DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Bldg 51, Rm 4225 Silver Spring, MD 20993 Phone: (301) 796-3334 Fax: (301) 847-8738 Industry Information: www.fda.gov/oc/industry	05/28/2018-06/01/2018
	FEI NUMBER 3003370212

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Miroslava Vargova, Chairman of Board of Director

FIRM NAME	STREET ADDRESS
Biotika A.S.	Slovenska Lupca 566
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Slovenska Lupca, Banskobystricky, 96713, Slovakia	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

Completion of significant steps in (b) (4) batch production and control records are not documented.

Specifically,

A. (b) (4) fermentation production records do not include complete documentation of in-process test results. For example,
i. (b) (4) in-process test results for batch (b) (4) at the (b) (4) fermentation.
ii. (b) (4) in-process test result for batch (b) (4) in the (b) (4) fermenter at cultivation hour (b) (4).
iii. (b) (4) in-process test results for batch (b) (4) in the (b) (4) fermenter at cultivation hour (b) (4).

B. Parameters of Class D cleanroom area during sampling of (b) (4) batch (b) (4) are not documented in the batch production record for sampling of product for (b) (4) analysis. For example,
i. Differential pressure of the personnel (b) (4) material (b) (4) and (b) (4) area.
ii. Relative humidity and temperature of the (b) (4) area.

C. Volume of (b) (4) water used to (b) (4) and (b) (4) of (b) (4) solution of (b) (4) in storage tank 78301 are not documented in the batch production records for (b) (4) of (b) (4) (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Tiara N Brown	Tiara N. Brown-Crosen, Investigator	6/01/2018

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OBSERVATION 2

Failure to document changes to computerized systems and provide adequate control to prevent omission or alteration of data.

Specifically,

a. There is no record of the review audit trails associated with your chromatography data systems used to analyze (b) (4) and (b) (4) to ensure data has not been altered or deleted. SOP 10.36/2017 Ver. 03 effective May 25, 2018 requires the review of audit trails. This procedure lacks details to describe how audit trail review will be performed and documented.

b. Changes to user roles and functions in chromatography data systems are not documented, in that, your QA Manager was added as the System Administrator of the chromatography data system and two QC Analysts were removed as System Administrators. No change control was opened to evaluate the risk of modification to user authorizations.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Tiara Brown-Crosby	Tiara N. Brown-Crosby, Investigator	6/01/2018

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 judgment, 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."