

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 200 Chestnut Street Suite 900 Philadelphia, PA 19106 (215)-597-4390 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 11/17-11/19/21,11/22-11/24/21,11/30-12/02/21,12/08, 12/13, 12/15/21
	FEI NUMBER 3013947845

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Matthew J. Davidson, Plant Manager

FIRM NAME Dupont Nutrition USA, Inc.	STREET ADDRESS 1301 Ogletown Road
CITY, STATE AND ZIP CODE Newark, DE 19711	TYPE OF ESTABLISHMENT INSPECTED Excipient Manufacturer

Item 3

Review of out-of-specification (OOS) results is not thorough enough to identify equipment or analyst errors.

Specifically, OOS investigations related to Avicel Microcrystalline Cellulose(MCC) are performed by the original analyst consisting of a review of tests performed. These reviews do not fully evaluate potential for human or equipment error.

Item 4

Your recall procedure does not clearly define the conditions that necessitate a recall so that it may be executed in a consistent and effective manner.

Specifically, your procedure has recall requirements if there are potential health hazards or if violations of law exist, but does not adequately define what constitutes these circumstances. Your procedure does not clearly define recalling distributed products later found to be out-of-specification.

Item 5

There was a failure to expand investigations into discrepancies to associated batches of drug products.

Specifically, your investigation into inaccurate readings of your conductivity meter/probe (b) (4) Conductivity Meter Model (b) (4), used for Avicel microcrystalline cellulose (MCC) conductivity testing, was not expanded to include all lots of drug product that were tested by the meter/probe and subsequently released. The meter/probe was used to conduct release testing on lots (b) (4) and (b) (4) immediately prior to the discovery of the discrepancy. No additional testing was performed on these lots as part of the investigation into the inaccurate readings.

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		Craig D. Zagata, Investigator Kristina L. Conroy, Investigator	12/15/2021

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Item 6

Batch records do not include complete information relating to the production and control of each batch.

Specifically, batch release by the Quality Unit does not include the review of all relevant production records, including critical in-process parameters, to confirm that the process remained in a state of control, and to identify discrepancies, including process disrupts, during operations that may require further evaluation to assess the adequacy of the finished product being released.

Item 7

Laboratory control records do not include complete data.

Specifically,

A. Laboratory records do not include a second employee verifying the documentation of the data for product testing, used for release determinations (composite and packaged samples), showing that the original entries on the records have been reviewed for accuracy, completeness, and compliance with established standards.

B. Laboratory controls were not followed and documented at the time of performance. The quality checks were not completed prior to use for microbiological media used in finished product testing. Departures from the procedure were not documented and explained. Your Microbiology Technician retrospectively back dated the completion of the quality checks for the media during the inspection.

C. Laboratory records containing analytical and microbiological testing for product release determinations do not include documentation showing that the sample preparation is in conformance with test requirements for all tests performed on each lot. For example, sample preparation weights and equipment used are not documented for microbiological testing.

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Item 8

Analytical methods were not adequately verified for suitability under actual conditions of use.

Specifically, your firm uses a compendial method for conductivity on composite samples of finished Microcrystalline Cellulose (MCC) and a non-compendial method for conductivity on packaged samples of finished MCC. Results from the composite samples and packaged samples are used for final disposition and release determinations. In approximately March 2021 your firm modified both your internal compendial and non-compendial methods for MCC without appropriate evaluation.

For example, your firm performed ^{(b) (4)} precision conductivity studies for MCC using the compendial method and a ^{(b) (4)} between January and March 2021. The conductivity data evaluated did not reflect a range of values that may be obtained during routine testing.

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