DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202 ORAPHARM2_RESPONSES@fda.hhs.gov	9/16/2024-9/20/2024* FEI NUMBER 1219592

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Adam R. Johnson, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Water-Jel Technologies, LLC	13359 Reese Blvd East
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Huntersville, NC 28078	Manufacturer and Own Label 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 OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, you consistently fail to complete your stability OOS and non-conformance investigations in a timely manner without adequate justification. Examples are as follows:

<u>OTC Stability OOSs</u>

(b) (4) Ointment
Lot # (b) (4) – (b) (4) potency too low @(b) (4). Investigation open for 340 days.

(b) (4) Ointment
Lot # (b) (4) – (b) (4) potency too low @(b) (4). Investigation open for 340 days.

(b) (4) Gel
Lot # (b) (4) – (b) (4) potency too high @(b) (4) too low @(b) (4). Investigation open for 290 days.

Lot # (b) (4) – (b) (4) potency too low @(b) (4) and @ (b) (4). Investigation open for 290 days.

(b) (4) Cream (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Susan O Oladeji, Investigator X Susan O Oladeji Investigator Signed By: Susan O. Oladeji -S Date Signed: 09-20-2024 13:32:20	9/20/2024

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Lot #(b) (4)-(b) (4) potency high @(b) (4). Investigation open for 163 days.

Lot #(b) (4)-(b) (4) potency high @(b) (4) & @(b) (4). Investigation open for 163 days.

(b) (4) Ointment
Lot #(b) (4) low potency @(b) (4). Investigation open for 93 days.

(b) (4) Ointment
Lot #(b) (4)–(b) (4) potency too low @(b) (4). Investigation open for 49 days.

(b) (4) Ointment
Lot #(b) (4) –(b) (4) high potency @(b) (4) and (b) (4). Investigation open for 39 days.

OTC Non-Conformances

Greater than 50% of the non-conformances you have initiated have been open for 156-681 days. The following investigations have been open for a year or more:

Product	Lot Number	Defect
(b) (4) (b) (4) Cream	(b) (4)	Packaging Error
(b) (4) Ointment	(b) (4)	Short Count

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(b) (4)	(b) (4)	Short Count
(b) (4)	(b) (4)	Limit Change
(b) (4) Gel	(b) (4)	Quarantine, Wrong
(b) (4) (b) (4) Cream	(b) (4)	Empty Doses
(b) (4) Cream	(b) (4)	Leaking
(b) (4)	(b) (4)	Leaking
(b) (4) Ointment	(b) (4)	Wrong Item Printed
(b) (4)	(b) (4)	Leaking

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Susan O Oladeji, Investigator

X Susan O Oladeji
Investigator
Signed By: Susan O. Oladeji -S
Date Signed: 09-20-2024
13:32:20

DATE ISSUED
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(b) (4) Cream		
(b) (4) Ointment	(b) (4)	Doses Leaking
(b) (4)	(b) (4)	Empty Doses
(b) (4) Ointment	(b) (4)	Short Count
(b) (4)	(b) (4)	Lot Number Issue
(b) (4) Gel	(b) (4)	Leaking

OBSERVATION 2

The written stability testing program is not followed.

Specifically, you have failed to adhere to section 5.9 of your "Stability Design" SOP in that you did not establish a protocol for each drug product stating the parameters of a stability study including storage conditions, length of the study, testing time intervals, and the total number of samples to be tested.

***DATES OF INSPECTION**

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9/16/2024(Mon), 9/17/2024(Tue), 9/18/2024(Wed), 9/20/2024(Fri)

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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."