Martin, Investigator X Robert J Martin Investigator Signed By: Robert J. Martin -S Date Signed: 11-10-2023 15:32:09	11/10/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	11/6/2023-11/10/2023
	FEI NUMBER 3012668529

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Tae Woo Ahn, CEO	
FIRM NAME C&T Dream Co., Ltd.	STREET ADDRESS 60 Baekseokgongdan-7-Ro, Seobuk
CITY, STATE, ZIP CODE, COUNTRY Cheonan, Chungcheongnam, 31094 Korea (the Republic of)	TYPE ESTABLISHMENT INSPECTED Pharmaceutical Manufacturer

Specifically,

The firm has not validated the manufacturing and packaging processes for the OTC drug product "Walgreens Dry Skin Healing Ointment". Specifically, the firm has not conducted a Process Validation to ensure that the manufacturing and packaging processes can consistently produce a product with known quality, strength, efficacy, and safety. The firm had (b) (4) packaged one batch (lot number WDT23108) which had been distributed to the US Market in (b) (4)

OBSERVATION 3

Where data from accelerated studies was used to project a tentative expiration date beyond a date supported by actual shelf life studies, there were no stability studies and drug product testing at appropriate intervals conducted until the tentative expiration date was verified or the appropriate expiration date determined.

Specifically,

There is no long-term stability study for OTC drug product. For example, on April 21, 2023 the firm had released one manufactured batch of the OTC drug product "Walgreens, Dry Skin Healing Ointment" lot number WDT23108; however, there were no accelerated or long-term stability studies conducted to demonstrate the (b) (4) expiration date. The firm had used an R&D study conducted in May 2022 for (b) (4) to establish the (b) (4) expiration date.

"Walgreens Dry Skin Healing Ointment" Lot Number WDT23108 was distributed to the US Market in (b) (4)

OBSERVATION 4

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Robert J Martin, Investigator	X Robert J Martin Investigator Signed By: Robert J. Martin -S Date Signed: 11-10-2023 15:32:09	11/10/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	11/6/2023-11/10/2023
	FEI NUMBER 3012668529

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Tae Woo Ahn, CEO

FIRM NAME	STREET ADDRESS
C&T Dream Co., Ltd.	60 Baekseokgongdan-7-Ro, Seobuk
CITY, STATE, ZIP CODE, COUNTRY Cheonan, Chungcheongnam, 31094 Korea (the Republic of)	TYPE ESTABLISHMENT INSPECTED Pharmaceutical Manufacturer

Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

The firm has no cleaning verification records between shared equipment for (b) (4) and OTC drug products. The firm's Standard Operating Procedure Mechanical Equipment Hygiene Control Procedure CTD-E600 requires chemical and microbiological testing be conducted post cleaning. For example, on April 12, 2023 the firm had manufactured (b) (4) Lot Number (b) (4) in (b) (4) 05 and then manufactured the bulk lot for OTC Drug Product "Walgreens, Dry Skin Healing Ointment" Lot Number WDT23108 on April 17, 2023; however, there is no record of cleaning verification analysis for chemical or microbial levels.

OBSERVATION 5

Equipment for adequate control over air pressure, micro-organisms, dust, humidity and temperature is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically,

The (b) (4) Buildings do not have a mechanical system that controls temperature, humidity, and differential pressure within manufacturing, packaging, and warehousing areas; however, the firm has classified these areas as Level 2 and Level 3 which are equivalent to ISO 7 (Level II) and ISO 8 (Level III). These (b) (4) buildings were used to manufacture, package and store the OTC drug product "Walgreens Dry Skin Healing Ointment" Lot Number WDT23108 which was distributed to the US Market in (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Robert J Martin, Investigator X Robert J Martin Investigator Signed By: Robert J. Martin -S Date Signed: 11-10-2023 15:32:09	11/10/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	11/6/2023-11/10/2023
	FEI NUMBER 3012668529

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Tae Woo Ahn, CEO

FIRM NAME	STREET ADDRESS
C&T Dream Co., Ltd.	60 Baekseokgongdan-7-Ro, Seobuk
CITY, STATE, ZIP CODE, COUNTRY Cheonan, Chungcheongnam, 31094 Korea (the Republic of)	TYPE ESTABLISHMENT INSPECTED Pharmaceutical Manufacturer

OBSERVATION 6

Buildings used in the manufacturing, processing, packing and holding of a drug product are not maintained in a good state of repair.

Specifically,

On November 6, 2023, I observed the following within the (b) (4) Building:

- Extensive water damage and apparent mold in and around the front entrance to the building. This area leads into the production area (filling and storage of finished products) of the facility.
- Plastic sheets were noted attached to the (b) (4)-floor warehouse ceiling to collecting water leaks from the roof.

The (b) (4) Building is where the firm had filled OTC drug product "Walgreens Dry Skin Healing Ointment" Lot Number WDT23108 which was distributed to the US Market in (b) (4)

OBSERVATION 7

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically,

A. The firm has not qualified their suppliers of raw materials used in the manufacturing of the OTC drug product "Walgreens, Dry Skin Healing Ointment" by evaluating the Certificate of Analyses of the materials via analytical testing. The firm will routinely conduct the following tests to release incoming raw materials: appearance, color, odor, specific gravity (when applicable) and

foreign substances. For example, the firm had released the active ingredient (b) (4) (b) (4) Petrolatum (lot number (b) (4) on 4/12/2023 via testing for appearance, color, fragrance and specific gravity and had accepted the material based on a review of the Certificate of Analysis for the following: consistency, melting point, density, residual solvent, residue on ignition, viscosity, and arsenic. The firm has never evaluated these tests via analytical testing.

B. The firm does not conduct identification testing of raw materials received for the manufacturing of OTC drug products. For example, the firm had not conducted identification testing the active ingredient, (b) (4) Petrolatum (lot number (b) (4) and Glycerin (lot number BGSXFAE036) which were used in the manufacturing of "Walgreens, Dry Skin Healing Ointment" lot number WDT23108. Furthermore, the by not conducting identification testing of Glycerin the firm has not determined that the DEG (diethyl glycol) and EG (ethyl glycol) content are at appropriate levels.

"Walgreens Dry Skin Healing Ointment" Lot Number WDT23108 was distributed to the US Market in (b) (4)

OBSERVATION 8

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

The chamber used for stability studies does not have the ability to control humidity. The stability chamber is comprised of (b) (4) chamber which are set to (b) (4) °C; however, there is no humidity settings. This chamber was used for R&D stability studies for the OTC drug product "Walgreens, Dry Skin Healing Ointment" lot number WDT23108.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	11/6/2023-11/10/2023
	FEI NUMBER 3012668529

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Tae Woo Ahn, CEO

FIRM NAME	STREET ADDRESS
C&T Dream Co., Ltd.	60 Baekseokgongdan-7-Ro, Seobuk
CITY, STATE, ZIP CODE, COUNTRY Cheonan, Chungcheongnam, 31094 Korea (the Republic of)	TYPE ESTABLISHMENT INSPECTED Pharmaceutical Manufacturer

"Walgreens Dry Skin Healing Ointment" Lot Number WDT23108 was distributed to the US Market in (b) (4)

OBSERVATION 9

The containers of components, or drug product containers or closures which are sampled are not opened in a manner to prevent contamination of their contents, contamination of other components, contamination of other drug product containers and contamination of other closures.

Specifically,

The Quality Control Unit routinely samples incoming bulk drug substance, in the (b) (4) Building's general warehouse area just inside the warehouse door without appropriate measures to prevent contamination. For example, the active ingredient, (b) (4) Petrolatum (lot number (b) (4), used in the manufacturing of "Walgreens, Dry Skin Healing Ointment" (lot number WDT23108), was sampled in an uncontrolled area of the warehouse on 4/12/2023.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Robert J Martin, Investigator

Robert J Martin
Investigator
Signed By: Robert J. Martin -S
Date Signed: 11-10-2023
15:32:09

X

DATE ISSUED

11/10/2023