DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	2/6/2018-2/27/2018*
	FEI NUMBER 3004483427

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hilary Thibault, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Lynnfield Drug, Inc. dba Freedom Fertility Pharmacy	12 Kent Way, Suite 120F
CITY, STATE, ZIP CODE, COUNTRY Byfield, MA 01922-1221	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile and Sterile Products

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 OBSERVED:

OBSERVATION 1

Disinfecting agents and cleaning pads and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically, your firm cleans the interior of the ISO-5 classified (b) (4) located within your sterile cleanroom suite using (b) (4) prior to the aseptic production of drug products. Your firm uses non-sterile wipes (b) (4) wipes) to perform this cleaning process. There has been no assessment related to the use of non-sterile wipes in the ISO-5 classified area where aseptic processing occurs.

OBSERVATION 2

You had inadequate HEPA filter airflow over the area to which sterile product was exposed.

Specifically, on April 12, 2017, your firm performed an air pattern analysis (smoke study) of the sterile cleanroom suite and ISO-5 classified areas. The smoke studies conducted within the ISO-5 classified areas were inadequate as the smoke used was faint and intermittent. The ISO-5 classified areas were not

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	John P Mistler, Investigator	X John P Mistler Investigator Signed By: 2001294085 Date Signed: 02-27-2018 08:44:58	2/27/2018

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certified under dynamic conditions and unidirectional airflow was not verified under operational conditions. The smoke studies did not include the transfer of starting components and materials into the ISO-5 classified areas, transfer of in-process products into a sterile (b) (4) or transfer of product into final container closure.

***DATES OF INSPECTION**

2/06/2018(Tue), 2/08/2018(Thu), 2/09/2018(Fri), 2/12/2018(Mon), 2/13/2018(Tue), 2/15/2018(Thu), 2/21/2018(Wed), 2/27/2018(Tue)

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