DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71-5128 Silver Spring, MD 20993-0002 240-402-8906	6/6/2022-6/17/2022* FEI NUMBER 3009256939

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christine H. Lee, MD, clinical investigator

FIRM NAME	STREET ADDRESS
Christine H. Lee, M.D.	1952 Bay Street, Royal Jubilee Hospital, Memorial Pavilion
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Victoria, British Columbia, Canada, V8R 1J8	Clinical Investigator

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

An investigation was not conducted in accordance with the signed statement of investigator and investigational plan.

Specifically,

For the 2014-01 and 2017-01 studies, human clinical studies of an investigational new drug, that you conducted under an IND, you failed to follow the protocols as follows.

A. You failed to ensure that all subjects you enrolled and dosed with study drug met all eligibility criteria for the studies. For study 2014-01, you enrolled (b) (6), (b) (7) (C) subjects and dosed (b) (6), (b) (7) (C) subjects with study drug. For study 2017-01, you enrolled (b) (6), (b) (7) (C) subjects and dosed (b) (6), (b) (7) (C) subjects with study drug. For each study, you enrolled and dosed with study drug one subject who failed to meet an inclusion criterion as follows.

1. Subject (b) (6), (b) (7) (C) in study 2014-01 did not meet inclusion criterion 4, in that you lacked documentation that the subject had a positive stool test for C. difficile within 60 days prior to enrollment. You documented the subject's most recent positive C. difficile stool test as (b) (6), (b) (7)(C), 73 days prior to the date you enrolled this subject, on (b) (6), (b) (7)(C). You dosed subject (b) (6), (b) (7) (C) with study drug on

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	Sherri N Rohlf, Investigator	X Sherri N Rohlf Investigator Signed By: Sherri N. Rohlf -S Date Signed: 06-17-2022 14:13:04	6/17/2022

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(b) (6), (b) (7)(C)

2. Subject (b) (6), (b) (7)(C) in study 2017-01, who you enrolled and dosed with study drug, did not meet inclusion criterion 2, in that the subject did not meet the protocol definition of recurrent C. difficile infection (CDI). The subject's second occurrence of CDI diarrhea began on (b) (6), (b) (7)(C) nine weeks after completion of treatment for previous CDI, on (b) (6), (b) (7)(C) The protocol required a recurrence of CDI diarrhea to start within eight weeks after completion of treatment for previous CDI to meet the definition of recurrent CDI for study entry. You enrolled subject (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C) and dosed the subject with study drug on (b) (6), (b) (7)(C). This subject completed the study.

B. For two subjects (subject (b) (6), (b) (7)(C) and subject (b) (6), (b) (7)(C)) who you enrolled into study 2014-01 and dosed with study drug, you failed to obtain the signatures of the subjects on informed consent forms (ICFs) and instead used the subjects' legally authorized representatives (LARs) to obtain informed consent. The 2014-01 protocol, section 6.2, requires all subjects to sign the ICF. Furthermore, inclusion criterion 11 of study 2014-01 requires subjects to be willing and able to provide informed consent.

C. On (b) (6), (b) (7)(C), you dosed subject (b) (6), (b) (7)(C) in study 2014-01 with blinded study drug, batch (b) (4), which according to the packing slip from the sponsor, was intended for subject (b) (6), (b) (7)(C)

D. In study 2014-01, for subjects (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C), who you enrolled and dosed with study drug, you failed to obtain stool samples for C. difficile testing at the time you suspected reoccurrence of C. difficile

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infection, which was required by the protocol. You documented these subjects as treatment failures and then dosed them with open label study drug without testing their stool for C. difficile.

E. You dosed subject (b) (6), (b) (7)(C) in study 2014-01 with blinded study drug at visit 2 on (b) (6), (b) (7)(C) after the subject had taken antibiotics on the same morning prior to dosing. The protocol required you to confirm a 24-48 hour antibiotic washout period prior to dosing at visit 2.

OBSERVATION 2

Failure to prepare or maintain adequate case histories with respect to observations and data pertinent to the investigation.

Specifically,

In the 2014-01 study, for subject (b) (6), (b) (7)(C), who you dosed with study drug on (b) (6), (b) (7)(C) and who completed the study on (b) (6), (b) (7)(C), you documented the subject had been admitted to the hospital (b) (6), (b) (7)(C) for acute coronary syndrome, but you lack documentation that you assessed this hospital admission for adverse events. You failed to enter into the subject's electronic case report form any serious adverse events or adverse events associated with this hospital admission. Subject (b) (6), (b) (7)(C) received study drug and completed the study.

***DATES OF INSPECTION**

6/06/2022(Mon), 6/07/2022(Tue), 6/08/2022(Wed), 6/09/2022(Thu), 6/10/2022(Fri), 6/13/2022(Mon), 6/14/2022(Tue), 6/15/2022(Wed), 6/16/2022(Thu), 6/17/2022(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."