DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 10 Waterview Blvd., 3rd Floor<br>Parsippany, NJ 07054<br>(973)331-4900 Fax:(973)331-4969<br>[redacted]<br>Industry Information: www.fda.gov/oc/industry | 03/08/2023-03/21/2023<br>FEI NUMBER<br>3022210898 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Abraham Green, Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| EzriCare, LLC | 1525 Prospect Street, Suite 204 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Lakewood NJ 08701-4642 US | TYPE ESTABLISHMENT INSPECTED<br>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 WE OBSERVED:

**The observations below are regarding own-label OTC drug products such as Bacitracin Zinc Ointment, USP (First Aid Antibiotic); Clotrimazole Cream 1% (Antifungal); Hydrocortisone Ointment USP 1% (Anti-itch); Hydrocortisone Cream USP 1% with Aloe Vera (Anti-itch); Miconazole Nitrate Cream USP 2% (Anti-fungal); Triple Antibiotic Ointment (First Aid); and Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium 10mg/ml) received and distributed by EzriCare LLC.**

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## OBSERVATION 1

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**There is no quality control unit.**

Specifically, your firm does not have a quality control unit that ensures own-label OTC sterile and non-sterile drug products which are manufactured by contract manufacturing organizations/firms (CMOs) and received and distributed by your firm meets specification. Your firm lacks adequate oversight over the CGMP activities such as manufacturing, release and stability testing, and packaging of finished drug product performed by your CMOs.

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## OBSERVATION 2

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**The responsibilities and procedures applicable to the quality control unit are not in writing.**

Specifically, procedures and control systems applicable and describing the function(s) of the quality control unit are not established. There are no written procedures describing the handling of quality related events such as recalls, returns, complaints, annual product reviews, and supplier/vendor qualification for own-label OTC drug products received and distributed by your firm. As of the current inspection, your firm has not audited/qualified your CMOs used to manufacture, and test finished drug products. You rely on your CMOs to manufacture, package, and test products on your behalf; however, you do not have a quality agreement describing each firm's responsibility.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Adetutu M Gidado, Investigator<br>Karishma Gopaul, Investigator<br>X Adetutu Gidado Investigator<br>Karishma Gopaul | 03/21/2023 |

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| Abraham Green, Operations | |
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## OBSERVATION 3

**There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.**

Specifically, own-label OTC sterile and non-sterile drug products received and distributed are not verified against an approved and/or established specification. Your firm does not have an established and/or approved specification with CMOs used for the manufacture of its own-label OTC sterile and non-sterile drug products.

## OBSERVATION 4

**Procedures describing the handling of written and oral complaints related to drug products are not written or followed.**

Specifically, your firm does not have an established and/or adequate written procedure describing the handling of all written and oral complaints regarding own-label OTC sterile and non-sterile drug products received and distributed. There is no assurance that customer complaints received by your firm online and/or over the phone are handled or managed adequately.

## OBSERVATION 5

**Written procedures are not established for evaluations done at least annually and including provisions for a review of complaints, recalls, returned or salvaged drug products and investigations conducted for each drug product.**

Specifically, your firm has not conducted any annual product review for own-label OTC sterile and non-sterile drug products which are manufactured by CMOs and received and distributed by your firm nor has your firm established an agreement with its CMO to conduct the annual product review on behalf of your firm.

***DATES OF INSPECTION**
**03/08/2023 (Wednesday), 03/21/2023 (Tuesday)**

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Adetutu M Gidado, Investigator<br>Karishma Gopaul, Investigator<br>X [signature] Adetutu Gidado Investigator<br>Karishma Gopaul | 03/21/2023 |

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."