

### III. Participating in the Public Workshop

**Registration:** Persons interested in attending this public workshop must register online at [https://survey.co1.qualtrics.com/jfe/form/SV\\_6X23XS8WXHtfWAJ](https://survey.co1.qualtrics.com/jfe/form/SV_6X23XS8WXHtfWAJ). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by October 2, 2017, midnight, Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact Xiaohui Jiang (see **FOR FURTHER INFORMATION CONTACT**) no later than October 2, 2017.

**Streaming Webcast of the public workshop:** This public workshop will also be webcast. A live webcast of this workshop will be viewable at <https://collaboration.fda.gov/complex/genericdrugs/> on the day of the workshop.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

**Transcripts:** Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the Internet at <https://www.fda.gov/drugs/newsevents/ucm552461.htm>.

Dated: September 26, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

[Docket No. FDA-2017-N-2837]

#### Electronic Study Data Submission; Data Standards; Support for Analysis Data Model Implementation Guide Version 1.1

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) is announcing support for version 1.1 of Clinical Data Interchange Standards Consortium (CDISC), Analysis Data Model Implementation Guide (ADaM IG V1.1), an update to the FDA Data Standards Catalog (Catalog). (See <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>). ADaM IG V1.1 has been available from CDISC ([www.cdisc.org](http://www.cdisc.org)) since February 12, 2016. FDA is encouraging sponsors and applicants to use ADaM IG V1.1 in investigational study data provided in regulatory submissions to CDER.

**DATES:** Submit either electronic or written comments at any time.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2017-N-2837 for "Electronic Study Data Submission; Data Standards; Support for Analysis Data Model Implementation Guide Version 1.1." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the

electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1115, Silver Spring, MD 20993-0002, 301-796-5333, email: [CDERDataStandards@fda.hhs.gov](mailto:CDERDataStandards@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On December 17, 2014, FDA published final guidance for industry "Providing Regulatory Submissions in Electronic Format—Standardized Study Data" (eStudy Data) posted on FDA's Study Data Standards Resources Web page at <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>. The eStudy Data guidance implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k-1(a)) for study data contained in new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and investigational new drug applications (INDs) to the Center for Biologics Evaluation and Research (CBER) or CDER by specifying the format for electronic submissions. The implementation of electronic submission requirements for study data became effective on December 17, 2016 (24 months after issuance of final guidance for NDAs, BLAs, ANDAs, and 36 months for INDs). The eStudy Data guidance states that a **Federal Register** notice will specify the transition date for all version updates (with the month and day for the transition date corresponding to March 15).

The transition date for support of version 1.1 of ADaM 1G V 1.1 is March 15, 2018. ADaM 1G V.1.1 is supported as of this **Federal Register** notice and sponsors or applicants are encouraged to begin using it, the new version will only be required in submissions for studies that start after March 15, 2019. The Catalog will list March 15, 2019, which will be reflected in the Catalog, as the "date requirement begins." When multiple versions of an FDA-supported standard are listed in the Catalog, sponsors or applicants can select any of those version to use.

The transition date for the end of FDA support for ADaM 1G V 1.0, is March 15, 2018.

##### II. Electronic Access

Persons with access to the Internet may obtain the referenced material at <http://www.fda.gov/ectd>.

Dated: September 22, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-21081 Filed 9-29-17; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2017-N-0007]

##### Fee for Using a Material Threat Medical Countermeasure Priority Review Voucher in Fiscal Year 2018

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the fee rate for using a material threat medical countermeasure (MCM) priority review voucher for fiscal year (FY) 2018. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to determine and collect material threat MCM priority review user fees for certain applications for review of human drug products when those applications use a material threat MCM priority review voucher. These vouchers are awarded to the sponsors of material threat MCM applications that meet all of the requirements of this program upon FDA approval of such applications. The amount of the fee for using a material threat MCM priority review voucher is determined each FY based on the difference between the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous FY, and the average cost incurred in the review of an application that is not subject to priority review in the previous FY. This notice establishes the material threat MCM priority review fee rate for FY 2018 and outlines the payment procedures for such fees.

**FOR FURTHER INFORMATION CONTACT:**

Robert J. Marcarelli, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE-14202F, Silver Spring, MD 20993-0002, 301-796-7223.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 3086 of the Cures Act (Pub. L. 114-255) added section 565A to the FD&C Act (21 U.S.C. 360bbb-4a). In section 565A of the FD&C Act, Congress encouraged development of material threat MCMs by offering additional incentives for obtaining FDA approval of such products. Under section 565A of the FD&C Act, the sponsor of an eligible material threat MCM application (as defined in section 565A(a)(4)) shall receive a priority review voucher upon approval of the material threat MCM application. The recipient of a material threat MCM priority review voucher may either use the voucher for a future human drug application submitted to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), or transfer (including by sale) the voucher to another party. The voucher may be transferred (including by sale) repeatedly until it ultimately is used for a human drug application submitted to FDA under section 505(b)(1) of the FD&C Act or section 351(a) of the Public Health Service Act. A priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of 6 months after the receipt or filing date, depending on the type of application. Information regarding PDUFA goals is available at <https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf>.

The applicant that uses a material threat MCM priority review voucher is entitled to a priority review of its eligible human drug application, but must pay FDA a material threat MCM priority review user fee in addition to any user fee required by PDUFA for the application. Information regarding the material threat MCM priority review voucher program is available at: <https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm566498.htm#prv>.

This notice establishes the material threat MCM priority review fee rate for FY 2018 at \$2,830,579 and outlines FDA's procedures for payment of material threat MCM priority review user fees. This rate is effective on October 1, 2017, and will remain in effect through September 30, 2018.