DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax:(913) 495-5115 Industry Information: www.fda.gov/oc/industry	01/06/2015 - 01/07/2015 FEI NUMBER 1000147951

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mary Anne Auer, President/CEO

FIRM NAME	STREET ADDRESS
Wexford Labs Inc	325 Leffingwell Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kirkwood, MO 63122-6409	Medical Device 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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures to prevent contamination of equipment or product by substances that may have an adverse effect on product quality have not been adequately established.

Specifically, your firm reportedly does not have a procedure to govern the cleaning of the stainless steel mixing tanks used in the production of your company's line of hard-surface disinfecting agents. While you were able to produce a cleaning log of equipment (tanks) which would be used for multiple products, your Production Manager indicated that dedicated tanks are almost never cleaned. Additionally, all of the stainless steel tanks are of the open-top variety without lids which may allow foreign particles to fall into the interior of the vessels whether in production, or at rest.

OBSERVATION 2

Quality audits were not performed at sufficient frequency to determine whether the quality system activities and results comply with quality system procedures.

Specifically, you have not yet conducted the internal audits as prescribed by your standard operating procedure "Internal Audit" and your Internal Audit Schedule.

OBSERVATION 3

Procedures for training and identifying training needs have not been adequately established.

Specifically, while your firm has been documenting training conducted on departmental procedure, you do not yet have a procedure to govern this training, nor do you have a matrix or other tool which identifies training needs of personnel.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Matthew J. Morrison, Investigator	01/07/2015

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Observation Annotations

Observation 1: Promised to correct.
Observation 2: Promised to correct.
Observation 3: Promised to correct.

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	Matthew J. Morrison, Investigator	01/07/2015