DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768 ORAPHARM2_RESPONSES@fda.hhs.gov	5/23/2023-6/2/2023* FEI NUMBER 3013023419

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Kenneth G. Josefczyk, Director Centralized Pharmacy BayCare

FIRM NAME	STREET ADDRESS
BayCare Integrated Service Center, LLC /dba BayCare Central Pharmacy	7802 E Telecom Pkwy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Temple Terrace, FL 33637-0928	Outsourcing (503B) Facility

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

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, the following information is not found on your drug product labels:

a) Dosage form

Examples of your drug product labels that do not contain this information:

· Norepinephrine bitartrate 16 mg/250 mL

· Oxytocin 30 units in 500 mL NaCl 0.9%

· Ephedrine sulfate 25 mg/5 mL

· Neostigmine methylsulfate 4 mg/4 mL

· Succinylcholine chloride 100 mg/ 5 mL

· Iohexol 2.4 g Iodine/8 mL

b) A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient, as required under section 503B(a)(10)(A)(iii)(X).

Examples of your drug product labels that do not contain this information:

· Norepinephrine bitartrate 16 mg/250 mL

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Joanne E King, Investigator	X Joanne E King Investigator Signed By: 1300174867 Date Signed: 06-02-2023 13:33:08	6/2/2023

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*DATES OF INSPECTION

5/23/2023(Tue), 5/24/2023(Wed), 5/25/2023(Thu), 5/26/2023(Fri), 5/31/2023(Wed), 6/01/2023(Thu), 6/02/2023(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joanne E King, Investigator X Joanne E King Investigator Signed By: 1300174867 Date Signed: 06-02-2023 13:33:08	6/2/2023

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."