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	2/17/2026-3/11/2026* FEI NUMBER 3003799587

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Jamie M. Dworkin, Head of Legal Affairs

FIRM NAME	STREET ADDRESS
Allstar Marketing Group Llc	2 Skyline Dr
CITY, STATE, ZIP CODE, COUNTRY Hawthorne, NY 10532-2142	TYPE ESTABLISHMENT INSPECTED Importer of (b) (4) and (b) (4) Class II Medical Devices

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 extent of verification activities for purchased product was not based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

Specifically, distribution of marketed products, such as: (b) (4) designed with or without (b) (4) and / or (b) (4) are regulated as class II medical devices, and were associated with reports of serious injuries, to include 3rd degree skin burns, skin blisters, as well as overheating issues that caused property damage to bedding or furniture. There was no effective mitigation implemented by the importer to reduce or eliminate such risks that may contribute to potential harm to the end user.

OBSERVATION 2

Criteria for the evaluation and selection of suppliers were not adequately established.

(a) Specifically, a review of supplier evaluation surveys of contract manufacturers of (b) (4) and (b) (4) made in (b) (4) showed evidence of one or more quality system deviations, such as: lack of written work instructions, failure to approve internal specifications, no record of inspections for

AMENDMENT 1

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(b) (4) prior to packaging; failure to calibrate test equipment, non-conforming materials were not properly segregated, failure to maintain work instructions for employees, no inspection results were recorded, and/ or a lack of internal specifications; yet, one or more contract manufacturers were listed as approved without showing actual evidence that prior deviations that existed at the production plant had been corrected prior to final approval of contract manufacturers in (b) (4)

(b) Procedure titled Supplier Qualification Procedure SOP # RAQA -008, dated 2/16/2026 under section #5.3 identifies a need to establish the type and extent of control to be exercised over the product, services, suppliers and contractors based on the evaluation results to be defined, based on risk where applicable. Nevertheless, the procedure does not proceed to describe the actual evaluation process to be exercised for products, services, suppliers and contractors. In addition, there is no description of the risk-based approach to apply and what evidence , if any was maintained to show test labs and other service providers were evaluated and approved prior to use. Currently your establishment is using service providers to test finished products, and / or enter data for complaint files or submit MDRs to the FDA and/ or conduct post market surveillance activities without an assessment of their capabilities to perform such tasks.

OBSERVATION 3

Records of risk management activities in product realization were not maintained.

Specifically, a record of risk management activities associated with the marketing of (b) (4) (b) (4) and (b) (4) does not exist to ensure reported design changes, product improvements and post production changes are periodically evaluated to monitor risk management activities throughout the product's realization and such records should also be maintained.

OBSERVATION 4

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The importer failed to submit a report to FDA, with a copy to the manufacturer, within 30 days after receiving information that one of its marketed devices may have caused or contributed to a serious injury.

a) Specifically, a MedWatch report was not filed and submitted to the FDA within 30 days of becoming aware of a serious injury associated with the use of a (b) (4) under ticket #872817E, dated 7/25/23. The complaint reported a consumer experienced a severe burn to the thigh after using a (b) (4) and the burn was later diagnosed as a 3rd degree burn. The consumer visited the hospital's ER on (b) (6), (b) (7)(C), at which time the surgeon suggested the patient needed a skin graft. Your establishment did not file a MDR to report a serious injury to the FDA. In addition, the foreign manufacturer in (b) (4) was not made aware of this reported incident.

(b) A complaint was filed under ticket # 608605E, dated 9/27/23 to report a consumer experienced a second degree skin burn on the back after use of a (b) (4). Photos of the consumer's back showed burn grill marks and a large blister, which developed in the area where the pad was placed. The consumer was treated by a doctor and prescribed antibiotics. A MDR was not filed within 30 days of receipt of this complaint to send a MDR to the FDA. In addition, there is no documented evidence that the contract manufacturer was informed of this complaint.

c) A complaint was filed under Ticket #582187E, dated 3/21/23 and reported a 3rd skin burn to the right breast after use of product, (b) (4) whereby the consumer visited a health care provider, but a MDR was not filed to cover a serious injury reported within 30 days of becoming aware of the above complaint. In addition, there was no documented evidence that your establishment also contacted the manufacturer to alert manufacturer of this reported incident.

~~d) A complaint filed under Ticket # 512738E, dated 8/26/25 reported a (b) (4) designed with an attached (b) (4) had been linked to skin burns and resulted in a visit to the ER whereby the consumer was administered pain medication with codeine. This incident was not associated with a filed~~

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~~MDR sent to the FDA, and your establishment also did not forward the complaint to the manufacturer in~~ (b) (4) ~~for further investigation.~~

OBSERVATION 5

Records of the review, evaluation, and investigation for any complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications were not adequately maintained.

Specifically, as it relates to complaints not limited to, but including those complaints filed under ticket #s: 310314E, 653397E, 375476E and 165331E, some of these complaints were missing one or more of the following information , such as documentation of the product codes: Item/LOT/UDI numbers, an investigation into the cause of skin burns or blisters, no documentation to support forwarding complaints to the manufacturer in (b) (4) for evaluation when product returns were available for review and / or maintenance of a QC inspection report in support of test results documented in the file, where applicable.

OBSERVATION 6

The quality management system documentation does not include required procedures and records.

Specifically, the following procedures were <u>not</u> maintained at the facility:

- A procedure for timely reporting and processing of complaints that include
  - A description of employee roles and responsibilities for handling complaints to include mention of applicable service providers designated to handle data entry for complaint records, as well as to investigate complaints and handle product feedback and/ or handle post market surveillance related issues.

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☐ Evidence of complaint evaluation to spot adverse incidents associated with serious injuries or deaths for reporting to the FDA.

☐Evidence that the contract manufacturer was notified of complaints in order to investigate and identify root cause.

☐Documentation of model number or relevant product codes, such as: LOT number and UDI number.

☐Documentation justifying why a complaint could not be investigated

☐Replies to the consumer
☐Documentation of Corrective Action(s)
☐Results of an investigation, to include copies of supporting records, such as: photos, Quality Control test reports, and/ or copies of product labeling
☐Evidence to show adverse events were reported to regulatory bodies

- A procedure for handling nonconforming products, to include handling of non-conforming goods shipped to warehouse distribution centers to ensure proper identification, documentation, evaluation, segregation, investigation and final disposition of non-conforming goods, in order to prevent unintended use or delivery to customers.

- A procedure for handling internal audits to describe a need to conduct planned audits to cover different quality system areas, to ensure a record of the audit is maintained, verify deficient areas are linked to a corrective action, and have those persons conducting the audits maintain all audit results, and ensure each qualified auditor does not audit his or her own work. To date, no such audits of your establishment were documented.

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- A procedure for management reviews, to ensure coverage of discussions related to topics related to review of audit results of suppliers & internal audit functions, review of product changes, non-conformity reports, results of monitoring and measurement data, complaint trends, customer feedback, product improvements, corrective actions, as well as information on the suitability and effectiveness of your quality policy and quality objectives.

- Procedures under your quality manual that outline your quality policy statement, emphasize an evaluation of quality objectives and a need to appoint a *management representative* to oversee the suitability and effectiveness of your quality system records and procedures.

***DATES OF INSPECTION**

2/17/2026(Tue), 2/18/2026(Wed), 2/19/2026(Thu), 2/24/2026(Tue), 3/11/2026(Wed)

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Annotations to Observations

Observation 1: Under consideration

Observation 2: Under consideration

Observation 3: Under consideration

Observation 4: Promised to correct

Observation 5: Under consideration

Observation 6: 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."