**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 250 Marquette Ave, Ste. 600<br>Minneapolis, MN 55401<br>(612)334-4100 Fax:(612)334-4134 | 06/08/2026-06/12/2026 |
| | FEI NUMBER<br>3010471640 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Adam C. Johnson, Vice President of Quality, Regulatory and Research and Development

| FIRM NAME | STREET ADDRESS |
|---|---|
| Apex International Mfg. LLC. | 10000 Valley View Rd |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Eden Prairie, MN 55344-3510 | Human 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

Your firm's procedures for supplier qualification are inadequate.

Specifically,

The Standard Operating Procedure SP-00-078, *Supplier Qualification*, does not define a requalification process for approved suppliers, including the frequency or criteria by which requalification is to be conducted.

## OBSERVATION 2

Drug products were observed stored on the floor of the warehouse and not in a manner that ensures the identity, strength, quality, and purity of the drug product is not adversely affected.

Specifically,

During a walkthrough of the warehouse on June, 8th 2026, finished drug products in both open and unopened boxes were observed stored on the floor of aisle (b) (4).

| | | | |
|---|---|---|---|
| **SEE REVERSE OF THIS PAGE** | Soyinka S. Eneng, Investigator | X SOYINKA S. ENENG -S Digitally signed by SOYINKA S. ENENG -S Date: 2026.06.12 13:58:06 -05'00' | 06/12/2026 |

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."