DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	9/16/2024-9/20/2024
	FEI NUMBER 3006403166

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert C. Munday, Quality and Regulatory Advisor

FIRM NAME	STREET ADDRESS
International Laboratories Corp	Bangplee District, 62 Moo 8 Bang Na-Trat Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bang Phli, Samut Prakan, 10540 Thailand	OTC Drug 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 WE OBSERVED:

OBSERVATION 1

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

A. Your firm could not provide test release data for review for any of the OTC products shipped to the US market. You do not collect and maintain raw data for review. For example, your laboratory balances and pH meters do not have printing or data storing capabilities and the reported values are not documented and not attributed to any analyst.
B. No test sample preparation details were documented and was not available for review for the OTC drug products for the US market.
C. OTC drug products test data were not available for review in the (b) (4) HPLC system (HPLC#1) running on Lab Solutions. The QA Manager stated that QC personnel may have deleted these data due to lack of writing space on the computer. These data include finished product release and stability data for (b) (4) and (b) (4) preservatives.
D. Test samples are not traceable as there is no sample receipt log and no usage log for the QC laboratory instruments.
E. Though your firm has generated a stability summary sheet for the US market OTC products, the raw data attributable to an analyst was not available for review including

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electronic or hard copies. This includes the following batches for time points 1M, 3M, 6M, 9M, 12M and 18M:

Product	Batch#
[redacted] (b) (4)	

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

We observed discrepancies on the OOS investigation logs and corresponding investigation reports relating to the microbiological testing of [redacted] (b) (4) The microbiology manager acknowledged that they fabricated these documents with falsified information and backdated signatures. For example, the OOS investigation reports showed the following dates and conclusions:

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OOS#	Analyst Signed Date (DD/MM/Year)	Section Manager Signed Date (DD/MM/Year)	Manager QC Approved Date (DD/MM/Year)	Investigation Conclusion
01/012024	22/01/2024	22/01/2024	25/01/2024	Genuine Lab Error
01/072024	30/07/2024	30/07/2024	16/08/2024	Genuine Lab Error
02/072024	05/08/2024	05/08/2024	16/08/2024	Genuine Lab Error
03/072024	05/08/2024	05/08/2024	16/08/2024	Genuine Lab Error

On further enquiry, the microbiology manager confirmed that they did not open the investigations and sign the investigation reports on these specified dates, and they were fabricated and created only on 12SEP2024, four days before the start of the inspection. The OOS investigation log, an uncontrolled document which was not issued by the QA, also reported entries on these dates. The microbiology manager confirmed that the logbook entry dates were also fabricated and created the bound logbook three days before the inspection. These purported OOS investigations concluded that 'genuine lab error' was the cause of out of specifications and no corrective actions were taken.

Also, in 2023, no OOS investigation was opened when gram negative species was observed in [redacted] (b) (4) sample taken from the storage tank on 10/03/2023.

OBSERVATION 3

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Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

A. An analyst was able to alter the time and date on the computer system that runs the stand alone HPLC unit.
B. A QC analyst demonstrated that they could create and delete a folder in the computer system that runs the stand alone HPLC unit.
C. Recycle bin in the computer system contained several project related folders and files. The QA manager stated that analysts may be deleting files to save recording space. The firm could not show any historical backed-up data. No written procedure is available to prevent/govern file deletions.
D. The firm does not review electronic data generated at the HPLC instruments. For example, no one at the firm was able to explain what each of the sample injections in a (b)(4) injections sequence that included stability samples for an OTC drug product for the US market.
E. Master Batch Records are maintained as hard copies and freely available to all production personnel for copying and using as many times as needed. The QA manager confirmed that the quality unit does not document the issuance of batch records thus making it impossible to reconcile them.
F. SOPs have been in use with a shown effective date on them but have never been approved by anyone including QA. For example, audit trail review of the documentation control system showed no approval signature for the following SOPs:
   -Data Integrity Procedure (PM7.5-02, Rev 00, Eff Date: 2024-01-12)
   -Document and Form Preparation (PM7.5-03, Rev 00, Eff Date: 2023-12-12)
G. The OOS SOP PM8.7-03, titled, 'Handling of Out of Specification (OOS) Results' which was issued by the electronic document control system shows an effective date of 2022-

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11-10. However, the audit trail review of the ISO Document Management system showed that the OOS procedure was approved only on 2023-01-09.

H. Microbiology lab used a logbook for documenting OOS investigations that was not issued or reviewed by QA and was not described or linked with any written procedure.

I. The microbiology test results are reported in a form that is uncontrolled, freely available in a shared folder and microbiologists can print without any trace and copy them as well for use.

J. The (b) (4) tank (BT09) use log (FRM-PMT20-00-0967) is not described or found associated with any written procedure but appear to have been in use since the beginning of this month. The initial entry on the log was on 03SEP2024 but the log wasn't approved until 09SEP2024.

OBSERVATION 4

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

A. Your firm has not conducted any clean hold time studies on the critical equipment used in the manufacturing of OTC drug products to the US market. These equipment include the (b) (4) tank (BT09) and the filling machines.

B. Your firm has not conducted any bulk hold time studies for any of the (b) (4) OTC drug products.

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OBSERVATION 5

Samples taken to determine conformance to appropriate written specifications for the acceptance of each lot within each shipment of components are not representative.

Specifically,

(b) (4) sampling for microbiological testing is not representative of the dispensing for regular production use. For example, the firm's (b) (4) sampling procedure requires preparing the user point sampling area by cleaning the sample tap with (b) (4) However, during commercial production, the firm used the (b) (4) directly for (b) (4) of the product without any preparation.

OBSERVATION 6

Laboratory controls do not include the establishment of scientifically sound and appropriate designed to assure that conform to appropriate standards of identity, strength, quality and purity.

Specifically,

A. Microbial method suitability testing has not been performed for the following US market drug products:

(b) (4)

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These OTC drug products have release specifications for the total aerobic count and total yeast and mold.

B. There has been no risk assessment to determine whether specifications for elemental impurities are necessary for the US market drug products.

OBSERVATION 7

The responsibilities and procedures applicable to the quality control unit are not in writing.

Specifically,

A. Your firm does not have procedures in place and lacks written documentation on recording out of trend test results.
B. Your firm does not have a procedure requiring the QC unit to review and release the data. Also, you could not provide documentation demonstrating the data review by the QC unit prior to batch release.

X Samantha E Cleek
Investigator
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Date Signed: 09-20-2024 17:50:33

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