



Our STN: BL 125254/802

SUPPLEMENT APPROVAL

Seqirus Pty Ltd
Attention: Ruben Ojeda
Seqirus, Inc.
475 Green Oaks Parkway
Holly Springs, NC 27540

February 17, 2022

Dear Mr. Ojeda:

We have approved your request submitted and received October 18, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Influenza Vaccine (AFLURIA), manufactured at your Parkville, Australia and Marburg, Germany facilities to include the 2022 Southern Hemisphere formulation and associated labeling changes.

LABELING

We hereby approve the draft content of labeling Package Insert submitted October 18, 2021, and the draft carton and container labeling submitted October 18, 2021.

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 as described in guidance for industry *Providing Regulatory Submissions in Electronic Format – Content of Labeling* at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-content-labeling>.

The SPL will be accessible via publicly available labeling repositories.

PACKAGE AND CONTAINER LABELS

Please electronically submit final printed package and container labels that are identical to the package and container labels submitted on October 18, 2021, 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 125254 at the time of use (prior to marketing) 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)).

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.

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

Sincerely,

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