DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	3/18/2026-3/25/2026* FEI NUMBER 3029983589

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jessica (NMI) Martinez, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Agupunt USA Corp	2655 S Le Jeune Rd Ste 404
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Miami, FL 33134-5832	Importer

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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The written MDR procedure does not include documentation and recordkeeping requirements for all information that was evaluated to determine if an event was reportable.

Specifically,

Your firm received five (5) complaints in 2024 and 2025 from your top customer regarding dry needling devices used for physiotherapy, sold under brand names APS Click and APS Regular. The complaints reported that some needles were dull, not smooth, not polished, caused friction upon skin insertion, and had poor incorrect needle handle attachment. Your firm failed to evaluate these complaints to determine whether they met the criteria for MDR reporting. The reported device deficiencies can result in patient pain and discomfort during physiotherapy treatment. This constitutes a malfunction that could reasonably be expected to lead to or contribute to a death or serious injury if the malfunction were to recur.

Additionally, your firm did not maintain access to an Electronic Submission Gateway (ESG) account necessary for timely submission of MDRs to FDA. While your firm initiated an ESG account during the inspection, this delay compromised your ability to meet the reporting timelines.

This observation demonstrates a systemic failure to implement adequate procedures for MDR evaluation

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EMPLOYEE(S) SIGNATURE		DATE ISSUED
Ebony D Sanon, Investigator	X Ebony D Sanon Investigator Signed By: 2001003788 Date Signed: 03-25-2026 14:16:29	3/25/2026

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and reporting as required by 21 CFR Part 803.

OBSERVATION 2

The inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements were not adequately established and implemented.

Specifically,

Your firm has not established requirements for releasing lots for distribution upon arrival to your supplier's warehouse in (b) (4) Your procedure for receiving and shipping goods, ALM 01 Rev 12 dated 10/10/25, does not include inspection requirements and responsibilities for releasing product into the United States market after importation.

For example, your APS Regular Dry Needles from Lot (b) (4) (lot size of (b) (4) boxes) was approved for release by your Technical Manager on 08/17/2025 at your contract manufacturer in (b) (4) However, upon arrival to the U.S. warehouse, there was no documentation demonstrating that your firm performed verification activities or approved the release of this lot after (b) (4) inspection was completed.

The absence of adequate incoming inspection and release controls creates a risk that non-conforming dry needling devices could be distributed to healthcare providers without detection. This could result in the distribution of defective needles that may cause patient harm, including increased pain, tissue damage, or infection risk during physiotherapy treatments due to undetected manufacturing defects or damage during transportation. Your firm's failure to implement verification activities upon receipt of imported medical devices represents a critical gap in your supply chain controls, potentially allowing non-conforming product to reach patients without appropriate quality assurance oversight. This observation demonstrates inadequate implementation of purchasing controls for ensuring purchased product conformity.

***DATES OF INSPECTION**

3/18/2026(Wed), 3/19/2026(Thu), 3/20/2026(Fri), 3/23/2026(Mon), 3/24/2026(Tue), 3/25/2026(Wed)

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	Ebony D Sanon, Investigator X Ebony D Sanon Investigator Signed By: 2001003788 Date Signed: 03-25-2026 14:16:29	3/25/2026

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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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."