DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA / CBER / Office of Compliance and Biologics Quality 10903 New Hampshire Avenue WO71 - 5128 Silver Spring, MD 20993-0002 TEL: (240) 402-2973 Industry Information: www.fda.gov/oc/industry cber483responses@fda.hhs.gov	5/12/2022-5/20/2022 FEI NUMBER 3004835647

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Christophe C. Mulfinger, Site Director of ID Biomedical Corporations of Quebec

FIRM NAME	STREET ADDRESS
ID Biomedical Corporation of Quebec	2323 Du Parc Technologique Blvd
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Quebec, Quebec G1P 4R8	Licensed Biological 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 WE OBSERVED:

1. The following investigation was inadequate. Specifically, on April 25, 2022, event 200926036 was opened when the in-process endotoxin test data performed on 4/22/2022 could not be located on the (b) (4) (b) (4) The system administrator was contacted to retrieve a copy of the (b) (4) (b) (4) in order to save the data onto the (b) (4) There was no investigation into why the (b) (4) did not retain the endotoxin test data or a determination as to where the data file went. The event was closed after a work order determined no error occurred with the (b) (4) (b) (4)

2. The following complaint records were found incomplete and/or deficient:

   a. Between 10/17/2017 and 12/21/2021, your company has received syringe defect complaints associated with multiple lots of FluLaval in which three separate investigations were opened. The complaints included needle connectivity issues to the luer lock, leaking from luer lock, crack at luer lock, and spinning of luer lock on the syringe. The first investigation concluded "incorrect manipulation of the syringe during preparation for injection"; second investigation concluded most probable root cause of "mishandling by the healthcare professional"; and the third was a most probable cause "the defect (LLA crack) was originated in the LLA suppliers process". No "internal root cause at GSK level". A crack in the LLA (luer lock adaptor) on the syringe was confirmed by the supplier for multiple lots of syringes, one of which was provided to your company. FDA was not notified with regards to the defective devices that were released to the market.

   b. Complaint files do not always include reply to complainant. For example, the complaint files for complaints 1500115512, 1500093176, and 1500115907 do not contain a reply to complainant.

3. Procedures designed to prevent microbial contamination of drug products purporting to be sterile are inadequate. Specifically,

   a. There are (b) (4) styles worn by aseptic operators. The following deficiencies were noted for the (b) (4) worn by the operators working in the aseptic (b) (4)

      i. There are (b) (4) on the (b) (4) with the (b) (4) of approximately (b) (4) has been specifically evaluated by sterility assurance for the impact to the aseptic environment.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	/S/	Debra M. Emerson, Investigator Linda Thai, Investigator	5/20/2022

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

ii. The (b) (4) are (b) (4) with no maximum life span. The (b) (4) are wiped with a (b) (4) (b) (4) and are then (b) (4) and then (b) (4) for (b) (4)

iii. On 5/18/2022, a (b) (4) which had been previously wiped with (b) (4) and (b) (4) for processing in the (b) (4) were opened and (b) (4) (b) (4) were observed on the (b) (4)

b. The (b) (4) used within the Grade (b) (4) is not sterile. This (b) (4) is a (b) (4) grade (b) (4) Particles from the (b) (4) have been recovered within the Grade (b) (4) on more than one occasion.

c. There is a (b) (4) the Grade (b) (4) room which (b) (4) and can be used by the operators working in aseptic (b) (4) This (b) (4) is wiped with (b) (4) This (b) (4) has not been included in the routine environmental monitoring for a (b) (4)

4. Preventative maintenance activities were incomplete. Specifically, the (b) (4) in the (b) (4) on the (b) (4) are not part of a routine preventative maintenance program to include visual inspection. These (b) (4) are used during (b) (4)

5. The sampling of the (b) (4) is not representative of use. Specifically, manufacturing (b) (4) (b) (4) and this is documented on a log. After the (b) (4) (b) (4) Quality control takes a (b) (4) when QC takes the sample, (b) (4) (b) (4)