Material Threat Medical Countermeasures Priority Review Voucher Eligibility Checklist

Instructions for completing checklist:

1. Include the application information in the appropriate row
2. Indicate Yes or No with requested information as appropriate
3. This checklist is intended to help determine if an NDA or BLA is eligible for a material threat Medical Countermeasures (MCM) PRV. An application that does not meet all these criteria is not eligible for a voucher.

Application Information	
Application Type and STN Number	BLA STN 125752/2
Responsible Office	OVRR
Chair	Sudhakar Agnihothram, Ph.D.
Product Name	COVID-19 Vaccine, mRNA (SPIKEVAX)
Proposed Indication	For active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
Requirement	**Respond as indicated**
Was this application submitted in an NDA under section 505(b)(1) of the FD&C Act or a BLA under section 351(a) of the Public Health Service Act? *If yes list the application STN*	**YES** (The application for Material Threat MCM PRVC was submitted in a BLA under section 351(a) of the Public Health Service Act, STN 125752/2)

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Requirement	**Respond as indicated**
Is this application: • for a human drug, that contains no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been previously approved in any other application under section 505(b)(1), 505(b)(2), or 505(j) of the FD&C Act or • for a biological product that contains no active ingredient that has been previously approved in any other application under section 351(a) or 351 (k) of the Public Health Service Act and is the subject of an application submitted under section 351(a) of the Public Health Service Act. *If no, list the previous product containing the active ingredient that was approved*	**YES** **A biological product** that contains no active ingredient that has been previously approved in any other application under section 351(a) or 351 (k) of the Public Health Service Act and is the subject of an application submitted under section 351(a) of the Public Health Service Act

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Requirement	**Respond as indicated**
The application is approved to: Intended for use to prevent or treat harm from a chemical, biological, radiological, and nuclear (CBRN) agent identified as a material threat under section 319F-2(c)(2)(A)(ii) of the PHS Act; (*See Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Strategic Implementation Plan (SIP), published by HHS*) or contact the CBER Preparedness and Response Team at CBERPREP@fda.hhs.gov Or intended to mitigate, prevent or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug or biological product against such agent. If you are unsure, please contact the CBER Preparedness and Response Team at CBERPREP@fda.hhs.gov. *If yes, list the CBRN agent and indication.*	Intended for use to prevent harm from a biological agent identified as a material threat under section 319F-2(c)(2)(A)(ii) of the PHS Act. Biological agent: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Indication: For active immunization to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2
If you answered yes to all questions above, this product is eligible to receive a Material threat MCM PRV voucher.	This product is eligible to receive a Material threat MCM PRV voucher.
Does FDA deem this application eligible for priority review? *If yes, include the date of Filing meeting.*	**YES** September 28, 2021

Chair _____

Applications Division Director or Office Associate Director for Regulatory Policy

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CBER Associate Director for Review Management_____

History

Written/ Revised	Approved By	Effective Date	Version Number	Comment
Adrienne Hornatko-Munoz	BOS Chief	Dec 28, 2021	2	Updated to reflect the change in the definition of active ingredient.
Chris Joneckis/OD	BOS Chief	June 10, 2019	1	First issuance of this checklist.