DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Christopher Downey, Ph.D., OPMA Division Director - Biotechnology US Food & Drug Administration, Office of Pharmaceutical Quality-OPMA 10903 New Hampshire Avenue, Bldg. 22, Silver Spring, Maryland 20993 OPFBLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	02/19-23, 26-29/2024
	FEI NUMBER 3007255826

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Aldo Braca, CEO and President (aldo.braca@bspusa-inc.com)

FIRM NAME	STREET ADDRESS
BSP Pharmaceuticals S.p.A.	Via Appia Km 65,561
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Latina Scalo, Italy 04013	Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1:
Personnel monitoring is inadequate. Specifically, following Grade A critical RABS [redacted] (b) (4) setup operations, for the introduction of packaged and bagged sterile components into the filling line prior to RABS [redacted] (b) (4) sanitization, [redacted] (b) (4) air operators are not monitored via finger dab plates for those Grade A operations in Sterile [redacted] (b) (4) and Sterile [redacted] (b) (4)

OBSERVATION 2:
Indirect product contact surfaces used in aseptic drug product filling operations are not always sterile. Specifically, the loading of sterile stoppers into sterile [redacted] (b) (4) Bags uses a sanitized transfer chute within the Grade A transfer [redacted] (b) (4) located in Bldg [redacted] (b) (4) Sterile [redacted] (b) (4) Suite Room [redacted] (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Michael R. Shanks -S Digitally signed by Michael R. Shanks -S Date: 2024.02.29 10:08:05 +01'00' Deborah Schmiel -S Digitally signed by Deborah Schmiel -S Date: 2024.02.29 10:09:48 +01'00'	Michael R. Shanks, Senior Biologist Deborah Schmiel, Biologist	02/29/2024