DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OS, White Oak Building 51, Room 4316 10903 New Hampshire Avenue Silver Spring, MD 20993 Phone: 1-301-796-3254 ; Email: cderosiab@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	06/05 - 09/2017 FEI NUMBER 3002807048

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Roland Winkler, CEO and Administrator Unico

FIRM NAME	STREET ADDRESS
Capua BioServices SpA	Strada Statale Appia 46/48
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
81043 Capua (Caserta) - Italy	(b) (4) API 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

The water (b) (4) distribution system is not designed and monitored so as to prevent contamination of drug substances. (b) (4) water is used as a (b) (4) component during the (b) (4) (b) (4) stages. For example,

a) Routine monitoring practices for sampling points and points of use at the dedicated (b) (4) production plant (b) (4) are described in, "Official List for Sampling Points and Frequency of Utilities" v.2, implemented on 04/21/16. Sampling and testing practices are not performed to determine conformance with chemical specifications from the sampling point located at (b) (4) or sample point (b) (4) located (b) (4) of the (b) (4) Samples are not collected near the point of use at (b) (4)

b) Your firm does not perform any identification testing on growth identified in samples collected from the (b) (4) water line supporting the dedicated (b) (4) production plant (b) (4).

c) The (b) (4) water system used during production of (b) (4) is designed linearly with no recirculating loop. Several legs of the system are used during (b) (4) production, but innumerable others are not used as frequently. All individual legs have not been identified and evaluated for the purpose of monitoring on an established frequency.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Samantha J. Bradley Zachary A. Bogorad	Samantha J. Bradley, Drug Investigator Zachary A. Bogorad, Drug Investigator	06/09/2017