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]

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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.*