DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	9/24/2020-10/9/2020* FEI NUMBER 3002815949

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Michael Tursi, CEO	
FIRM NAME Stokes Healthcare Inc. dba Epicur Pharma	STREET ADDRESS 8000 Commerce Pkwy Ste 600
CITY, STATE, ZIP CODE, COUNTRY Mount Laurel, NJ 08054-2211	TYPE ESTABLISHMENT INSPECTED Outsourcing 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:

For the manufacturing of sterile injectable drug products and ophthalmics such as Buprenorphrine 0.5mg/mL Injection Solution, Lot D200562, Exp 9/25/2021 (Shelf Life 1 year); Guaifenesin 50 mg/mL Inj in 1000mL IV Bags, Lot R200560, Exp 3/23/2021 (Shelf Life 180 days); Fentanyl Citrate PF 50 mcg/mL Injection Solution, Lot D200260, Beyond Use Date 10/28/2020 (Shelf Life 180 days); and Cidofovir 0.5% Ophthalmic Solution, 5 mL, Lot R200148, Use By 11/21/2020 (Shelf Life 240 days):

OBSERVATION 1

Deviations from written production and process control procedures are not justified.

Specifically, after the (b) (4) were dropped or knocked to the floor following visual inspection. There was no investigation or justification as to why those units were not incubated for the balance of the (b) (4) and then inspected for turbidity/microbial growth. This media fill, (b) (4), was performed in 6/2020. It was the (b) (4) used to validate aseptic processing in cleanroom C704, using your new ophthalmic bottle filling line.

OBSERVATION 2

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, your firm lacks process control validation data to support the filling of ophthalmic drug products into 8ml and 4ml plastic bottles. Your validation data from 15ml bottles does not directly (b) (4), which operate at (b) (4). Data is missing

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Russell J Glapion, Investigator	X Russell J Glapion Investigator Signed By: Russell J. Glapion -S Date Signed: 10-09-2020 09:33:38	10/9/2020

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on line speed correlation to downtime, the number of interventions in the ISO 5 area, and your firm's ability to maintain aseptic conditions throughout the manufacturing process.

OBSERVATION 3

Procedures describing the handling of all written and oral complaints regarding a drug product are not established and followed.

Specifically, product complaints received between 3/10/2020 and 9/23/2020 were not entered into your Client Notice of Event Report and evaluated for product quality issues. At least seven (7) examples (complaints 20-007 to 20-0013) were noted.

OBSERVATION 4

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, your firm has not established bulk hold times in your master batch records or written procedures. The existing practice of (b) (4) ophthalmic liquids and injectable drug products (b) (4) does not establish a formal process control parameter. This deficiency could result in further processing and/or the release of a drug product which was not processed within validated parameters.

*DATES OF INSPECTION

9/24/2020(Thu), 9/25/2020(Fri), 9/28/2020(Mon), 9/29/2020(Tue), 9/30/2020(Wed), 10/01/2020(Thu), 10/05/2020(Mon), 10/09/2020(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."