DEPARTMENT OF HEALTH AND HUMAN SERVICES
DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. FOOD AND [ ]

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New York District 158-15 Liberty Avenue Jamaica, NY 11433 Phone:7183407000 Industry Information: www.fda.gov/oc/industry	07/13/2026-07/17/2026*
	FEI NUMBER 3012696190

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Maneesh Gandhi, V.P and Site Head

FIRM NAME	STREET ADDRESS
InvaGen Pharmaceuticals, Inc.	550 S Research Pl
CITY, STATE AND ZIP CODE Central Islip, NY 11722-4415	TYPE OF ESTABLISHMENT INSPECTED Manufacturer and Packager

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

Your firm could not provide evidence of sufficient systems and processes to ensure compliance with the requirements of section 582(b)(4) of the FD&C Act, as amended by the Drug Supply Chain Security Act (DSCSA).

Specifically,

Your firm lacks sufficient systems and processes to ensure compliance with the requirements of section 582(b) of the FD&C Act, as amended by the Drug Supply Chain Security Act (DSCSA). For example, your Standard Operating Procedure, (b)(4) : SOP-0012, titled "Drug Supply Chain Security Act (DSCSA)", Revision 0, effective date 05, December 2025 and SOP#PK046"Operational Procedure for Serialization and Aggregation Operations in Packaging Lines", Revision 02, effective date 25, July,2023, lacks sufficient systems and processes for the following:

- Identifying suspect products and conducting suspect product investigations in coordination with trading partners.
- Responding to notifications of illegitimate product
- Notifying FDA and relevant immediate trading partners of illegitimate product and product with a high-risk of illegitimacy.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Fredrick Razzaghi, Investigator Luxuly Abraham, Investigator	07/17/2026

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."