Quality Division Use Only

Quality Tracking #:	2021-052	**Classification:**	Corrective Action
Non-Conformance Level:	Class II	**Section:**	Seized Drugs
Date of Discovery:	08/25/21	**Date of Incident:**	07/01/21

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2021-23341	**046574121**

Description of Non-conformance:

A Seized Drugs report was issued listing the results of a substance as "No controlled substance identified". Further research determined that the substance requires a medical prescription, therefore it should have been reported as a dangerous drug.

Additional Information/Follow-Up:

After issuance of the original report, HFSC received an additional analysis request by the submitting officer for evidence not previously analyzed. A supervisor retrieved the folder for review and noticed the reported footnote listed cyproheptadine as a non-controlled substance. Research performed by the supervisor determined that the substance was a dangerous drug.

The Texas Controlled Substances Act Chapter 481 of the Health and Safety Code defines a controlled substance as a substance, including a drug, an adulterant, and a dilutant, listed in Schedules I through V or Penalty Group 1, 1-A, 1-B, 2, 2-A, 3, or 4. A dangerous drug is defined as a device or drug regarded as unsafe for self-medication (medical prescription required) and not listed under Schedules I-V or Penalty groups 1 through 4 per the Dangerous Drugs Chapter 483.

Cyproheptadine is not listed in Schedules I through V nor Penalty Groups 1, 1-A, 2, 2-A, 3, or 4, however, because it requires a medical prescription; by definition it is a dangerous drug.

It is the section's procedure to identify and report substances that are controlled, but also those that require medical prescription (reported as dangerous drug). For instances when a substance is not a controlled substance, the analyst must conduct additional research to determine if it requires a prescription or if it's available as an over-the-counter medication.

Summary of Root Cause Analysis:
Note: Incidents are documented for tracking purposes and trend analysis. Root Cause Analysis is not required for incidents.

The analyst was able to determine that the substance was not controlled, however his additional research wasn't thorough enough to identify this substance as a dangerous drug. All seized drugs cases need to undergo an administrative and technical review prior to the report being released. From their recollection, both reviewers verified that the substance was not controlled, however their additional research was also not thorough enough to identify the substance as a dangerous drug.

The additional research was not as thorough because there was a preconceived notion that this substance did not require a medical prescription due to the following contributing causes: Cyproheptadine is an antihistamine that is not commonly encountered nor received by the laboratory. This was the first instance both the laboratory, analyst, and reviewers had seen this type of substance. Although some antihistamines are available by prescription and as over-the-counter medication, this classification is dependent on dosage. The cyproheptadine tablets were contained within a blister pack that described them as multivitamins and were from a foreign manufacturer. Because the tablets were described as multivitamins, this contributed to their conclusion that the tablets would be available as over-the-counter medication. However, cyproheptadine requires a medical prescription regardless of the dosage level.

Actions Taken:

During the section meeting held October 8, 2021, analysts were shown various resources that are available for instances when additional research is needed to determine if a non-controlled substance requires a medical prescription and therefore needs to be reported as a dangerous drug.

The original report was amended and includes the following header statement: This report amends Laboratory Report # 0002 dated 7/1/2021 at 8:12:56 AM to include the results of additional analysis and research into the control status of cyproheptadine. Please refer to Quality Report 2021-052 for more information.

The requesting officer was contacted via email regarding the control status of cyproheptadine and sent a copy of the amended report.

Section Manager: James Miller **Date:** 11/03/21

Division Director: Amy Castillo **Date:** 11/08/21

Incidents or Corrective Actions that involve the Biology/DNA section are reviewed by the Technical Leader and CODIS Administrator.

Technical Leader: N/A **Date:** N/A

CODIS Administrator: N/A **Date:** N/A

Quality Director: Erika Ziemak **Date Closed:** 11/10/21