

Establishment Inspection Report

FEI:

Biova, L.L.C.

EI Start: 01/30/2023

Ames, IA 50010-8220

EI End: 01/30/2023

SUMMARY

Inspection	
Operation ID and Name	231859: FY23 CVM2 / HR1, Tier 07, Biova, L.L.C., Ames, IA

Summary Data	
This is a comprehensive report.	
Inspection Basis	Surveillance

Summary
<p>This comprehensive surveillance inspection of an ingredient manufacturer use for human and animal dietary supplements was conducted per OPID: 231859 and assigned under the HAFW2 FY-23 work plan. This was a GMP for human and animal foods and a limited scope preventive controls at a human food facility inspection. Compliance Program Guidance Manuals 7303.040 Preventive Controls and Sanitary Human Food Operations and 7371.000 Comprehensive Animal Food Inspection were used.</p> <p>The last inspection was conducted by the State under FDA contract on 06/26/2018. The inspection was classified as No Action Indicated, no form FDA483, Inspectional Observations was issued, and no significant observations were discussed with management.</p> <p>The current inspection covered a walk-through of the facility during which the firm was manufacturing a test product, cGMPs (current Good Manufacturing procedures under 117 and 507), firm history, interstate commerce, jurisdiction, responsibility, employee training, manufacturing operations, manufacturing codes, complaints, and recall procedures. I went through the process of Ovacore as the main product of the firm, the firm was not manufacturing during this inspection.</p> <p>This inspection found the firm to be operational. No Form FDA 483, Inspectional Observations was issued, and no significant observations were noted.</p> <p>The firm's facility registration is current, which I verified before the start of this inspection.</p> <p>No refusals were encounter during this inspection and no samples were collected.</p> <p>A close out meeting was held with firm management where I warned them of their responsibility to be in compliance with the FD&C Act and the potential penalties for failing to do so.</p> <p>This inspection was pre-announced (b) (5) and no discrepancies were noted.</p>