DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse 200 Chestnut St, Rm 900 Philadelphia, PA 19106 (215) 597-4390 Ext: 4200 Fax (215) 597-0875 Industry Information: www.fda.gov/oc/industry	06/15/26-06/18/2026
	FEI NUMBER 2517101

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dan Hedemann, Operations Manager

FIRM NAME	STREET ADDRESS
Copperhead Chemical Company, Inc.	120 River Rd.
CITY, STATE AND ZIP CODE Tamaqua, PA 18252	TYPE OF ESTABLISHMENT INSPECTED 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:

OBSERVATION 1

Cleaning procedures for manufacturing equipment are not established, validated, or consistently documented across applicable written procedures to support the established clean hold time.

Specifically,

Per your firm's procedure, SOP P03-08-0070, "Equipment cleaning will be performed by the Pharmaceutical Operators: If not cleaned within (b) (4) of manufacture." , Cleaning validation report Doc. No. VR-PH-068 failed to validate a clean hold time of (b) (4) for the (b) (4) Blender (ID T-301), (b) (4) (ID SC-301), (b) (4) (ID SR-301), and (b) (4) Mixer (ID T-302). There are no studies, data, or acceptance criteria to support the duration for which cleaned equipment may be held prior to use. This equipment is used to manufacture (b) (4) API drug substances.

OBSERVATION 2

Your firm's OOS investigation process does not ensure that conclusions are supported by documented evidence, that all relevant analytical data are fully evaluated, or that corrective actions are defined when investigations acknowledge an inability to prevent recurrence.

Specifically,

a) OOS Investigation No. 25-007 for (b) (4) is inadequate. The investigation failed to characterize, identify, or evaluate an unidentified chromatographic peak that contributed to the OOS result and failed to conduct additional testing to determine whether the peak represented an impurity, degradant, or process-related substance.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		John McIntosh, Investigator Anastasia Shields, Investigator	06/18/2026

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b) OOS Investigation No. 24-003 for (b) (4) is inadequate. The investigation attributed the OOS result to analyst error based solely on unverified analyst self-reporting, without independent corroboration through witness statements, bench records, instrument audit trails, or other objective evidence. There was no analytical confirmation that the identified error was the root cause.

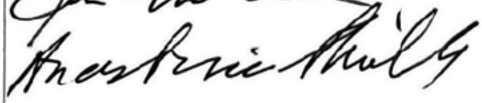
c) OOS Investigation No. 26-002 for (b) (4) is inadequate. The investigation attributed the OOS result to a suspected injection irregularity without conducting instrument troubleshooting, system suitability or data review. There was no documented instrument malfunction to substantiate this hypothesis.

OBSERVATION 3

Warehouse storage conditions are not being adequately monitored in accordance with the firm's temperature mapping study. The temperature mapping study identified the hottest and coldest locations within the warehouse; however, continuous temperature monitoring devices are not placed at these critical locations.

Specifically,

Your firm's temperature mapping studies (Doc. #: P999-09, Doc. #: P999-08) identified the hottest and coldest locations within the warehouse (building ID #(b) (4)); however, continuous temperature monitoring devices were not placed at these critical locations. The firm cannot ensure that materials stored in these areas are maintained within required storage conditions.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		John McIntosh, Investigator Anastasia Shields, Investigator	06/18/2026

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."