DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER Division of Inspectional Assessment; Attn. Mahesh Ramanadham, Director E-MAIL: Mahesh.Ramanadham@fda.hhs.gov; PHONE +1-301-796-3272 Mail address: 10903 New Hampshire Ave. White Oak Building 51, Room 4328 Silver Spring, MD-20993 Industry Information: www.fda.gov/oc/industry	September 13 to September 20, 2018 FEI NUMBER 3007255826

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Aldo Braca, CEO and President

FIRM NAME	STREET ADDRESS
BSP Pharmaceuticals S.p.A.	Via Appia km. 65,561
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
04013 Latina Scalo LT, Italy	Drug Substance and Drug product Manufacturing Facility

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:

1. There are discrepancies between the information included in the (b) (4) and the operations at the contract manufacturing facility. Specifically,
   a. Section 3.2.P.3.3 of the (b) (4) states that in case of a post-use integrity failure of the (b) (4) the batch will be rejected. However, neither the (b) (4) integrity test procedure OP-002, section 5.10 nor the deviation procedure DQA-013 indicates whether a confirmed failure of the (b) (4) integrity test will result in batch rejection.
   b. Information provided in section 3.2.P.3.5 of the (b) (4) to support stopper (b) (4) ST3-032 corresponds to validation studies conducted to support (b) (4) of seals for a different product not related to (b) (4)

2. Pressure monitored during routine (b) (4) of the (b) (4) drug product is not representative of the pressure validated during the microbial retention studies. Specifically, pressure is monitored in the holding tank (b) (4) of the (b) (4) but is not monitored immediately (b) (4) of the (b) (4) and is not continuously monitored (b) (4) of the (b) (4)

3. Procedure QC-001 for Management of Out of Specification and Out-of-Alert limits is inadequate. Specifically, the procedure does not specify the disposition of a batch with a confirmed release out-of-specification.

9/21/2018

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Rachel Novak	Reyes Candau-Chacon, PhD, Microbiologist; Jessica Hankins, PhD, Microbiologist; Rachel Novak, PhD, Biologist; Ephrem Hunde, PhD, Chemical Engineer	09/21/2018