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**SUMMARY**

(ACP)

This routine CGMP inspection of a manufacturer of non-sterile Active Pharmaceutical Ingredient (API) and Excipient was conducted as part of FY'24 CDER abbreviated and CVM surveillance GMP work plans as per eNspect OP ID 264816. The scope of the inspectional assignment was to provide GMP surveillance coverage for the APIs manufactured by the firm used in the human and animal drug products. This inspection was conducted in accordance with Compliance Program 7356.002F, entitled, Active Pharmaceutical Ingredient (API) Process Inspection, and Compliance Program 7371.001, entitled, Animal Drug Manufacturing Inspections, ICH Q7, entitled, Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients was used for guidance. The profile class CSN was covered during this inspection.

The previous FDA inspection of the firm was conducted as CGMP from 04/29/2021 – 05/04/2021 and provided coverage of the firm's Quality System, Production System, and Laboratory Control Systems. No Form FDA 483, Inspectional observation, was issued. The inspection was classified as NAI. [redacted]

The current inspection revealed that the firm's continues to be a manufacturer of APIs. This CGMP inspection covered firm's Quality, Facilities and Equipment, Materials, Production, Packaging and Labeling and Laboratory Control Systems. The corrective actions to the previous verbal observations were reviewed and found to be adequate. No FDA-483, Inspectional Observations was issued, [redacted]

[redacted] The firm's registration is current to December 2024. No samples were collected, and no refusals were encountered.

**ADMINISTRATIVE DATA**

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|---|---|
| Inspected firm: | BioSpectra, Inc. |
| Location: | 100 Majestic Way<br>Roseto, PA 18013-2860 |
| Phone: | 610-599-3400 |
| FAX: | 610-610-599-3410 |
| Mailing address: | 100 Majestic Way<br>Bangor, PA 18013-2860 |
| Email address: | dmeissner@biospectra.us |
| Website: | www.biospectra.us |
| Dates of inspection: | 1/29/2024-2/2/20245 |
| Days in the facility: | **Ankur C Patel, Investigator** |
| Participants: | **Robin P Mathew, Investigator**<br>**Karishma G Gopaul, Investigator** |