preceding fiscal quarter and to estimate program expenditures to be made in the upcoming fiscal quarter. This form also allows States and Tribes to report the actual and estimated average monthly number of children assisted in each of the three IV–E entitlement grant programs in the preceding and upcoming fiscal quarters, respectively.

The Administration for Children and Families provides Federal funding at the rate of 50 percent for nearly all allowable and legitimate administrative costs of these programs and at other funding rates for other specific categories of costs as detailed in Federal statute and regulations. The information collected in this report is used by this agency to calculate quarterly Federal grant awards and to enable oversight of the financial management of the programs.

Respondents: States (including Puerto Rico and the District of Columbia) and Tribes* with approved title IV–E plans. (*An estimated 10 Tribes will have approved title IV–E plans within the next 3-year period.)

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Form CB–496: Title IV–E Programs Quarterly Financial Report	62	4	20	4,960

Estimated Total Annual Burden Hours: 4,960.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–28340 Filed 11–21–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1090]

Provisions of the Food and Drug Administration Safety and Innovation Act Related to Medical Gases; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket for information pertaining to FDA's implementation of the provisions of the Food and Drug Administration Safety and Innovation Act (FDASIA) related to medical gases. This action is intended to ensure that information submitted to FDA on the implementation of the medical gas provisions of FDASIA is available to all interested persons in a timely fashion.

DATES: Submit electronic or written comments by November 25, 2013.

ADDRESSES: Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6368, Silver Spring, MD 20993–0002, 301–796–3522, *patrick.raulerson@fda.hhs.gov;* or Germaine Connolly, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., MPN2, Rockville, MD 20855, 240–276–8331, *germaine.connolly@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, President Obama signed into law FDASIA (Pub. L. 112–144, 126 Stat. 993). Title XI, Subtitle B, section 1111 of FDASIA added new sections 575, 576, and 577 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) regarding medical gases. Among other things, these new sections define the terms ''designated medical gas'' and ''medical gas'' and establish the process for the certification of a medical gas as a designated medical gas. (See sections 575(1) and (2) of the FD&C Act.) The sections describe the process for filing a request for certification and describe the information that should be included in the request for certification. (See section 576(a) of the FD&C Act.) Under section 576(a)(3) of the FD&C Act, if a certification is granted for a designated medical gas, the designated medical gas will be deemed to have in effect an approved new human drug application under section 505 (21 U.S.C. 355) or an approved new animal drug application under section 512 (21 U.S.C. 360b) of the FD&C Act for certain specified indications and subject to all applicable postapproval requirements. Under section 576(a)(1) of the FD&C Act, requests for certification may be submitted to FDA beginning 180 days after the enactment of FDASIA, or January 5, 2013.

FDA is establishing a public docket for information pertaining to FDA's implementation of these new medical gas provisions. This action is intended to ensure that information submitted to FDA on the implementation of the medical gas provisions of FDASIA is available to all interested persons in a timely fashion. The Compressed Gas

Association and the Gases and Welding Distributors Association voluntarily submitted to the Agency its views on implementation of the medical gas provisions of FDASIA. FDA plans to place these comments in the public docket so they are readily available to all interested members of the public. FDA expects to place all additional submissions containing recommendations on how the Agency should implement the medical gas provisions of FDASIA in this docket, and directs the public to submit all comments related to these provisions to this docket. This docket will be open for comments for 1 year from the date of publication of this notice. In addition, as FDA implements the medical gas provisions of FDASIA, FDA plans to open other dockets. For example, we plan to issue a separate **Federal Register** notice in the future to provide the public with an opportunity to submit comments on section 1112 of FDASIA. Section 1112(a)(1) of FDASIA provides that not later than 18 months after the date of the enactment of FDASIA, the Secretary, after obtaining input from medical gas manufacturers and any other interested members of the public, must determine whether any changes to the Federal drug regulations are necessary for medical gases.

II. Comments

Interested persons may submit either written comments to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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.*

Dated: November 19, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–28431 Filed 11–21–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1120]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft 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 for the prevention of human immunodeficiency virus (HIV) infection. The guidance outlines the types of nonclinical studies and clinical trials recommended throughout the drug development process to support approval of vaginal microbicides.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 21, 2013.

ADDRESSES: Submit written requests for single copies of the draft 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 draft guidance document.

Submit electronic comments on the draft 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 draft 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 provides some information on approaches for developing combination microbicide products such as drug-drug combinations, drug-device combinations containing a microbicide, or combination products containing a microbicide that are intended for multiple indications. With the recent approval of oral emtricitabine/tenofovir for HIV pre-exposure prophylaxis (PrEP), the effect of oral PrEP on microbicide trial designs is an emerging topic. The guidance discusses this issue; however, it should be noted the pertinent sections may be revised as FDA takes into consideration evolving opinions in the prevention field as well as public comments on this topic.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 draft guidance refers to previously approved collections of information 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 collections of information in 21 CFR part 312 have been approved under OMB control number 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 OMB control number 0910–0581.

III. Comments

Interested persons may submit either written comments regarding the draft guidance to the Division of Dockets