Our STN: BL 125419/166

SUPPLEMENT APPROVAL
INCLUDING AN ACCELERATED APPROVAL
April 28, 2026

ID Biomedical Corporation of Quebec
Attention: Mariana Machado
GlaxoSmithKline Biologicals
14200 Shady Grove Road
VR1500
Rockville, MD 20850-7464

Dear Ms. Machado:

We have approved your request received January 29, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Influenza A [H5N1] Virus Monovalent Vaccine, Adjuvanted (AREPANRIX) to update the influenza virus strain from A/Indonesia/05/2005 (H5N1) to A/Astrakhan/3212/2020-like (H5N8, clade 2.3.4.4b) for use in individuals 6 months of age and older at increased risk of exposure to the influenza A virus H5 subtype contained in the vaccine and to include associated labeling revisions. Use of AREPANRIX containing the influenza virus strain A/Astrakhan/3212/2020-like (H5N8, clade 2.3.4.4b) in individuals 6 months through 17 years of age is approved according to the regulations for accelerated approval, 21 CFR 601.41.

Under this approval, the following changes are also included:

- The proper name is changed from “Influenza A [H5N1] Virus Monovalent Vaccine, Adjuvanted” to “Influenza A [H5] Monovalent Vaccine, Adjuvanted.”

- The indication and use is changed from:

  “AREPANRIX is a vaccine indicated for active immunization for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine. AREPANRIX is approved for use in individuals 6 months and older at increased risk of exposure to the influenza A virus H5N1 subtype contained in the vaccine.”

  to:

  “AREPANRIX is indicated for active immunization for the prevention of disease caused by the influenza A virus H5 subtype contained in the vaccine. AREPANRIX is approved for use in individuals 6 months of age and older at increased risk of exposure to the influenza A virus H5 subtype contained in the vaccine.”

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT05975840.

ACCELERATED APPROVAL REQUIREMENTS

Under accelerated approval statutory provisions and regulations, we may grant marketing approval for a biological product on the basis of an adequate and well-controlled study establishing that the biological product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Approval of AREPANRIX containing the influenza virus strain A/Astrakhan/3212/2020-like (H5N8, clade 2.3.4.4b) for use in individuals 6 months through 17 years of age at increased risk of exposure to the influenza A virus H5 subtype contained in the vaccine requires you to study the biological product further, to verify and describe its clinical benefit, where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit, or of the observed clinical benefit to ultimate outcome.

Approval under these statutory provisions and regulations requires, among other things, that you conduct an adequate and well-controlled study to verify and describe clinical benefit attributable to this product. Clinical benefit is evidenced by effects such as demonstration of effectiveness of AREPANRIX containing the influenza virus strain A/Astrakhan/3212/2020-like (H5N8, clade 2.3.4.4b) in individuals 6 months through 17 years of age.

Accelerated Approval Required Study

We remind you of your postmarketing requirement specified in your amendment dated April 24, 2026:

1. Study 300790, entitled “A Phase 2, partially-blind, randomized, placebo-controlled, dose-confirmation study to evaluate the safety, reactogenicity and immunogenicity of AREPANRIX (Influenza A [H5] Virus Monovalent Vaccine, Adjuvanted) in healthy participants 6 months through 17 years of age.”

   Final Draft Clinical Protocol Submission: May 12, 2026

   Study Implementation Readiness Verification Submission: September 15, 2026

   Final Protocol Submission: 5 business days following FDA notification to proceed with study initiation

   Study Initiation: 8 weeks following FDA notification to proceed with study initiation

   Interim Analysis (Observer-blind part of study): 6 months following FDA notification to proceed with study initiation

Study Completion (Observer-blind part of study): 10 months following FDA notification to proceed with study initiation

Final Study Report Submission (Observer-blind part of study): 14 months following FDA notification to proceed with study initiation

FDA will issue notification to proceed with study initiation when increasing numbers of human cases or clusters of human influenza A/H5 infection are identified anywhere in the world, and the virus characteristics indicate an increased potential for ongoing human-to-human transmission.

We expect you to achieve design, initiation, accrual, completion, and reporting of this study within the framework described in your amendment dated April 24, 2026.

Please submit the draft clinical protocol, study implementation readiness verification, final protocol, and interim analysis to your IND 29447, with a cross-reference letter to this BLA, STN BL 125419, explaining that these items were submitted to the IND.

You must conduct this study with due diligence following FDA notification to proceed with study initiation. If the required postmarketing study fails to verify that clinical benefit is conferred by AREPANRIX containing the influenza virus strain A/Astrakhan/3212/2020-like (H5N8, clade 2.3.4.4b) in individuals 6 months through 17 years of age, or is not conducted with due diligence, including with respect to the conditions set forth below, we may withdraw this approval.

You must submit reports of the progress of each study listed above as required under section 506(c) of the FDCA to this BLA 180 days after the date of approval of this supplement and approximately every 180 days thereafter (see section 506B(a)(2) of the FDCA) (hereinafter “180-day reports”).

You are required to submit two 180-day reports per year for each open study or clinical trial required under 506(c) of the FDCA. The initial report will be a standalone submission and the subsequent report will be combined with your application’s postmarketing annual status report required under section 506B(a)(1) of the FDCA and 21 CFR 601.70. The standalone 180-day report will be due 180 days after the date of approval (with a 60-day grace period). Submit the subsequent 180-day report with your application’s postmarketing annual status report. Submit both of these 180-day reports each year until the final report for the corresponding study or clinical trial is submitted.

Your 180-day report must include the information listed in 21 CFR 601.70(b). FDA recommends that you use form FDA 3989 PMR/PMC Annual Status Report for Drugs and Biologics, to submit your 180-day reports. Form FDA 3989, along with instructions for completing this form, is available on the FDA Forms web page at https://www.fda.gov/about-fda/reports-manuals-forms/forms.

Your 180-day reports, including both the standalone 180-day report submitted 180 days after the date of approval and the 180-day report submitted with your annual status report, must be clearly designated as **180-Day AA PMR Progress Report**.

FDA will consider the submission of your annual status report under section 506B(a)(1) of the FDCA and 21 CFR 601.70, in addition to the submission of reports 180 days after the date of approval each year (subject to a 60-day grace period), to satisfy the periodic reporting requirement under section 506B(a)(2) of the FDCA. You are also required to submit information related to your confirmatory trial as part of your annual reporting requirement under section 506B(a)(1) of the FDCA until the FDA notifies you, in writing, that the Agency concurs that the study requirement has been fulfilled or that the study either is no longer feasible or would no longer provide useful information.

Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Postmarketing Requirements and 506B Commitments are fulfilled or released.

Please submit the final study report as a supplement to this BLA, STN BL 125419. For administrative purposes, all submissions related to this postmarketing study requirement must be clearly designated as "**Subpart E Postmarketing Study Requirements.**"

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 49, dated April 28, 2026, and the draft carton and container labels submitted under amendment 48, dated April 27, 2026.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at https://www.fda.gov/industry/fda-data-standards-advisory-board/structured-product-labeling-resources. Content of labeling must be identical to the Package Insert submitted on April 28, 2026. 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 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/spl-standard-content-labeling-technical-qs.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on April 27, 2026, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125419, at the time of use and include implementation information on Form FDA 356h.

PROMOTIONAL MATERIALS

(b) (4) However, please note that the accelerated approval regulation concerning promotional materials (21 CFR 601.45) stipulates that all advertising and promotional labeling items that you wish to distribute in the first 120 days following approval, must have been received by FDA prior to the approval date. After approval, promotional items intended for dissemination after the first 120 days following approval must be submitted to the FDA at least 30 days prior to the anticipated distribution date. Please submit draft materials with a cover letter noting that the items are for accelerated approval and an accompanying FORM FDA 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)).

Alternatively, you may submit promotional materials for accelerated approval products electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf.

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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

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

Sincerely,

Andrea Hulse, MD, for
Acting Division Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research