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	9/23/2024-9/27/2024
	FEI NUMBER 3004758248

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Emil Miles Kaegi Jr., President

FIRM NAME	STREET ADDRESS
Packaging On Demand, Inc.	1284 Puerta Del Sol
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Clemente, CA 92673-6310	Contract OTC Drug Manufacturer

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:

LABORATORY CONTROL SYSTEM

OBSERVATION 1

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, identification testing of the active pharmaceutical ingredients has not been performed on final finished OTC drug products. For examples but not limited to the following:

1. No identification test was performed on the final release active ingredient of (b) (4) that was used in the final finished OTC drug product (b) (4) - (b) (4) Lot No.: (b) (4) - (b) (4) that was produced on (b) (4) and expires on (b) (4) with (b) (4) total finished goods produced and released by the quality unit on 04/30/2024.

2. No identification test was performed on the final release active ingredient of (b) (4) (b) (4) that was used in the production of final finished drug product (b) (4) Lot No.: (b) (4) Manufactured on (b) (4) and expired on (b) (4) with total of (b) (4) finished goods produced and released by the quality unit on 04/03/2024.

3. No identification test was performed on the final release active ingredient of (b) (4) that was used in the final finished OTC drug product (b) (4) Lot No.: (b) (4) that was produced on (b) (4) and expires on (b) (4) with (b) (4) total finished goods produced and released by the quality unit on 06/28/2024.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kham Phommachanh, Investigator - Dedicated Drug Cadre Pearl C Ozuruigbo, Investigator Wenzheng Zhang, Investigator X Pearl C Ozuruigbo Investigator Signed By: Pearl C. Ozuruigbo -S Date Signed: 09-27-2024 16:07:55	9/27/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	9/23/2024-9/27/2024
	FEI NUMBER 3004758248

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Emil Miles Kaegi Jr., President	
FIRM NAME Packaging On Demand, Inc.	STREET ADDRESS 1284 Puerta Del Sol
CITY, STATE, ZIP CODE, COUNTRY San Clemente, CA 92673-6310	TYPE ESTABLISHMENT INSPECTED Contract OTC Drug Manufacturer

4. No identification test was performed on the final release active ingredient of (b) (4) that was used in the final finished OTC drug product (b) (4) Lot. No.: (b) (4) that was produced on (b) (4) and expires on (b) (4) with (b) (4) total finished goods produced and released by the quality unit on 03/14/2024.

OBSERVATION 2
Drug product reserve samples are not stored in the same immediate container-closure system as the marketed product and an immediate container-closure system that has essentially the same characteristics as the marketed product.

Specifically, OTC drug products retain samples are not maintained in the same immediate container-closure system as the marketed product. For examples, OTC drug products (b) (4) lot (b) (4) (b) (4) manufactured on (b) (4) and (b) (4) lot (b) (4) manufactured on (b) (4) were observed not in the same container closure in the retain sample room.

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 3
Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, your firm's equipment qualification is inadequate. For example, your attempt of performance (PQ) references Batch production records: (b) (4), Lot # (b) (4) (b) (4), manufactured on (b) (4), (b) (4), Lot # (b) (4) manufactured on (b) (4) - (b) (4), and (b) (4), Lot # (b) (4) manufactured on (b) (4), for the qualification is inadequate in that it does not provide full documentation of IQ, OQ, and PQ for compounding tanks. For filling equipment there is no IQ, OQ, and PQ used in the qualification of OTC drug products.

OBSERVATION 4
Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kham Phommachanh, Investigator - Dedicated Drug Cadre Pearl C Ozuruigbo, Investigator Wenzheng Zhang, Investigator X Pearl C Ozuruigbo Investigator Signed By: Pearl C. Ozuruigbo -S Date Signed: 09-27-2024 16:07:55	9/27/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	9/23/2024-9/27/2024
	FEI NUMBER 3004758248

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Emil Miles Kaegi Jr., President

FIRM NAME	STREET ADDRESS
Packaging On Demand, Inc.	1284 Puerta Del Sol
CITY, STATE, ZIP CODE, COUNTRY San Clemente, CA 92673-6310	TYPE ESTABLISHMENT INSPECTED Contract OTC Drug Manufacturer

Specifically, your firm's cleaning validation for the equipment used to manufacture and package the over-the-counter (OTC) drug products is deficient. Your firm used (b) (4) and (b) (4) methods to test cleaning procedures in the equipment cleaning validation (Validation Report: Cleaning and Sanitization of Production Equipment, Document Number: VR-12-03, Approved Date: September 18, 2014).

However, the recovery study conducted in your equipment cleaning validation demonstrates that (b) (4) and (b) (4) testing failed to detect the dirty and clean surfaces of the production equipment. As a result, your firm's proper equipment cleaning procedures cannot be assured.

Without validated cleaning procedures for the equipment, the potential contamination that would alter the safety, identity, strength, quality, or purity of the drug products cannot be prevented.

OBSERVATION 5
The persons performing and double-checking the cleaning and maintenance are not dating and signing or initialing the equipment cleaning and use log.

Specifically,

Your equipment cleaning and sanitization log which is your firm's confirmation of which equipment was used have discrepancies with information on the batch production record. For example:

1. Batch production record for (b) (4) Lot # (b) (4) manufactured on (b) (4) indicated Tank (b) (4) as the production tank, and this lot is not on the cleaning log.

2. Batch production record for (b) (4) Lot # (b) (4) manufactured on (b) (4) indicated Tank (b) (4) as the production tank, and this lot is not on the cleaning log.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	9/23/2024-9/27/2024
	FEI NUMBER 3004758248

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Emil Miles Kaegi Jr., President

FIRM NAME	STREET ADDRESS
Packaging On Demand, Inc.	1284 Puerta Del Sol
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Clemente, CA 92673-6310	Contract OTC Drug Manufacturer

3. Batch production record for (b) (4) Lot # (b) (4) manufactured on (b) (4) indicated Tank (b) (4) as the production tank, and this lot is not on the cleaning log.

4. Batch production record for (b) (4) Lot # (b) (4) manufactured on (b) (4) indicated Tank (b) (4) as the production tank, and this lot is not on the cleaning log.

5. Batch production record for (b) (4) Lot # (b) (4) manufactured on (b) (4) indicated Tank (b) (4) as the production tank, and this lot is not on the cleaning log.

PRODUCTION SYSTEM

OBSERVATION 6
In-process specifications are not derived from previous acceptable process average and process variability estimates where possible.

Specifically, process validation is inadequate. There is no data to assure that bulk blends are uniform. For examples,

1. Your firm does not perform blend uniformity testing during the manufacturing process which prevents your firm from detecting potential variability in the homogeneity of active ingredients throughout the batch.

2. Your firm has not fully established appropriate time-based and temperature-based process control during manufacturing for example:

a. The batch production record for (b) (4), Lot # (b) (4) manufactured on (b) (4) (b) (4) states "(b) (4) - (b) (4) " Stabilized temperature was not recorded for this batch, and thermometer ID and Calibration due date were also not recorded.

b. The batch production record for (b) (4) Lot # (b) (4) manufactured on (b) (4) states "(b) (4) (b) (4)"

3. Your firm relies solely on content uniformity testing as the primary method for process validation and it is not consistent. For example:

a. The batch production record for (b) (4) Lot # (b) (4) manufactured (b) (4)-(b) (4) was distributed to the customer on 7/9/2024. Samples of finished drug products were collected from the (b) (4) of filling operation and tested separately for assay content. ***"Special Instructions:*** Drug Uniformity"

b. The batch production record for (b) (4) Lot # (b) (4) manufactured (b) (4)-(b) (4) was distributed to the customer on 9/28/2024. Samples of finished drug products were collected from the (b) (4) of filling operation and (b) (4) for assay content. ***"Special Instructions:*** Drug Uniformity ((b) (4) of Run)"

MATERIALS SYSTEM

OBSERVATION 7
The number of containers to be sampled and amount of material taken from each container is not based upon appropriate criteria.

Specifically,

Between January 2024 and August 2024, your firm used (b) (4) as the drug component to manufacture

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	9/23/2024-9/27/2024
	FEI NUMBER 3004758248

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Emil Miles Kaegi Jr., President

FIRM NAME	STREET ADDRESS
Packaging On Demand, Inc.	1284 Puerta Del Sol
CITY, STATE, ZIP CODE, COUNTRY San Clemente, CA 92673-6310	TYPE ESTABLISHMENT INSPECTED Contract OTC Drug Manufacturer

(b) (4) batches of (b) (4) different over-the-counter (OTC) drug products for wholesale and distribution. (b) (4) is a high-risk drug component for (b) (4) and (b) (4) (b) (4) contaminations.

However, your firm did not adequately sample and test (b) (4) for (b) (4) and (b) (4) from each container of each lot of each shipment before the high-risk drug component was used in the manufacture of drug products.

Without appropriate sampling and testing of drug components, the quality and safety of drug products could not be ensured.

OBSERVATION 8
Records fail to include an individual inventory record of each component and reconciliation of the use of each component with sufficient information to allow determination of any associated batch or lot of drug product.

Specifically, your firm has no inventory control records or reconciliation of the use of each lot of drug substances and excipients for any batch of the over-the-counter (OTC) drug products.

X Wenzheng Zhang
Investigator
Signed By: 2001330516
Date Signed: 09-27-2024 16:08:34

X Kham Phommachanh
Investigator - Dedicated Drug Cadre
Signed By: Kham Phommachanh -S
Date Signed: 09-27-2024 16:09:14

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Kham Phommachanh, Investigator - Dedicated Drug Cadre
Pearl C Ozuruigbo, Investigator
Wenzheng Zhang, Investigator

X Pearl C Ozuruigbo
Investigator
Signed By: Pearl C. Ozuruigbo -S
Date Signed: 09-27-2024 16:07:55

DATE ISSUED
9/27/2024

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."