

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718)340-7000; Fax: (718)662-5661 E-mail correspondence and responses to ORANYKFirmResponses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 2/22/2017, 2/24/2017, 2/28/2017
	FEI NUMBER 3013118095

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Philip E. Altman, Supervising Pharmacist

FIRM NAME Jacobs Pills, Inc. d/b/a The Healthy Choice Apothecary	STREET ADDRESS 250 Clearbrook Rd
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CITY, STATE AND ZIP CODE Elmsford, NY 10523	TYPE OF ESTABLISHMENT INSPECTED Producer of non-sterile drugs
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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


There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, the pharmacy failed to thoroughly review the compounding records to ensure all ingredients used in compounding of drug products are within expiry. Sildenafil (b) (4) (Lot (b) (4) ; Exp. Date: (b) (4))

- was used on 8/1/2016 to compound (b) (4) capsules of Sildenafil 100 mg Capsule (Lot #08012016@27). On 8/1/2016, (b) (4) capsules of Sildenafil 100 mg Capsule (Lot #08012016@27) were dispensed to patient under Rx (b) (4), (b) (6).
- was used on 11/2/2016 to compound (b) (4) capsules of Sildenafil 100 mg Capsule (Lot #11022016@35). On 11/3/2016, (b) (4) capsules of Sildenafil 100 mg Capsule (Lot #11022016@35) were shipped to patient via (b) (4) under Rx (b) (4), (b) (6).
- was used on 12/19/2016 to compound (b) (4) suppositories of Sildenafil 100 mg Suppository (Lot #12192016@69). On 12/20/2016, (b) (4) suppositories of Sildenafil 100 mg Suppository (Lot #12192016@69) and (b) (4) suppositories of Sildenafil 100 mg Suppository (Lot #12192016@64) were shipped to patient via (b) (4) under Rx (b) (4)

***DATES OF INSPECTION**

2/22/2017 (Wed), 2/24/2017 (Fri), 2/28/2017 (Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Mindy Chou, Investigator	DATE ISSUED 02/28/2017
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