

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

550 W. Jackson Blvd, Suite 1500
Chicago, IL 60661
312-353-5863Email Responses To: ORAPHARM3_RESPONSES@fda.hhs.gov
Attn: Program Division Director

DATE(S) OF INSPECTION

6/19, 6/20, 6/21, 6/22, 6/27/2018

FEI NUMBER

3011581046

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: William J. Kalman, Owner

FIRM NAME

Kalman Health & Wellness, Inc. dba Essential Wellness Pharma 2

STREET ADDRESS

4625 N University St.

CITY, STATE AND ZIP CODE

Peoria, IL 61614-5828

TYPE OF ESTABLISHMENT INSPECTED

Producer of Non-Sterile Drugs

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

Procedures for cleaning and sanitization of common, nondedicated equipment used to make drug products have not been shown to prevent contamination or cross contamination with other drug substances such as beta lactams or potent drugs.

OBSERVATION 2

Your firm is currently using (b) (4) water in (b) (4) plastic containers to make human drug products. On 6/20/18, I observed the compounding of Dexamethasone Ionto 4 mg/mL (liquid) formula ID 1160 Lot 1160-062018 using this water. You do not have objective evidence that this water is of sufficient quality to be used for pharmaceutical purposes.

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE



EMPLOYEE(S) NAME AND TITLE (Print or Type)

Brian D. Nicholson, C.S.O.

DATE ISSUED

06/27/2018