

*Estimated Total Annual Burden Hours: 317.*

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 14 days of this publication.

*Authority:* 45 CFR 98.64.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2022-03462 Filed 2-16-22; 8:45 am]

**BILLING CODE 4184-55-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-0895]

#### Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that **SPIKEVAX** (COVID-19 Vaccine, mRNA), meets the criteria for a material threat priority review voucher, which has been issued to ModernaTX, Inc., the holder of the biologics license application.

**FOR FURTHER INFORMATION CONTACT:** Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301,

Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the issuance of a material threat MCM priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb-4a), which was added by the Cures Act (Pub. L. 114-255), FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria upon approval of those applications. FDA has determined that **SPIKEVAX** (COVID-19 Vaccine, mRNA), meets the criteria for a material threat MCM priority review voucher. **SPIKEVAX** is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation>. For further information about **SPIKEVAX**, (COVID-19 Vaccine, mRNA), go to the Center for Biologics Evaluation and Research Approved Vaccine Products website at <https://www.fda.gov/vaccines-blood-biologics/vaccines/approved-vaccine-products>.

Dated: February 11, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-03420 Filed 2-16-22; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-0386]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Class II Special Controls for Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by March 21, 2022.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0437. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Medical Device Reporting—21 CFR Part 803

*OMB Control Number 0910-0437—Revision*

In the **Federal Register** of February 21, 2020 (85 FR 10110), we published a proposed order to reclassify certain human immunodeficiency virus (HIV) serological diagnostic and supplemental tests and HIV nucleic acid (NAT) diagnostic and supplemental tests from class III (premarket approval) into class II (special controls) (the proposed order). In the proposed order, FDA proposed special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness for these devices. The proposed special controls would require the submission of a log of all complaints annually for a period of 5 years following FDA clearance of a traditional premarket notification (510(k)) submission for a device within the scope of the proposed order.

Currently, manufacturers of HIV serological diagnostic and supplemental tests and HIV NAT diagnostic and supplemental tests are subject to FDA