DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	2/17/2022-2/24/2022*
	FEI NUMBER 3021030637

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Arad A. Goudarzi, Pharmacist, Partial Owner

FIRM NAME	STREET ADDRESS
Ark Pharmacy, PC (dba Regency Medical Pharmacy)	1000 Newbury Rd Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Newbury Park, CA 91320-6436	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 I OBSERVED:
OBSERVATION 1
You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

(b) (4) is used as a component in the compounding of non-sterile drug product, (b)(4) . A total of (b)(4) lots ((b)(4)) of the (b)(4) were compounded in the past six (6) months.

***DATES OF INSPECTION**
2/17/2022(Thu), 2/18/2022(Fri), 2/22/2022(Tue), 2/23/2022(Wed), 2/24/2022(Thu)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Scott N Lim, Consumer Safety Officer

X Scott N Lim
Consumer Safety Officer
Signed By 2002619245
Date Signed 02-24-2022
12 47 06

DATE ISSUED
2/24/2022

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."