Material Threat Medical Countermeasure Priority Review Vouchers

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document contact the Office of Counterterrorism and Emerging Threats (OCET) at 301-796-8510 or AskMCMi@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner
Office of the Chief Scientist
Office of Counterterrorism and Emerging Threats

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Procedural

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides information on implementation of section 3086 of the 21st Century Cures Act (Cures Act) (Public Law 114-255), which added section 565A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb-4a). Section 565A of the FD&C Act requires FDA to award a priority review voucher (PRV) to sponsors of certain medical countermeasure (MCM) applications that meet the criteria specified in that section. Since the enactment of the Cures Act, the Agency has received inquiries about the scope of section 565A of the FD&C Act, its relation to other PRV programs, and how various aspects of section 565A of the FD&C Act should be interpreted. The purpose of this guidance is to provide responses to those questions.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

[1] This guidance was prepared by the Office of Counterterrorism and Emerging Threats (OCET) in collaboration with the Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER). Please note that FDA updates guidance documents periodically. To make sure you have the most recent version of a guidance, check the FDA Regulatory Information Web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

II. BACKGROUND AND OVERVIEW

Under section 565A of the FD&C Act, the sponsor of a human drug application[2] for a material threat MCM, defined below, may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug application submitted under section 505(b)(1)[3] of the FD&C Act or section 351 of the Public Health Service (PHS) Act after the date of approval of the material threat MCM drug product.

Section 565A of the FD&C Act was designed to encourage development of new drug and biological MCMs, by offering additional incentives for obtaining FDA approval of certain MCMs. While there are existing incentive programs to encourage the development and study of drugs and biologics that may also be applicable to MCMs, section 565A of the FD&C Act provides an incentive specifically for development of certain MCMs, which may be used alone or in some cases in combination with other incentive programs. Other FDA incentive programs include: orphan-drug designation and the associated benefits under the Orphan Drug Act for rare disease drugs;[4] programs to encourage study of drugs used in pediatric populations;[5] various programs to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions;[6] and programs for

[2] A "human drug application" is defined in section 735(l) of the FD&C Act (21 U.S.C. 379g(l)); it includes applications for drugs submitted under section 505(b) of the FD&C Act and applications for most biological drugs, including vaccines, submitted under section 351(a) of the PHS Act, but excludes applications for whole blood or a blood component for transfusion and certain other biological products. For details, refer to section 735(l) of the FD&C Act (21 U.S.C. 379g(l)). The definition does not cover applications for medical devices.

[3] Section 505(b)(2) new drug applications (NDAs) are submitted under section 505(b)(1) of the FD&C Act, so all references to NDAs submitted under section 505(b)(1) of the FD&C Act include 505(b)(2) applications.

[4] Public Law 97-414, as amended, codified at sections 526-528 of the FD&C Act (21 U.S.C. 360aa-560ee).

[5] Section 505A of the FD&C Act (21 U.S.C. 355a-355c), which provides marketing exclusivity for the conduct of certain pediatric studies, and section 529 of the FD&C Act, which provides a PRV program for rare pediatric diseases (see https://www.fda.gov/forindustry/developingproductsforrarediseasesconditions/rarepediatricdiseasepriorityvoucherprogram/default.htm).

[6] These programs include, among others, fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation; see FDA's guidance *Expedited Programs for Serious Conditions—Drugs and Biologics* (May 2014).

certain tropical disease products[7] and antibacterial products.[8] In addition, sections 319F through 319F-4 of the PHS Act (42 U.S.C. 247d-6 through 247d-6e) provide incentives outside of FDA authorities for MCM research and development from the Biomedical Advanced Research and Development Authority (BARDA) and other agencies, including direct funding to developers, special liability protections, and the creation of a Special Reserve Fund for procurement of some MCMs for stockpiling.[9]

III. DEFINITIONS, POLICIES, AND PROCEDURES – QUESTIONS AND ANSWERS

A. Material Threat MCM Applications

Q1: What is an MCM?

Medical countermeasures or *MCMs* are medical products intended to diagnose, prevent, or treat diseases or conditions associated with chemical, biological, radiological, and nuclear (CBRN) threats and emerging infectious diseases. MCMs can also include medical products 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 CBRN agent. MCMs include drugs, biological products (e.g., vaccines, blood products, and biological therapeutics), and devices (e.g., in vitro diagnostics and personal protective equipment). Note that not all MCMs qualify for PRVs under this provision. See Question 2.

Q2: What is a material threat MCM application for purposes of considering eligibility for a PRV?

The term *material threat medical countermeasure application* is defined in section 565A(a)(4) of the FD&C Act by reference to an application that is:

- A human drug application as defined in section 735(l) of the FD&C Act:[10]

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[7] Section 524 of the FD&C Act provides a PRV program for drugs intended to prevent or treat tropical diseases. See https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm534162.htm and FDA's guidance *Tropical Disease Priority Review Vouchers* (Oct. 2016).

[8] For example, section 505E (21 U.S.C. 355f) provides an extension of the exclusivity period for certain qualified infectious disease products and section 506 of the FD&C Act, as amended by section 3042 of the Cures Act, establishes a limited population pathway for antibacterial and antifungal drugs.

[9] For a general overview of HHS MCM programs, see the *2017-18 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan*, available at: https://www.phe.gov/Preparedness/mcm/phemce/Documents/2017-phemce-sip.pdf.

[10] See footnote 2.

- Intended for use to prevent or treat harm from a CBRN agent identified as a material threat under section 319F-2(e)(2)(A)(ii) of the PHS Act; 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.

- Determined by FDA to be eligible for priority review[11]

- Approved by FDA after the date of enactment of the Cures Act (December 13, 2016)

- For a human drug, no active ingredient (including an ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) of the FD&C Act or section 351(a) of the PHS Act

Q3: What are the identified material threat agents under section 319F-2(e)(2)(A)(ii) of the PHS Act?

The Department of Health and Human Services (HHS), within its annual *Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Strategic Implementation Plan*, publishes a list of high-priority threats including those that the Secretary of the Department of Homeland Security (DHS) determines to pose a material threat sufficient to affect national security and therefore are the threats that may qualify an MCM application for a PRV under section 565A(a)(4)(i) of the FD&C Act.[12] For additional information about whether or not a specific CBRN agent is an identified material threat under section 319F-2(e)(2)(A)(ii) of the PHS Act, please refer to the *2017-18 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan,*[13] or a successor plan. You may also contact: FDA's Office of Counterterrorism and Emerging Threats at AskMCMi@fda.hhs.gov or HHS's Office of the Assistant Secretary for Preparedness and Response at EEC.PHEMCE@hhs.gov.

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[11] Certain applications may receive priority review pursuant to a statutory mandate (i.e., sections 524A and 505A of the FD&C Act). However, in determining whether an application qualifies for priority review within the meaning of this provision (i.e., section 565A), if a material threat MCM PRV is requested, the Agency will determine whether the application satisfies the criteria for eligibility for a priority review designation, i.e., whether the drug treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. For more information on the priority review designation, see footnote 6, referring to FDA's guidance *Expedited Programs for Serious Conditions—Drugs and Biologics* (May 2014); see also *CDER Manual of Policies and Procedures 6020.3 Rev. 2, Review Designation Policy: Priority (P) and Standard (S)*, 6/25/13, available at:
https://www.fda.gov/downloads/aboutfda/centersoffices/cder/manualofpoliciesprocedures/ucm082000.pdf.

[12] See footnote 9.

[13] See footnote 9.

Q4: How are material threat agents added to or subtracted from the list?

The DHS, in consultation with the Secretary of HHS and the heads of other agencies as appropriate, is authorized to make determinations of CBRN threat agents that are material threats to the U.S. population under section 319F-2(e)(2)(A)(ii) of the PHS Act.[14] To obtain a PRV, the material threat must be listed at the time of the application's approval (see also the response to Question 6).

Q5: What user fees apply to a material threat MCM application?

User fees for human drug applications are described in section 736 of the FD&C Act. In general, a material threat MCM application would be subject to these statutory requirements like any other application. However, FDA anticipates that some MCMs may qualify for designation as orphan drugs because the diseases or conditions associated with a CBRN threat agent that the MCM is intended to prevent or treat may affect fewer than 200,000 persons in the United States (see section 526 of the FD&C Act) (see also the response to Question 28). Under section 736(a)(1)(F) of the FD&C Act, if a human drug application for a prescription drug product has been designated as a drug product for a rare disease or condition under section 526 of the FD&C Act, the application is not subject to an application user fee, unless the application includes an indication other than for a rare disease or condition. In addition, section 736(k) of the FD&C Act provides for an exemption from annual prescription drug program fees for certain orphan-designated drug products.

For more information regarding user fees related to Center for Drug Evaluation and Research (CDER) regulated products, contact the User Fee staff in the CDER Office of Management at CDERCollections@fda.hhs.gov. For more information regarding user fees related to Center for Biologics Evaluation and Research (CBER) regulated products, contact the User Fee staff in the CBER Office of the Director at CBERPDUFAStaff@fda.hhs.gov.

Q6: Is there a designation process for MCM medical products comparable to the process established for medical products for rare pediatric diseases?

No. Section 565A of the FD&C Act does not provide for a designation process, such as is provided for in section 529 of the FD&C Act for rare pediatric diseases. Sponsors of candidate MCMs should review the list of material threat agents (see Question 3), recognizing that, to obtain a PRV, the material threat must be listed at the time of the application's approval.

[14] For additional information, see: https://www.medicalcountermeasures.gov/phemce/dhs.aspx.

B. Priority Review Vouchers: General Information

Q7: What is a material threat MCM PRV and when is it awarded?

The term *priority review voucher*, for purposes of a material threat MCM, is defined in section 565A(a)(3) of the FD&C Act. It refers to a voucher issued by FDA to the sponsor of a material threat MCM application (see Question 2) at the time of approval of the application that entitles the holder of such voucher to designate a single human drug application submitted under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act as qualifying for priority review. Such a subsequent application would not otherwise have to meet the usual requirements for a priority review, but would be entitled to a priority review by operation of the voucher.

Q8: What is a priority review?

A priority review is a review conducted within a time frame prescribed in FDA commitments made in connection with the Prescription Drug User Fee Act (PDUFA). Normally, an application for a drug product will qualify for a priority review if FDA determines that the drug product, if approved, would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition.[15]

For the fiscal years 2018 through 2022, FDA has committed to a goal to review and act on 90 percent of priority new molecular entity (NME) New Drug Application (NDA) and original Biologics License Application (BLA) submissions within 6 months of the 60-day filing date, and 90 percent of priority non-NME original NDA submissions within 6 months of receipt, as described in the PDUFA VI goals letter.[16] An application that does not receive a priority designation will receive a *standard* review, wherein the FDA commits to a goal to review and act on 90 percent of standard applications for NME NDA and original BLA submissions within 10 months of the 60-day filing date, and 90 percent of the standard non-NME original NDA submissions within 10 months of receipt. Note that an FDA review within a specific time frame does not mean an application will be approved within that time frame. The term *review and act on* is understood to mean the issuance of an approval or complete response letter after the review of a filed application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies that need to be addressed before the application can be approved.

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[15] See footnote 11.

[16] This section refers to the commitments made by FDA under the FDA Reauthorization Act of 2017 (FDARA) for fiscal years 2018-2022 (commonly referred to as PDUFA VI). See the PDUFA VI performance goals letter for fiscal years 2018-2022 available on the Internet at: https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf.

In sum, and subject to the qualifications discussed above for FDA's current user fee commitments, a priority review is one undertaken with an action goal date that is four months shorter than that applicable to a standard review.

Q9: What form will the PRV take?

FDA will include information related to the PRV in the approval letter for the material threat MCM application. This letter will include a PRV identification number, which should be referred to when redeeming the PRV.

Q10: When can a PRV be used?

After the PRV is issued, the sponsor redeeming the PRV must notify FDA of its intent to submit a human drug application with a PRV at least 90 days before submission of the human drug application for which the PRV will be used. This timeline is mandated by section 565A(b)(3)(A) of the FD&C Act. The notification must include the date the sponsor intends to submit the application (hereinafter referred to as the *intended submission date*). The application for which the PRV is being used should not be submitted before that date. If a sponsor does not submit the application on the intended submission date, the sponsor should inform FDA as soon as possible of the new intended submission date. The PRV user fee for the fiscal year in which the application is submitted is due upon the submission of the human drug application for which the PRV is used (for more information on when to pay the PRV user fee, see Question 25).

If the sponsor decides not to use the PRV for the application described in the notification, the sponsor should notify FDA and withdraw the notification. The sponsor should submit a new notification informing FDA that the sponsor intends to submit a different human drug application with a PRV at least 90 days before application submission, as noted above, and include the date by which the application will be submitted.

C. Priority Review Vouchers: Eligibility

Q11: Can FDA determine whether an application will be eligible to receive a PRV before an application is approved or licensed (i.e., before NDA/BLA submission or during review of the application)?

No. It is important to note that a drug product that meets the criteria at the time of submission may not meet those same criteria at the time of approval action and, in that case, would not be eligible to receive a PRV. This could occur, for example, if another application for a drug containing the same active moiety is approved first. For this reason, FDA will not make PRV determinations until the time of the application approval.

Although FDA will not make a determination that an application is eligible to receive a material threat MCM PRV before the application is approved, the Agency may render a

preliminary, nonbinding opinion, before approval, that a given application appears to meet the criteria for PRV eligibility as of the date of such preliminary determination.

Q12: Are drug-drug combinations eligible for PRVs?

A drug-drug combination is eligible if the product meets the criteria established in section 565A of the FD&C Act. In general, an application for a fixed-combination drug product submitted under section 505(b) of the FD&C Act will be eligible for a PRV if the product contains at least one active moiety that has not been approved in any other application under section 505(b) of the FD&C Act.[17]

Q13: Are combination products eligible for PRVs?

A combination product, as defined under 21 CFR 3.2(e), is eligible if the product meets the criteria established in section 565A of the FD&C Act. In general, an application for a combination product submitted under section 505(b) of the FD&C Act or section 351 of the PHS Act, as assigned to either CDER or CBER in accordance with 503(g) of the FD&C Act,[18] will be eligible for a PRV if the product contains at least one active moiety that has not been approved in any other application under section 505(b) of the FD&C Act or section 351 of the PHS Act and meets the other criteria for eligibility. (See Question 2.)

Q14: Are drug products that have been approved and used in other countries but have not previously been submitted for review by FDA eligible for PRVs?

Yes. Drug products that have been approved and used in other countries but have not previously been submitted for review by FDA are eligible for a PRV as long as they meet all the criteria for a material threat MCM product application described in section 565A(a)(4) of the FD&C Act.

[17] See section 565A(a)(4)(D) of the FD&C Act. Because section 565A(a)(4)(D) of the FD&C Act contains the same phrase ("no active ingredient (including any ester or salt of the active ingredient) of which has been approved …") as is used in, among other laws, sections 505(c)(3)(E)(ii) and (j)(5)(F)(ii) of the FD&C Act, FDA will follow, for drug products approved under the FD&C Act, its guidance on exclusivity for combination drugs under those provisions. See the guidance for industry *New Chemical Entity Exclusivity Determinations for Certain Fixed-Drug Combination Drug Products* (2014). For drug products approved under the PHS Act, FDA will make decisions on eligibility under section 565A(a)(4)(D) of the FD&C Act on a case-by-case basis.

[18] For additional information on FDA-regulation of combination products, see FDA website at: https://www.fda.gov/combinationproducts/default.htm.

Q15: Is a drug product that is already approved for another indication eligible for a PRV for a material threat MCM product application?

No. For an application to qualify, it must be for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act.

Q16: If a drug product is being developed for both a material threat MCM indication and other indications, can multiple indications be submitted simultaneously in one application?

Yes. One application may be submitted for more than one indication, and each indication will be assessed on its own merits. For example, if an application is submitted for a material threat MCM indication and another indication that is not for a material threat, a material threat MCM PRV will be awarded only if the material threat MCM criteria are met and if the material threat MCM indication is approved first or approved simultaneously with the other indication (see also the response to Question 15).

Q17: Can an MCM PRV be used for a supplemental application?

No. Section 565A(a)(3) of the FD&C Act states that a priority review voucher entitles the holder to priority review of a single human drug application submitted under section 505(b)(1) or section 351(a) of the PHS Act. Section 565A(1) of the FD&C Act states that the term "human drug application" has the meaning given in section 735(1) of the FD&C Act. The definition of "human drug application" in section 735(1) of the FD&C Act specifically states that the term does not include a supplemental application.

Q18: Would a new pediatric formulation for a drug already approved for adults be eligible for a PRV?

No. As previously noted, an application for a human drug containing an active ingredient (including any ester or salt of the active ingredient) of which has been previously approved in any other application under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act is not eligible to receive a material threat MCM PRV.

Q19: Would an application for a material threat MCM drug product submitted to the FDA before enactment of the statute but not yet approved qualify for a PRV?

Yes. Under section 565A of the FD&C Act the relevant date is the date of approval, see section 565A(a)(4)(c) of the FD&C Act (i.e., approval must occur after December 13, 2016).

D. Priority Review Vouchers: Transferability

Q20: Will the PRVs be transferable?

Yes. As section 565A(b)(2) of the FD&C Act states, the MCM sponsor receiving a material threat MCM PRV may transfer the entitlement to such PRV (including by sale) to another sponsor of a human drug application. The statute does not limit the number of times a PRV may be transferred before the PRV is used.

Q21: What is the procedure for PRV transfer?

The transfer should be documented with a letter of transfer from the material threat MCM application holder awarded the PRV and a letter from the new PRV owner acknowledging the transfer. These letters should be included in the application submitted by the sponsor redeeming the PRV. A PRV cannot be redeemed unless a complete record of transfer is made available to FDA.

E. Priority Review Voucher Fees and Use

Q22: Through what mechanism should a sponsor notify FDA that it intends to submit an application eligible to receive a PRV?

The original submission of the MCM product application should include the sponsor's request describing how the application meets the eligibility criteria for a PRV. FDA encourages early communication with the review division in which these issues could be discussed; however, notification before submission of the medical product marketing application is not required. The sponsor's request in the original submission of the MCM product application should be prominently marked, "Material Threat Medical Countermeasure Priority Review Voucher Request," and be included or referenced in the cover letter.

Q23: What is a priority review?

The definition of *priority review* in section 565A(a)(1) of the FD&C Act refers to the PDUFA goals letter, which commits FDA to a goal of completing 90 percent of priority reviews within the prescribed time frames.[19] FDA intends to treat any human drug application for which a PRV is used as if it were any other priority review drug application under the goals letter.

[19] See the PDUFA VI goals letter for fiscal years 2018-2022 available on the internet at: https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf.

Q24: What fees apply when using a PRV?

The sponsor of a human drug application that is the subject of a PRV must pay FDA a PRV user fee in addition to any other fee required under PDUFA. As the statute requires, the amount of the PRV user fee will be determined each fiscal year and is based on the difference between the average cost incurred by FDA in the review of the human drug application subject to priority review in the previous fiscal year, and the average cost incurred in the review of an application that is not subject to priority review in the previous fiscal year.

FDA will establish the fee amount before the beginning of each fiscal year and will publish the fee schedule in the *Federal Register*.[20]

Q25: When does the sponsor pay the PRV user fee?

According to the statute, the PRV user fee is due upon submission of the application for which the PRV is used. The statute specifies that the application will be considered incomplete if the PRV user fee and all the other applicable user fees are not paid in accordance with FDA payment procedures.

Prior to payment of the PRV user fee, the sponsor should provide notification of the intent to pay a PRV user fee to the CDER User Fee staff at CDERCollections@fda.hhs.gov for applications regulated by CDER or the CBER User Fee staff at CBERPDUFAStaff@fda.hhs.gov for applications regulated by CBER. The notice to the User Fee staff should be provided concurrently with and include a copy of the notice of intent to submit a human drug application with a PRV, along with letters documenting the complete record of transfers, if any.

Q26: Can the PRV user fee be waived or refunded? For example, if the sponsor pays the PRV user fee and submits an application with the intent of using the PRV and during the filing review FDA determines that the application meets the criteria for a priority review on its own merit, can the sponsor get a refund for the PRV user fee so that the sponsor can use the PRV for another application?

No. Once the application is submitted and the PRV user fee is paid, it cannot be refunded. As the statute states (section 565A(c)(4)(C) of the FD&C Act), "[t]he Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section."

[20] See, e.g., *Fee for Using a Material Threat Medical Countermeasure Priority Review Voucher in Fiscal Year 2018* (82 FR 45859, October 2, 2017).

F. Relationship Between the Material Threat MCM Priority Review Voucher Program and Other Programs

Q27: Could a material threat MCM also qualify as a tropical disease drug product?

It is possible that a drug product meeting the requirements of section 565A of the FD&C Act (material threat MCM PRV) also may meet the requirements of section 524 of the FD&C Act (which enables sponsors of certain tropical disease applications to receive a PRV). However, under section 565A(e) of the FD&C Act, the same application is not permitted to receive more than one PRV.

Q28: Could a material threat MCM also qualify as an orphan drug?

It is possible that a drug product meeting the requirements of section 565A of the FD&C Act also may qualify for designation as an orphan drug under section 526 of the FD&C Act. If designated as an orphan drug, such a drug product may be eligible for orphan drug marketing exclusivity and tax credits for qualified clinical testing as well as fee exemptions under section 736 of the FD&C Act. (See Question 5.) For information regarding these orphan drug incentives, potential sponsors should contact the Office of Orphan Products Development.[21]

Q29: Whom should a sponsor contact for answers to other questions about a material threat MCM application?

FDA encourages potential sponsors to contact the Agency early to discuss these types of questions. Such interactions may begin as early as the pre-investigational new drug application phase of drug development.

For additional questions not addressed in this guidance, sponsors should contact:

- The appropriate review division within CDER or CBER.
- For OCET: AskMCMi@fda.hhs.gov.
- For contact information related to MCMs regulated by CDER, see https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm320759.htm.
- For MCMs regulated by CBER: CBEREUA@fda.hhs.gov.

[21] For general and contact information, see: https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm.

IV. PAPERWORK REDUCTION ACT OF 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 8 hours to prepare a PRV request, 8 hours to prepare notifications of intent to use a voucher, and 8 hours to prepare the necessary letters informing FDA of the transfer of a voucher and acknowledging the receipt of a transferred voucher. These estimates include the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection.

Send comments regarding this burden estimate or suggestions for reducing this burden to: Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.