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	11/13/2023-11/17/2023
	FEI NUMBER 3005260401

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tao NMN Zeng , General Manager

FIRM NAME	STREET ADDRESS
Jiangsu Intco Medical Products Co., Ltd.	298 Yandunshan Road, Dagangzhen Jingkou
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Zhenjiang, Jiangsu, 212132 China	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 WE OBSERVED:
PRODUCTION SYSTEM

OBSERVATION 1
Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,
Your firm failed to retain records to support your process validation for OTC (b) (4) manufacturing. You did not maintain batch production records used as part of you process performance qualification for your OTC liquid (b) (4) at (b) (4)% and OTC gel (b) (4) at (b) (4)%. The following batches were used to for your process validation; however, your firm did not retain these records in support of your validation:

Product	Batch 1	Batch 2	Batch 3
(b) (4)			

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	Khoa Nathan V Tran, Investigator Crystal Monroy, Investigator	X Crystal Monroy Investigator Signed By: 2003660870 Date Signed: 11-17-2023 11:25:32	11/17/2023

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LABORATORY SYSTEM

OBSERVATION 2

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,
Your firm's stability program is deficient. For example:

(a) You did not maintain batch production records used to support your stability testing used to establish a (b) (4) expiration date for your OTC liquid (b) (4) at (b) (4) % and OTC gel (b) (4) at (b) (4) %. The following batches were used for your accelerated and long-term stability study, however your firm did not maintain the batch records and destroyed them on February 10, 2023.

Product	Batch 1	Batch 2	Batch 3 cm 11/17/2023
(b) (4)			

(b) Your firm failed to evaluate the stability of OTC (b) (4) in the container-closure system in which they are being marketed. You manufacture liquid (b) (4) products in the following configurations (b) (4) oz. However, you only conducted stability testing for liquid (b) (4) (b) (4) in the (b) (4) oz configuration and you do not have data to support the expiration date in your liquid (b) (4) products in (b) (4) oz configurations.

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MATERIALS SYSTEM

OBSERVATION 3

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

Specifically,

Drug components used in the manufacture of (b) (4) products lack identification testing. For example, your firm does not perform spectroscopic identification tests and limit of (b) (4) for (b) (4) or spectroscopic identification tests and limit of (b) (4) for (b) (4) Each assessment is described as an identification test per the material's USP monograph.

OBSERVATION 4

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically,

a) Your firm has never fully tested a drug component supplier's certificate of analysis for any (b) (4) (b) (4) drug components.
b) Your firm qualified (b) (4) suppliers despite not having fully performed testing of drug components per USP.

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X Khoa Nathan V Tran
Investigator
Signed By: 2003026741
Date Signed: 11-17-2023 11:25:58

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