DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661 Industry Information: www.fda.gov/oc/industry	05/13/2015 - 05/26/2015* FEI NUMBER 3003950641

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dr. Sudhakar Rao Vidiyala, President & CEO

FIRM NAME	STREET ADDRESS
InvaGen Pharmaceuticals, Inc.	7 Oser Ave 600 Old Willets Path
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hauppauge, NY 11788-3811	Pharmaceutical Manufacturer

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

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically:

1)The firm's Corrective And Preventive Action (CAPA) system is not routinely employed as described in their written *procedure SOP* # QA036 "Corrective Actions and Preventive Actions (CAPA)" which states in the "SCOPE" section: "(b) (4)
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In the period 10/26/2010 to present, the firm has initiated eight (8) CAPAs, the most recent being initiated 11/12/2013. It is noted that corrective actions proposed/ initiated in response to several specific regulatory observations cited by an FDA inspection two months prior to the current inspection were handled by change control rather than through the CAPA system. As acknowledged in the firm's CAPA procedure, it is the CAPA system which is intended to track and evaluate over time, the adequacy of corrective actions.

In citing this FDA 483 observation, it is noted, for example, regulatory issues which were not handled through the CAPA system include:

- Failure to initiate CAPAs to evaluate the effectiveness of corrective actions which were limited to multiple retraining sessions of the same personnel for the same issues following ten (10) Laboratory Failure Reports and Fifty-six (56) Laboratory Deviation Notices in the year 2014 which concerned analyst errors.
- Failure to initiate CAPAs to evaluate the identified root cause(s) and corrective actions despite ninety (90) Laboratory Deviation Notices in 2014 which led to retesting of the sample sets in each case.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Robert C. Horan, Investigator	05/26/2015

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Finally, it is noted that in response to inquiry during the current inspection as to why issues such as the examples given above were handled through change control rather than CAPA, it was stated that if management determines at a later date that the issues continue, they can decide to initiate a CAPA. This approach fails to recognize the cGMP role and regulatory expectation regarding the use of a CAPA system as the mechanism for initiating corrective actions and for conducting documented tracking and evaluation of the effectiveness of corrective actions initiated for the various operations identified in the "SCOPE" section of the firm's written procedure SOP QA036.

2)The firm has not determined the root cause for the discoloration of Hydroxyzine HCl Tablets which has been the subject of a number of complaints received by the firm nor the extent of the physical appearance change within individual batches. During the current inspection, the firm's V.P. Quality, stated that the percentages of discolored tablets in bottles examined as complaint samples have been low, however, in a separate discussion, the same individual stated that one principal reason for initiating a change control to replace the previous white film coating with a beige colored coating is that it is possible that in the past, some tablets may not have received sufficient coating due to core tablets and coating both being white.

3)There is a quality agreement between InvaGen Pharmaceuticals, Inc. and the contract packager (b) (4) (b) (4) which addresses responsibility of (b) (4) regarding complaints received by InvaGen for packaging related issues such potential introduction of foreign tablets/ capsules during packaging operations, however, review of InvaGen investigation for complaint (b) (4) which reported two different types of tablets in a sealed bottle of Amlodipine 5 mg, 90 count, lot I1409363 concluded that "this has happened outside our facility and is beyond our scope of investigation". There is no reference to any communication with (b) (4) nor to any investigation on the part of the referenced firm.

4)The quality agreement between drug manufacturer InvaGen and the firm (b) (4) does not define the responsibilities of the two firms with respect to communication with end user concerning complaint investigations/ resolutions. During discussion with InvaGen quality management concerning this issue, the verbal response given was that the responsibility is delegated to (b) (4) via the statement included in response letters sent to (b) (4) from InvaGen which reads "Please communicate through copy of this letter to all concerned".

* DATES OF INSPECTION:
05/13/2015(Wed), 05/14/2015(Thu), 05/15/2015(Fri), 05/19/2015(Tue), 05/22/2015(Fri), 05/26/2015(Tue)

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	Robert C. Horan, Investigator	05/26/2015