FDA Warning Letters Summary

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Warning Letter Information

Warning Letter Link
Letter issue date: 04/30/2024
Company name: Ward Smelling Salts
Ward Smelling Salts, a company that sells stimulant drug products, received a warning letter from the FDA for violating the Federal Food, Drug, and Cosmetic Act. The company's products are unapproved new drugs and are misbranded. The company has 15 working days to respond to the FDA and explain the steps they are taking to address the violations.

Warning Letter Link
Letter issue date: 05/13/2024
Company name: Aruba Aloe Balm N.V.
Aruba Aloe Balm N.V. received a warning letter from the FDA on May 13, 2024, due to significant violations of CGMP regulations for finished pharmaceuticals. The violations included failure to test incoming raw materials, use of methanol-contaminated ethanol, and inadequate water system controls. The firm was also cited for failing to adequately test and release finished drug products, and for lacking a stability testing program. Additionally, the firm's ISLAND REMEDY ALL-DAY REVITALIZING MOISTURIZER was found to be misbranded. The firm was required to take corrective actions and respond to the FDA within 15 working days.

Warning Letter Link
Letter issue date: 05/14/2024
Company name: Genpro Imports & Export Inc.
Genpro Imports & Export Inc. received a warning letter from the FDA on May 14, 2024, for failing to comply with the Foreign Supplier Verification Program (FSVP) requirements. The company did not develop, maintain, and follow an FSVP for the foods it imports from the foreign suppliers indicated in the attached list, including summer squash, eggplant, and bitter melon, imported from (b)(4), located in Mexico. The company also did not conduct a hazard analysis for each type of food it imports to determine whether there are any hazards requiring a control, as required by 21 CFR 1.504(a). Specifically, during our inspection, you did not provide a written hazard analysis or any FSVP records for your fresh ginger from (b)(4)Â China.

Warning Letter Link
Letter issue date: 05/05/2024
Company name: Amin Trading Agency LLC
Amin Trading Agency LLC received a warning letter from the FDA on May 5, 2024, for failing to comply with the Foreign Supplier Verification Program (FSVP) requirements. The company did not develop, maintain, and follow an FSVP for the foods they import from India, including Masala E Magic, Garam Masala, and Sambar Masala. The FDA may take further action, such as refusing admission of the imported foods or placing them on detention without physical examination.

Warning Letter Link
Letter issue date: 05/09/2024
Company name: Biomic Sciences, LLC dba ION Intelligence of Nature
Warning Letter Summary: Biomic Sciences, LLC dba ION Intelligence of Nature
Date: May 9, 2024
Product: Food & Beverages
Recipient: Biomic Sciences, LLC dba ION Intelligence of Nature
Issuing Office: Division of Human and Animal Food Operations East II
Key Violations:
* Adulterated Human Drugs:
* Gross microbial contamination in ION Intelligence of Nature Sinus Support Nasal Spray drug product.
* Failure to conduct appropriate laboratory testing for objectionable microorganisms.
* Use of preservatives as a substitute for comprehensive microbial control.
* Drug CGMP Violations:
* Inadequate quality control unit.
* Failure to establish adequate procedures for preventing objectionable microbiological contamination.
* Failure to establish adequate testing of components with potential for microbiological contamination.
* Failure to establish and follow procedures for master manufacturing records.
* Failure to establish adequate batch records.
* Failure to establish an adequate stability program.
* Failure to establish adequate documentation for quality unit review and release of drug product.
* Unawareness of the identity of numerous proprietary components used to manufacture many drug products.
* Inadequate quality systems.
* Adulterated & Misbranded Dietary Supplements:
* Failure to register with the FDA as a commercial processor of low-acid foods.
* Failure to file scheduled processes with the FDA for each low-acid food in each container size.
* Failure to establish identity specifications for each component used in the manufacture of a dietary supplement.
* Failure to establish product specifications for the identity, strength, and composition of the finished batch of the dietary supplement.
* Failure to quarantine components before use.
* Failure to include all required information in batch production records.
* Failure to establish and follow written procedures for calibrating instruments and controls.
* Misbranding of Dietary Supplement Products:
* Failure to declare all common or usual names of each ingredient used.
* Non-compliance with presentation of nutrition information requirements.
* Failure to include all intended groups in the Supplement Facts label.
* Misleading statement of identity on the principal display panel.
Corrective Actions Required:
* Recall all lots of ION Intelligence of Nature Sinus Support Nasal Spray.
* Engage a qualified consultant to evaluate operations and assist in meeting CGMP requirements.
* Register with the FDA as a commercial processor of low-acid foods.
* File scheduled processes with the FDA for each low-acid food in each container size.
* Establish identity specifications for each component used in the manufacture of a dietary supplement.
* Establish product specifications for the identity, strength, and composition of the finished batch of the dietary supplement.
* Quarantine components before use.
* Include all required information in batch production records.
* Establish and follow written procedures for calibrating instruments and controls.
* Declare all common or usual names of each ingredient used.
* Comply with presentation of nutrition information requirements.
* Include all intended groups in the Supplement Facts label.

* Correct the misleading statement of identity on the principal display panel.
Response Deadline: 15 working days from receipt of the letter.
Consequences of Non-Compliance: Legal action, including seizure and injunction.
Additional Notes:
* The company has already initiated a voluntary recall of all lots of ION Intelligence of Nature Sinus Support Nasal Spray.
* The company has also stated that they will stop producing and discontinue sales of the current formulation of ION Intelligence of Nature Sinus Support but plan to market a nasal product in the future.
* The company is required to notify the FDA before marketing any new drug products.
* The company should engage a qualified consultant to evaluate their operations and assist them in meeting CGMP requirements.
* The company's executive management remains responsible for resolving all deficiencies and systemic flaws to ensure ongoing CGMP compliance.

Configuration Data

web-url-table: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters

web-url-page:

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filter-exclude:

filter-from-date: 04/30/2024

report-title: FDA Warning Letters Summary

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AI-SummaryPrompt: Explain the following warning letter succinctly in just a couple of sentences, without any introductions, notes, conclusions, or additional information. Include all important details and references. Do not include these instructions in your response.

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