DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Pl, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	09/09/19, 09/11/19
	FEI NUMBER 3010166882

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Patrick E. Riley, Owner and Manager

FIRM NAME	STREET ADDRESS
DAP Pharmaceuticals, LLC	1408 N Killian Dr., Ste 210
CITY, STATE, ZIP CODE, COUNTRY Lake Park, FL 33403-1961	TYPE ESTABLISHMENT INSPECTED API Repacker

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

Failure of your quality unit to ensure that there is stability data to support retest or expiry dates and storage conditions of the API.

Specifically, your firm has failed to perform stability testing to justify the use of the manufacturer's expiration date for your repackaged (b) (4), which is maintained at room temperature. The manufacturer's expiration/retest dating is based on a storage condition of (b) (4)

OBSERVATION 2

Failure to test the identity of each batch of incoming production material or appropriately qualify suppliers to rely upon their Certificate of Analysis.

Specifically, your firm has failed to perform at least one test to ensure the identity of the API prior to release for repackaging. In addition, your firm failed to qualify the supplier of (b) (4), Lot (b) (4), used in the repackaging of (b) (4), Lot (b) (4).

OBSERVATION 3

Failure to prepare and use production and control records for each API batch.

Specifically, your firm has failed to establish master packaging records and labeling used for the

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	Jennifer L. Huntington -S Digitally signed by Vivin George -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Vivin George -S, 0.9.2342.19200300.100.1.1=2002852115 Date: 2019.09.11 09:51:56 -04'00'	Jennifer L. Huntington, Investigator Vivin George, Investigator	09/11/2019

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repackaging of (b) (4) In addition, your firm does not prepare a batch record containing a representative label for each lot of repackaged (b) (4) .

OBSERVATION 4

Failure to establish written procedures describing the receipt, specifications, examination, and release of packaging and labeling materials.

Specifically, your firm has failed to establish procedures describing the receipt, specifications, examination, and release of packaging materials used for the repackaging of (b) (4) . In addition, your firm has failed to establish written procedures for the examination and release of labeling produced for repacked (b) (4)

OBSERVATION 5

Failure to provide the manufacturer's Certificate of Analysis with shipments of repackaged API to your customer.

Specifically, your firm has failed to provide customers a copy of the manufacturer's Certificate of Analysis (COA) with shipments of (b) (4)

OBSERVATION 6

Failure to have a quality unit that is independent of production and fulfills quality assurance (QA) and quality control (QC) duties.

For example, the same employees that perform repackaging activities also released batches for distribution. For example, (b) (4) was repacked and released for distribution by the same employee. This was observed a minimum of 12 additional times from 01/14/14 to 09/30/15.

OBSERVATION 7

Failure to establish a procedure for the training of employees and to ensure training is regularly conducted by qualified individuals and covers, at a minimum, the particular operations that each employee performs and cGMP as they relate to the employee's functions.

Specifically, your firm has failed to ensure employees are routinely provided training on cGMP and

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procedures required to perform their duties.

OBSERVATION 8

Failure to ensure that your cleaning and sanitization methods for equipment used in the repackaging of API are effective.

Specifically, your firm has failed to provide sufficient evidence that the cleaning and sanitization procedures used to clean dedicated equipment used for the repackaging of (b) (4) , is effective at eliminating microbial contamination and removes residual cleaning agents.

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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."