TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Adult Screener	24,000	1	24,000	0.03 (2 minutes)	720
Study 1 (Adults)	1,800	1	1,800	0.333 (20 minutes)	599
Study 2 (Adults)	600	1	600	0.333 (20 minutes)	200
Total adult hours					1,519
Youth Screener	6,000	1	6,000	0.03 (2 minutes)	180
Study 3 (Youth)	600	1	600	0.333 (20 minutes)	200
Total youth hours					380
Total Hours					1,899

FDA's burden estimate is based on prior experience with research that is similar to this proposed study. Approximately 30,000 respondents will complete a screener to determine eligibility for participation in a study, estimated to take approximately 2 minutes (0.03 hours), for a total of 900 hours for screening activities. Three thousand respondents will complete a full study, estimated to last 20 minutes (0.333 hours), for a total of 999 hours for completion of both adult studies and one youth study. The estimated total hour burden of the collection of information is 1,899 hours.

Dated: November 12, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27283 Filed 11–18–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1840]

Electronic Study Data Submission; Data Standards; Validation Rules for Study Data Tabulation Model Formatted Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) is announcing the availability of a document entitled ''Validation Rules for Study Data Tabulation Model (SDTM) Formatted Studies.'' CDER is making this document available to improve the standardization and quality of clinical data submitted to CDER, as well as to improve the predictability of data quality and usefulness.

FOR FURTHER INFORMATION CONTACT: Office of Strategic Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993, email: *edata@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: CDER supports the regulatory submission of standardized clinical study data based on the Clinical Data Interchange Standards Consortium SDTM. Upon receipt of the data, CDER validates the data using a set of validation rules. The ''Validation Rules for SDTM Formatted Studies'' is an Excel file that provides a human readable description of a rule set for validation. Submitters of clinical study data can use this information to understand how FDA validates the data. The file is available on FDA's Study Data Standards Resources Web page at *http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm.* It contains a combination of conformance rules (i.e., how well the data conform to the standard) and business rules (i.e., quality checks; how well the data may support useful analysis). The rules may be updated periodically as new or updated validation rules are developed. The Change History tab will provide a descriptive change history of the document.

Dated: November 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–27384 Filed 11–18–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1120]

Vaginal Microbicides: Development for the Prevention of Human Immunodeficiency Virus Infection; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Vaginal Microbicides: Development for the Prevention of HIV Infection.'' The purpose of this guidance is to assist sponsors in all phases of development of vaginal microbicides, defined as vaginal drug products that prevent human immunodeficiency virus (HIV) acquisition. The guidance outlines the types of nonclinical studies and clinical trials recommended throughout the drug development process to support approval of vaginal microbicides. This guidance finalizes the draft guidance issued on November 23, 2012.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.*

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Charu Mullick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6365, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Vaginal Microbicides: Development for the Prevention of HIV Infection.'' This guidance addresses nonclinical development, early phases of clinical development, phase 3 trial considerations, and safety considerations in vaginal microbicide development including safety considerations in adolescent and pregnant populations. The guidance also outlines development of combination microbicide products such as drug-drug combinations, drug-device combinations, or combination products that include microbicide and are intended for multiple indications. This guidance finalizes the draft guidance issued on November 23, 2012 (77 FR 70167). The majority of public comments submitted to the docket were related to clinical trial considerations and nonclinical pharmacology/toxicology issues. This guidance incorporates FDA responses to the public comments.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on developing vaginal microbicides for preventing HIV transmission. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under 0910–0014, and the collections of information referred to in the guidance for clinical trial sponsors entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under 0910–0581.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 13, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27287 Filed 11–18–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1741]

Proposed Criteria for ''First Generic'' Submissions for Purposes of Abbreviated New Drug Application Review Prioritization Under the Generic Drug User Fee Amendments; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the opening of a public docket and requesting comments on proposed criteria for ''first generic'' abbreviated new drug application (ANDA) submissions. The purpose is to facilitate FDA's establishment of review prioritization under the Generic Drug User Fee Amendments of 2012 (GDUFA). Establishing clear criteria for this review prioritization category will allow FDA to appropriately prioritize ANDA submissions and track them in a manner consistent with the review prioritization commitments FDA made under GDUFA. Clear criteria for this category will also lead to less industry confusion and more consistent identification of ''first generic'' submissions.

DATES: Submit either electronic or written comments by December 19, 2014.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments as follows:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written comments as follows:

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

Instructions: All submissions must include the Docket No. found in brackets in the heading of this document. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://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 or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Maryll Toufanian, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1682, Silver Spring, MD 20993–0002, 240–402–7944.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, GDUFA (Title III of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144)) was signed into law by the President. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and to reduce costs to industry. GDUFA is based on an agreement negotiated by FDA and representatives of the generic drug industry to address a growing number of regulatory challenges. An attendant