DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115 ORABIMOW.Correspondence@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	12/14/2021-12/20/2021* FEI NUMBER 3020908057

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Charles E. Canter, MD

FIRM NAME	STREET ADDRESS
Charles E. Canter, MD	1 Children's Place, Department of Pediatrics
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
St Louis, MO 63110	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) (WE) OBSERVED:

OBSERVATION 1

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

Specifically,

A) For 3 of the 3 subjects enrolled in protocol (b) (4) exclusion criteria cannot be confirmed from source medical history records. The exclusion criteria that cannot be confirmed are as follows:

Subject (b) (6), (b) (7)(C)	Subject (b) (6), (b) (7)(C)	Subject (b) (6), (b) (7)(C)
Exclusion Criteria	Exclusion Criteria	Exclusion Criteria
#3	#6	#4
#4	#14	#14
#7	#15	#15
#14		#16
#15		
#16		

B) For 3 of the 3 subjects enrolled in protocol (b) (4) source records do not indicate if a clinical investigator or sub-investigator reviewed inclusion/exclusion criteria to determine if subjects were eligible to be enrolled into the study.

C) For the 3 subjects enrolled in (b) (4) an end of study visit cannot be confirmed as occurring.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Karen Montgomery	Karen M. Montgomery, Investigator	12/20/21

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St Louis, MO 63110	Clinical Investigator

OBSERVATION 2

Investigational drug disposition records are not adequate with respect to quantity and use by subjects.

Specifically,

For all 3 enrolled subjects, drug accountability records do not indicate who dispensed study drug to subjects, how much of the study drug was taken by subjects and what the study drug disposition was. The chart below lists the drug accountability that cannot be determined:

Subject ID	Bottle #	Date Dispensed	Dispensed By	How Much Study Drug Returned/Used
(b) (6), (b) (7)(C)	(b) (4)	12/12/2019	Unknown	Unknown
		12/12/2019	Unknown	Unknown
		1/14/2020	Unknown	Unknown
		1/14/2020	Unknown	Unknown
		2/17/2020	Unknown	Unknown
		3/12/2020	Unknown	Unknown

OBSERVATION 3

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

Specifically,

Source paper case report forms do not indicate who is conducting the study visit procedures for 3 of the 3 enrolled subjects in the (b) (4) study. From the source paper case report forms it cannot be determined who conducted the following study visits:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	KMM	Karen M. Montgomery, Investigator	12/20/21

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St Louis, MO 63110	Clinical Investigator

Subject (b) (6), (b) (7)(C)	**Subject** (b) (6), (b) (7)(C)	**Subject** (b) (6), (b) (7)(C)
Screening	Screening	Screening
Baseline	Baseline	Baseline
1 Month Visit	1 Month Visit	1 Month Visit

***DATES OF INSPECTION**

12/14/2021(Tue), 12/15/2021(Wed), 12/16/2021(Thu), 12/17/2021(Fri), 12/20/2021(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Karen Montgomery	Karen M. Montgomery, Investigator	12/20/21

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 judgement, 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."