Our STN: BL 125408/685

SUPPLEMENT APPROVAL
July 1, 2026

Seqirus Inc.
Attention: Caroline Beauregard
475 Green Oaks Parkway
Holly Springs, NC 27450

Dear Ms. Beauregard:

We have approved your request received April 9, 2026, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Influenza Vaccine (FLUCELVAX), manufactured at your Holly Springs, NC, (b) (4), (b) (4) and (b) (4)., (b) (4) facilities, to include the 2026-2027 United States formulation and the associated labeling revisions.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 4, dated May 18, 2026, the draft carton labels submitted under amendment 7 on June 11, 2026, and container labels submitted on April 9, 2026.

We acknowledge your commitment to implement the labeling changes approved under this supplement, including the United States Prescribing Information (USPI), package, and container labels for Flucelvax, during the next seasonal update. We recognize that immediate reprinting of labels to incorporate the FDA-requested revisions would significantly impact the timely availability of vaccine supply for the 2026–2027 season. We also acknowledge your commitment to submit the final USPI incorporating FDA-approved revisions under STN 125408 in Structured Product Labeling (SPL) format no later than 14 days from the date of this letter.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the: Package Insert, submitted on

May 18, 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 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

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 June 11, 2026, and April 9, 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 125408 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with 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 advertising 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)).

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

Sincerely,

Jerry P. Weir, PhD
Director
Division of Viral Products
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research