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	5/15/2023-5/19/2023
	FEI NUMBER 3025922936

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Konrad Rejdak, MD, Clinical Investigator, Professor & Head of Neurology Dept.

FIRM NAME	STREET ADDRESS
Konrad Rejdak, M.D.	Nr 4 w Lublinie ul.Jaczewskiego 8, Samodzielny Publiczny Szpital Kliniczny
CITY, STATE, ZIP CODE, COUNTRY Lublin, Lubelskie, 20-090 Poland	TYPE ESTABLISHMENT INSPECTED 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:

Observations list below were found as a result of my review of the clinical research (b) (4) : A Phase III Efficacy, Safety, and Tolerability Study of (b) (4)

OBSERVATION 1

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

Specifically, source data was not available for several Subject's adjusted (b) (4) , which were not directly recorded in the (b) (4) at the time of the (b) (4) as required by Protocol Section 18.2 Study Documentation and Case Report Forms. For Example:

A. Subject (b) (6), (b) (7)(C) :
(b) (4) Assessment Time: (b) (4) Upload Date/Time (b) (4)
(b) (4) Assessment Time: (b) (4) Upload Date/Time (b) (4)
(b) (4) Assessment Time: (b) (4) Upload Date/Time (b) (4)

B. Subject (b) (6), (b) (7)(C)
(b) (4) Assessment Time: (b) (4) Upload Date/Time (b) (4)

C. Subject (b) (6), (b) (7)(C)
(b) (4) Assessment Time: (b) (4) Upload Date/Time (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Alanna L Mussawwir Bias, Investigator - Dedicated BIMO Cadre X	DATE ISSUED 5/19/2023

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Lublin, Lubelskie, 20-090 Poland	Clinical Investigator

(b) (4) Assessment Time: (b) (4) Upload Date/Time (b) (4)

D. Subject (b) (6), (b) (7)(C):

(b) (4) Assessment Time: (b) (4) Upload Date/Time (b) (4)
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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Alanna L Mussawwir Bias, Investigator - Dedicated BIMO Cadre	X	5/19/2023

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."