

Form Approved: OMB No. 0910 - 0297 Expiration Date: March 31, 2022. See instructions for OMB Statement, below.

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

**PRESCRIPTION DRUG USER FEE  
COVERSHEET FY 2021**

A completed form must be signed and accompany each new drug or biologic product application. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment instructions and fee rates can be found on FDA's website:

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119184.htm>

1. APPLICANT'S NAME AND ADDRESS

BioNTech  
Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz  
Germany

4. BLA SUBMISSION TRACKING NUMBER  
(STN) / NDA NUMBER

125742

2. NAME AND TELEPHONE NUMBER OF  
REPRESENTATIVE

Neda Aghajani Memar  
212-733-2613

5. DOES THIS APPLICATION REQUIRE  
CLINICAL DATA FOR APPROVAL?

YES  NO

IF YOUR RESPONSE IS "NO", STOP HERE  
AND SIGN THIS FORM.

IF RESPONSE IS "YES", CHECK THE  
APPROPRIATE RESPONSE BELOW:

THE REQUIRED CLINICAL DATA ARE  
CONTAINED IN THE APPLICATION

THE REQUIRED CLINICAL DATA ARE  
SUBMITTED BY REFERENCE TO:

3. PRODUCT NAME

COMIRNATY ( COVID-19 mRNA Vaccine  
(nucleoside modified) )

6. USER FEE I.D. NUMBER

PD3017966

7. ARE YOU REDEEMING A PRIORITY REVIEW VOUCHER FOR THE TREATMENT OF  
TROPICAL DISEASES?  YES  NO

PRIORITY REVIEW VOUCHER NUMBER:

8. ARE YOU REDEEMING A PRIORITY REVIEW VOUCHER FOR MEDICAL COUNTER  
MEASURES?  YES  NO

PRIORITY REVIEW VOUCHER NUMBER:

9. IS THIS APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS?  
IF SO, CHECK THE APPLICABLE EXCEPTION.

THE APPLICATION QUALIFIES FOR THE ORPHAN EXCEPTION UNDER SECTION 736(a)  
(1)(F) of the Federal Food, Drug, and Cosmetic Act

THE APPLICATION IS SUBMITTED BY A STATE OR FEDERAL GOVERNMENT ENTITY FOR A DRUG THAT IS NOT DISTRIBUTED COMMERCIALY

10. HAS A WAIVER OF AN APPLICATION FEE BEEN GRANTED FOR THIS APPLICATION?

YES  NO

If a waiver has been granted, include a copy of the official FDA notification with your submission.

**Privacy Act Notice:**

This notice is provided pursuant to the Privacy Act of 1974, 5 U.S.C. 552a. The collection of this information is authorized by 21 U.S.C. 371, 379, 379e, 379h, 379h-1, 379j, 379j-12, 379j-21, 387s, and 393(d)(2); 42 U.S.C. 263b(r)(1); 5 U.S.C. 301 and 552; and 42 U.S.C. 3101. FDA will use the information to assess, collect and process user fee payments, and, facilitate debt collection under the Debt Collection Improvement Act. FDA may disclose information to courts and the Department of Justice in the context of litigation and requests for legal advice; to other Federal agencies in response to subpoenas issued by such agencies; to HHS and FDA employees and contractors to perform user fee services; to the National Archives and Records Administration and General Services Administration for records management inspections; to the Department of Homeland Security and other Federal agencies and contractors in order to respond to system breaches; to banks in order to process payment made by credit card; to Dun and Bradstreet to validate submitter contact information, and to other entities as permitted under the Debt Collection Improvement Act. Furnishing the requested information is mandatory. Failure to supply the information could prevent FDA from processing user fee payments. Additional detail regarding FDA's use of information is available online: <http://www.fda.gov/RegulatoryInformation/FOI/PrivacyAct/default.htm>.

**OMB Statement:**

**Public reporting burden for this collection of information** is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paper Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

PRINTED NAME AND SIGNATURE OF AUTHORIZED REPRESENTATIVE	TITLE	DATE
 Neda Aghajani Memar <small>Digitally signed by Neda Aghajani Memar DN: cn=Neda Aghajani Memar, o, ou, email=neda.aghajanimemar@pfizer.com, c=US Reason: I attest to the accuracy and integrity of this document Date: 2021.04.20 09:40:33 -0400</small>	Director, Global Regulatory Affairs	4/20/2021

11. USER FEE PAYMENT AMOUNT FOR THIS APPLICATION

\$2,875,842.00

Form FDA 3397 (04/19)