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	6/14/2018-8/1/2018* FEI NUMBER 1000526871

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert Iannone, M.D., Cheif Medical Officer

FIRM NAME	STREET ADDRESS
Immunomedics, Inc.	300 The American Rd
CITY, STATE, ZIP CODE, COUNTRY Morris Plains, NJ 07950-2460	TYPE ESTABLISHMENT INSPECTED Sponsor

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:
The following observations pertain to the Clinical Study: (b) (4) [redacted]

OBSERVATION 1

Not all participating investigators were informed of new observations discovered by or reported to the sponsor.

Specifically:

- The Sponsor, Immunomedics, did not notify other investigators of a report of particulate matter discovered in Lot # (b) (4) of the Investigational Product (IP) at Site # 252.

OBSERVATION 2

Failure to ensure proper monitoring of the study and ensure the study is conducted in accordance with the protocol and/or investigational plan.

Specifically:

1) The Following Interim Monitoring Visit Reports could not be located:

Site Number	Visit Date
132	7/14-16/2015; 6/14-16/2016

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Peter R Lenahan, Investigator

X Peter R Lenahan
Investigator
Signed By: Peter R. Lenahan -S
Date Signed: 08-01-2018 16:56:32

DATE ISSUED
8/1/2018

2) The Following Site Initiation Visit Reports could not be located:

Site Number	Visit Date
068	Unknown
261	Unknown
263	10/11/2016
264	Unknown
266	Unknown

3) The following Interim Visit Monitoring Reports (IMVRS) were not finalized within 60 days of the monitoring visit:

Site Number	Visit Date
068	4/18-19/2017; 5/23-24/2017; 7/25-26/2017; 9/6/2017; 11/14-15/2017
132	5/5-9/2014; 6/23-26/2014
252	3/11/2014
255	2/28/2017-3/01-03/2017; 5/02-18/2016
206	2/04-05/2015; 5/27-28/2015; 7/23/2015; 10/18-19/2016; 1/31/2017-2/01/2017
260	9/07-08/2016; 10/29/2017-11/01/2017

OBSERVATION 3

The immediate package of the investigational new drug does not bear a label with the statement "Caution: New Drug- Limited by Federal (or United States) law to investigational use

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Specifically, the investigational drug labeling stated: "INVESTIGATIONAL DRUG FOR CLINICAL TRIAL USE ONLY. - STERILE."

OBSERVATION 4

Electronic records are used, but they do not meet systems validation and audit trail requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Specifically, Immunomedics utilized the computer program (b) (4) to record data from each of the clinical site's Case Report Forms (CRFs), including Adverse and Serious Adverse Events, from inception through May of 2017 for the reporting of clinical data to FDA. The program was not validated, and an audit trail to monitor use was not implemented.

***DATES OF INSPECTION**

6/14/2018(Thu), 6/15/2018(Fri), 6/18/2018(Mon), 6/19/2018(Tue), 6/20/2018(Wed), 6/21/2018(Thu), 7/10/2018(Tue), 7/11/2018(Wed), 7/12/2018(Thu), 7/16/2018(Mon), 7/17/2018(Tue), 7/18/2018(Wed), 7/19/2018(Thu), 7/20/2018(Fri), 8/01/2018(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Peter R Lenahan, Investigator	X Peter R Lenahan Investigator Signed By: Peter R. Lenahan -S Date Signed: 08-01-2018 16:56:32	8/1/2018