DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443 Industry Information: www.fda.gov/oc/industry	June 8, 2026 - June 12, 2026
	FEI NUMBER 3003568775

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Daniel M. Bowles, Vice President, General Manager

FIRM NAME	STREET ADDRESS
Cambrex High Point, Inc.	4180 Mendenhall Oaks Pkwy
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
High Point, NC 27265-8017	API manufacturer

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.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

The firm lacks adequate controls to ensure the accuracy of data recorded in batch production records, in that the (b) (4) Human Machine Interface (HMI)-generated data is not reviewed.

Specifically:

Your firm utilized the (b) (4) HMI (System ID # (b) (4)) for (b) (4) (b) (4) Process Performance Qualification (PPQ) batches and (b) (4) post-PPQ (b) (4) manufactured between April to December 2025. HMI-generated data, including batch temperatures and RPM/mixing speeds, constitutes the original raw data for critical process parameters. Your firm failed to have a procedure to review this data, and operators manually transcribe HMI readings into batch production records without any reconciliation or verification against the original electronic records. As a result, the accuracy of critical process parameter data used to support the PPQ batches cannot be assured.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Sonya M. Edmonds -S Digitally signed by Sonya M. Edmonds -S Date: 2026.06.12 10:49:32 -04'00'	Sonya M. Edmonds, Investigator	06/12/2026

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 judgement, 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."