DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Jack Scannelli, RPh
Sr. Director, Regulatory Ad Promo
Sanofi Vaccines US Inc.
100 Morris Street
Morristown, NJ 07960

**RE: BLA 761328**
BEYFORTUS® (nirsevimab-alip) injection, for intramuscular use
MA 745

Dear Jack Scannelli:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communication(s), professional emails (MAT-US-2514195-1 and MAT-US-2514837-1) (emails) for BEYFORTUS® (nirsevimab-alip) injection, for intramuscular use (Beyfortus) submitted by Sanofi Vaccines US Inc. (Sanofi) under cover of Form FDA 2253. FDA has determined that the emails are false or misleading. Thus, the emails misbrand Beyfortus and make the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The emails include claims and presentations such as (bolded emphasis original; underlined emphasis added):

- "**HELP PREVENT <u>RSV DISEASE</u> IN INFANTS WITH BEYFORTUS® AND SEE HOW YOU CAN AFFECT POPULATION HEALTH**"
- "As you may know, immunizing infants to help protect against the risk of <u>RSV disease</u> remains important through the entirety of the RSV season."
- "Beyfortus is a monoclonal antibody that helps prevent <u>RSV disease</u> starting from **Day 1** after injection."
- "Your efforts in immunizing infants against <u>RSV disease</u> can impact the population health burden in your community."

These claims and presentations create a misleading impression about the indication for Beyfortus. Specifically, they suggest the use of Beyfortus for the general prevention of Respiratory Syncytial Virus (RSV), including *both* upper and lower respiratory tract disease, when this is not the case. According to the INDICATIONS AND USAGE section of the FDA-approved Prescribing Information (PI) (in pertinent part), "BEYFORTUS is indicated for the prevention of <u>Respiratory Syncytial Virus (RSV) lower respiratory tract disease</u>…" (underlined emphasis added). By failing to adequately communicate the indication for Beyfortus, the emails create a misleading impression about the drug's FDA-approved indication. We acknowledge that the full FDA-approved indication is presented further down below in addition to the claims, "…to help protect infants from RSV-LRTI". However, the presentation

of this information is not sufficient to correct the overall misleading impression created by these claims.

**Conclusion and Requested Action**

For the reasons described above, the emails misbrand Beyfortus and make the distribution of the drug in violation of the FD&C Act.

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that Sanofi take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that are misleading as described above).

Please submit a written response to this letter within 15 working days from the date of receipt, addressing the concerns described in this letter, listing all promotional communications (with the 2253 submission date) for Beyfortus that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Beyfortus.

If you believe that your products are not in violation of the FD&C Act, please include in your submission to us your reasoning and any supporting information for our consideration within 15 working days from the date of receipt of this letter.

The concerns discussed in this letter do not necessarily constitute an exhaustive list of potential violations. It is your responsibility to ensure compliance with each applicable requirement of the FD&C Act and FDA implementing regulations.

Please direct your response to the undersigned at the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. Please refer to MA 745 in addition to the BLA number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. You are encouraged, but not required, to submit your response in eCTD format. All correspondence submitted in response to this letter should be placed under eCTD Heading 1.15.1.6.

Additionally, the response submission should be coded as an Amendment to eCTD Sequence 5739 under BLA 761328. Questions related to the submission of your response letter should be emailed to CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

L. Sheneé Toombs, PharmD, CPH
Regulatory Review Officer
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

{See appended electronic signature page}

Samuel Skariah, PharmD, RAC
Team Leader
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**

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/s/

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LATOYA S TOOMBS
07/15/2026 03:55:38 PM

SAMUEL M SKARIAH
07/15/2026 04:01:40 PM