Our STN: BL 125742/350 **ASSIGN / APPROVE**

BioNTech Manufacturing GmbH September 22, 2023
Attention: Leslie Sands
Pfizer, Inc.
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Sands:

Submission Tracking Number (STN) BL 125742/350 has been assigned to your recent supplement to your Biologics License Application (BLA) for COVID-19 Vaccine, mRNA (COMIRNATY), received September 22, 2023. Your submission is in the form of a Supplement – Changes Being Effected as described under 21 CFR 601.12(c)(5).

We have approved your request to supplement your Biologics License Application for COVID-19 Vaccine, mRNA to include the addition of a Patient Package Insert and to revise the Prescribing Information to refer to the FDA-approved patient labeling in your establishments located at Pfizer Manufacturing Belgium NV (Puurs, Belgium) and Pharmacia and Upjohn Company LLC (Kalamazoo, Michigan) facilities, operating under U.S. License Number 2229.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft content of labeling: Package Insert submitted to CBER via email on September 22, 2023 and Patient Package Insert submitted to CBER via email on September 22, 2023.

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 and Patient Package Insert submitted on September 22, 2023. 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.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125742 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)).

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 information contained in the above-referenced supplement in your biologics license application file.

If you have any questions, please contact the Regulatory Project Managers, Meghan Maguire Thon, Ph.D. (at Meghan.MaguireThon@fda.hhs.gov) and Julianne Clifford, Ph.D. (at Julianne.Clifford@fda.hhs.gov), or at (301) 796-2640.

Sincerely,

Joseph G. Toerner, M.D., M.P.H.
Acting Deputy Director - Clinical
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