DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661 ORAPHARM1_RESPONSES@fda.hhs.gov	3/21/2024-3/26/2024* FEI NUMBER 2428848

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Thomas Andrew Cook , VP of Operations

FIRM NAME	STREET ADDRESS
Cosco Enterprises Inc.	1930 Troutman St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ridgewood, NY 11385-1020	OTC drug 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

The written stability testing program is not followed.

Specifically,
Your standard operating procedure for Stability Testing states that (b) (4) of Tincture of Green Soap, U.S.P. (b) (4) will be placed on stability; however, no batches of Tincture of Green Soap, U.S.P. have been placed on stability since 2023. During this time, a total of (b)(4) batches of Tincture of Green Soap, U.S.P. were manufactured and distributed by your firm.

OBSERVATION 2

Drug product component testing is deficient in that at least one specific test to verify the identity of each component is not performed.

Specifically,

(A) Certificate of analysis from the raw material suppliers are accepted in lieu of testing, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

(B) Drug product component testing is deficient in that at least one specific test to verify the identity of the raw material is not performed. Additionally, every lot of (b) (4) (b) (4) U.S.P. received by the firm does not undergo limit of diethylene glycol (DEG) and ethylene glycol (EG) testing.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Syeda N Mahazabin, Investigator	X Syeda N Mahazabin Investigator Signed By: Syeda N. Mahazabin -S Date Signed: 03-26-2024 12:16:47	3/26/2024

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OBSERVATION 3

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components conform to appropriate standards of identity, strength, quality and purity.

Specifically,
Your firm has not established and approved any scientifically valid specifications for any of its raw materials used in manufacturing of Tincture of Green Soap U.S.P.

OBSERVATION 4

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.

Specifically,
Your firm has not conducted the following:

(A) Qualification of the purified water system used in the manufacturing of Tincture of Green Soap U.S.P
(B) Process validation for the manufacturing and packaging of Tincture of Green Soap U.S.P.
(C) Equipment cleaning validation on the equipment used in the manufacturing and packaging of Tincture of Green Soap U.S.P.
(D) Qualification of equipment used in the manufacturing and packaging of Tincture of Green Soap U.S.P.
(E) Preventive Maintenance on the manufacturing and packaging equipment used in the production of Tincture of Green Soap, U.S.P
(F) Any testing on all batches of Green Soap, U.S.P. manufactured in-house as in-process material for the finished product, Tincture of Green Soap U.S.P.
(G) Finished Product identification test on any batches of Tincture of Green Soap, U.S.P. manufactured and distributed by the firm.

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This is a repeat observation from the previous inspection ending on 10/27/2016.

OBSERVATION 5

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,
Tincture of Green Soap U.S.P. batch production and control records are deficient in that:

(A)The actual weight of each raw material used in manufacturing of each batch of Tincture of Green Soap is not documented.

(B)The identity of major equipment used in the manufacturing and packaging of Tincture of Green Soap U.S.P. is not documented.

(C)The critical operating parameters, such as mixing speed is not defined, and mixing time are not documented.

(D)The date manufacturing initiated and completed, the date bulk product was transferred from the manufacturing tank to holding tank, the date the bulk product was released by the quality unit, and the date the packaging operation was initiated and completed are not documented.

(E)Production records do not contain yield calculations at each relevant phase of manufacture.

(F)The Packaging process is not described.

(G)Number of samples taken for retain, and finished product testing is not documented.

(H)Finished Product Microbiological test results are not documented.

(I)Components and printed materials used in the packaging of Tincture of Green Soap U.S.P. are not reconciled and documented.

(J)There is no final review of the batch record by the quality control unit for completeness and accuracy, prior to batch release and distribution.

This is a repeat observation from previous inspection ending on 10/27/2016.

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OBSERVATION 6

Procedures describing the calibration of instruments, apparatus, gauges and recording devices are.

Specifically,
(A) The pH meter used in the testing of drug product is inadequately calibrated. The Tincture of Green Soap U.S.P. has a release specification of pH (b) (4). The pH meter was calibrated using pH (b) (4) buffer solutions.
(B) Scale (ID # (b) (4) used in the production of Tincture of Green Soap U.S.P. is inadequately calibrated. The scale was calibrated using (b) (4) calibration weights. The amount of Lavender Oil required to make (b) (4) of Tincture of Green Soap, USP is (b) (4) which is outside of the calibrated range.

This is a repeat observation from the previous inspection ending on 10/27/2016.

OBSERVATION 7

Written procedures are not followed for evaluations done at least annually and including provisions for a review of complaints, recalls and returned or salvaged drug products.

Specifically,
(A) Your firm has not conducted any annual product review for Tincture of Green Soap U.S.P. as per SOP, entitled, "Written Procedure for Annual Review", revised 7/22/2011.
(B) The procedures for the annual quality standards record evaluation are deficient in that they do not address a review of recall, returned drug product, salvaged drug product, and investigation records for each drug product.

This is a repeat observation from the previous inspection ending on 10/27/2016.

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OBSERVATION 8

Individual equipment logs do not show time, date, product and lot number of each batch processed.

Specifically,
Your firm does not maintain equipment use and cleaning logs for equipment used in the production of all batches of Tincture of Green Soap U.S.P.

OBSERVATION 9

GMP training is not conducted on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

Specifically,
Your firm has not conducted any cGMP training to assure that employees engaged in the manufacturing, processing, packing, holding of drug products are familiar with the cGMP requirements.

This is a repeat observation from the inspection ending on 06/28/2011 and the inspection ending on 10/27/2016.

OBSERVATION 10

Drug products are not stored under appropriate conditions of temperature and humidity so that their identity, strength, quality, and purity are not affected.

Specifically,
During the facility walk-through, several pallets of raw materials were observed being stored in the warehouse, which is not temperature or humidity controlled. Some examples are:

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Date ObservedItemLot #Storage Condition on Label			
03/21/2024	(b) (4)		Ambient
03/21/2024			Store in cool, dry, ventilated place. Protect from Heat.
03/21/2024			Store in tightly closed containers in cool, dry, isolated, well ventilated area.

***DATES OF INSPECTION**
3/21/2024(Thu), 3/26/2024(Tue)

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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."