DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718) 662-5661 Industry Information: www.fda.gov/oc/industry	09/12/2018-09/26/2018*
	FEI NUMBER 3008897678

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ms. Vinia Jeudy, Sr. Director of Quality Assurance

FIRM NAME	STREET ADDRESS
Chartwell Pharmaceuticals, LLC	77, Brenner Drive,
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Congers, New York, 10920	Pharmaceutical Drug 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) (WE) OBSERVED:

OBSERVATION 1

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, you have not completed protocol-driven equipment cleaning validation studies for any of the equipment used to the manufacture of commercial pharmaceutical drug products for the U.S market. The following are few examples of the equipment which lacked cleaning validation study.

I. (b) (4) (b) (4) Capsule Filling Machine, Equipment ID E#07&E#09
II. (b) (4) Capsule Weight Checker Machine, Equipment ID E#03
III. (b) (4) Powder Filling Machine, Equipment ID P#01

OBSERVATION 2

Procedures describing the warehousing of drug products are not established.

Specifically, the firm has not performed a complete temperature mapping study of the Finished Goods/ Raw material Warehouse (b) (4)), the Heating Ventilation and Air Condition (HVAC) unit was installed in 2011.

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not in writing. Electronic records are used, but they do not meet audit trail requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Your firm has no written procedure which describes how laboratory instruments audit trail reviews must be performed; who is qualified to do them and how often they must be conducted.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Sony Mathews, CSO- Drug Specialist.	09/26/2018

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OBSERVATION 4

The building lacks adequate space for the orderly placement of equipment and materials to prevent mix- ups between different components, drug product containers, closures, in-process materials and drug products and to prevent contamination.

Specifically, during the walk-through at your facility Raw material/ Finished Goods warehouse, it was observed that the released raw materials and released finished products were stored in the aisle between the racks. This limits the access to raw materials and finished products stored on the racks. The warehouse appeared to be limited in space which can potentially lead to cross contamination.

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*DATES OF INSPECTION

09/12/2018(Wed), 09/13/2018(Thu), 09/17/2018(Mon), 09/20/2018(Thu), 09/21/2018(Fri), and 09/26/2018(Wed).

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
SEE REVERSE OF THIS PAGE		Sony Mathews, CSO- Drug Specialist.	09/26/2018

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."