DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US FDA District Office 1431 Harbor Bay Parkway Alameda, CA 94502 (510) 337-6700 Industry Information: www.fda.gov/oc/industry	6/25/18 - 6/29/18, 7/2-18 - 7/3/18
	FEI NUMBER 3014548060

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jenny R. Wallner, Assistant General Counsel, US Pharma and Specialty Health

FIRM NAME	STREET ADDRESS
McKesson Corporation	1 Post Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
San Francisco, CA 94104	Wholesale Distributor

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

The systems in place to enable compliance with the requirements of the Food Drug and Cosmetic Act Section 582 (c) are deficient:

a. to identify all illegitimate product subject to a notification from a trading partner, upon receipt of that notification, that is in the possession or control of the firm or that is subsequently received by the firm

b. to quarantine suspect or illegitimate product upon receipt of notification.

Specifically,

Per your policy titled, “DC Security Policy Regarding Suspect and Illegitimate Drugs” Revision 1.9 Effective Date 10/01/2015:

a. Distribution center inventory is checked to verify if the product exists in the facility on receipt of a suspect or illegitimate product notification. Your firm did not demonstrate that “shelf-checks” were performed for these products after notification.

b. Suspect product must be placed into quarantine and not processed further until suspicion is cleared or confirmed. There is no documentation demonstrating that your firm quarantined said products after receiving notification and during your investigation.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Jolanna A. Norton -S Digitally signed by Jolanna A. Norton -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001770786, cn=Jolanna A. Norton -S Date: 2018.07.03 13:54:40 -07'00'	Jolanna A. Norton, Consumer Safety Officer	07/03/2018

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OBSERVATION 2

Failure to make a determination regarding product subject to an illegitimate product notification from a trading partner.

Specifically,

Your firm did not demonstrate compliance with the requirements of the FD&C Act Section 582(c)(4)(B) to:

a. quarantine such product
b. take reasonable and appropriate steps to assist a trading partner to disposition such illegitimate product not in the possession or control of the firm
c. retain a sample

OBSERVATION 3

Systems and procedures to make notifications following determination of an illegitimate product are deficient in that they do not instruct notifications to all immediate trading partners, and sufficient tracing information is not retained to identify trading partners that received such product.

Specifically,

a. Your policy titled “DC Security Policy Regarding Suspect and Illegitimate Drugs” Revision 1.9 Effective Date 10/01/2015, does not require that all immediate trading partners the firm has reason to believe received illegitimate product be notified within 24 hours.

b. Transaction data for prescription drug purchases from the firm show that lot/batch numbers are not captured/ retained ; as such the firm does not have sufficient processes in place to determine and notify, within 24 hours, all the immediate trading partners that the firm had reason to believe may have received illegitimate product.

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