DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

Our STN: **BL 125419/39** **SUPPLEMENT APPROVAL**

ID Biomedical Corporation of Quebec
Attention: Michael Schwartz, Ph.D.
2301 Renaissance Boulevard
P.O. Box 61540
King of Prussia, PA 19406-2772

September 9, 2016

Dear Dr. Schwartz:

We have approved your request to supplement your biologics license application (BLA) for Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted, manufactured in Quebec, Canada, to extend the age range for use to include persons 6 months through 17 years of age at increased risk of exposure to the influenza A virus H5N1 subtype contained in the vaccine.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT01310413 and NCT01051661.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. In addition, please submit three original paper copies for carton and container final printed labeling. All final labeling should be submitted as Product Correspondence to this BLA at the time of use (prior to marketing) and include implementation information on FDA Form 356h and FDA Form 2567 as appropriate.

In addition, please submit the final content of labeling (21 CFR 601.14) in SPL format via the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

You may submit two draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertisement and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80), and you must submit distribution reports as described in 21 CFR 600.81. For information on adverse experience reporting, please refer to the guidance for industry *Providing Submissions in Electronic Format —Postmarketing Safety Reports for Vaccines* at http://www.fda.gov/forindustry/electronicsubmissionsgateway/ucm387293.htm. For information on distribution reporting, please refer to the guidance for industry *Electronic Submission of Lot Distribution Reports* at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm061966.htm.

As stated in your September 2, 2016, submission, you will report all serious or non-serious cases of narcolepsy (with or without cataplexy), autoimmune hepatitis, anaphylaxis, Bell's palsy, convulsion, demyelinating disorders, encephalitis, Guillain-Barré syndrome, neuritis, vasculitis, and vaccination failure, following vaccination with Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted, as 15-day expedited reports to the Vaccine Adverse Event Reporting System (VAERS).

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Fulfillment of Pediatric Postmarketing Requirement

We note that this supplement contains the final study report for the following postmarketing requirement identified in the November 22, 2013, approval letter under STN 125419/0:

1. Deferred pediatric study Q-Pan H5N1=AS03-021 under PREA to evaluate the safety and immunogenicity of Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted when administered to healthy persons 6 months to < 18 years of age.

   Final Protocol Submission: March 2, 2012

   Study Completion Date: September 30, 2014

   Final Report Submission: April 30, 2015

We have completed the review of your submission and find that you have fulfilled the pediatric study requirement for ages 6 months to < 18 years for this application.

Release from Pediatric Postmarketing Requirement

We have completed the review of your submission and conclude that you are released from the following pediatric postmarketing requirements identified in the November 22, 2013, approval letter under STN 125419/0:

2. Deferred pediatric study Q-Pan-023 under PREA to evaluate the safety and immunogenicity of Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted when administered to healthy children 6 months to < 36 months of age.

   Final Protocol Submission: February 28, 2017

   Study Completion Date: December 31, 2018

   Final Report Submission: June 30, 2019

3. Deferred pediatric study Q-Pan-024 under PREA to evaluate the safety and immunogenicity of Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted when administered to healthy persons 6 months to < 18 years of age. Study Q-Pan-024 will be conducted only if study Q-Pan-023 identifies a pediatric dose that is different than that evaluated in study Q-Pan H5N1=AS03-021.

   Final Protocol Submission: June 30, 2018

   Study Completion Date: April 30, 2020

   Final Report Submission: October 31, 2020

You are released from the above postmarketing requirements for the following reason:

   This submission is sufficient to fulfill the pediatric study requirement for ages 6 months to < 18 years and no further studies are required.

The above pediatric postmarketing requirements are now considered closed.

Change in Schedule for Pediatric Postmarketing Requirement

We have completed the review of your submission and conclude that the timeline is revised for the following pediatric postmarketing requirement identified in the November 22, 2013, approval letter:

4. Deferred pediatric study Q-Pan-025 under PREA to evaluate the safety and immunogenicity of Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted when administered to healthy infants < 6 months of age.

   Final Protocol Submission: October 31, 2021

   Study Completion Date: July 31, 2022

   Final Report Submission: December 31, 2022

You requested a change in the milestone dates in your submission of August 10, 2016, because it would not be feasible to conduct the study in the absence of an H5N1 influenza virus pandemic.

The revised timeline for this pediatric postmarketing requirement is:

Deferred pediatric study Q-Pan-025 under PREA to evaluate the safety and immunogenicity of Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted when administered to healthy infants < 6 months of age.

Final Protocol Submission: 2 weeks after notification by the FDA to finalize the protocol in the event of an imminent H5N1 influenza virus pandemic (human to human H5N1 transmission)

Study Completion Date: 16 months after initiation of the study

Final Report Submission: 4 months after completion of data collection

Please submit the protocol to your IND 13413, with a cross-reference letter to this BLA 125419, explaining that this protocol was submitted to the IND. Please refer to the sequential number for each study/clinical trial and the submission number as shown in this letter.

Submit final study report to this BLA. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated as:

- **Required Pediatric Assessment(s).**

Your deferred pediatric study required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) is a required postmarketing study. The status of this postmarketing study

must be reported according to 21 CFR 601.28 and section 505B(a)(3)(B) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report an **Annual Status Report of Postmarketing Study Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the revised milestone schedule for the requirement, if appropriate;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and
- an explanation of the status for the study or clinical trial. The explanation should include how the study is progressing in reference to the original projected schedule, including the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our Web site (http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm).

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely yours,

Wellington Sun, M.D.
Division Director
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Attachment: Approved Final Draft Labeling