than 15 minutes (0.25 hour) per response. We estimate that we will receive 1 submission from 10 shell egg producers annually, for a total of 10 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 2.5 hours, rounded to 3. We estimate that we will receive 1 submission from 120 dairy product producers annually, for a total of 120 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 30 hours. We estimate that we will receive one submission from five game meat and game meat product producers annually, for a total of five annual responses. Each submission is estimated to take 0.25 hour per response for a total of 1.25 hours, rounded to 1 hour. We estimate that we will receive one submission from five animal casings producers annually, for a total of five annual responses. Each submission is estimated to take 0.25 hour per response for a total of 1.25 hours, rounded to 1 hour. We estimate that we will receive one submission from three gelatin producers annually, for a total of three annual responses. Each submission is estimated to take 0.25 hour per response for a total of 0.75 hour, rounded to 1 hour. We estimate that we will receive one submission from three collagen producers annually, for a total of three annual responses. Each submission is estimated to take 0.25 hour per response for a total of 0.75 hour, rounded to 1 hour. Therefore, the proposed annual burden for this information collection is 37 hours.

Dated: February 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04348 Filed 2–27–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0180]

Draft Guidance for Industry on Attachment to Guidance on Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting Human Immunodeficiency Virus-1 Resistance Data; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Attachment to Guidance on Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HIV–1 Resistance Data.'' The purpose of this guidance is to assist sponsors in submitting human immunodeficiency virus (HIV) clinical virology data that are important for supporting clinical trials of products in development for the treatment of HIV. HIV resistance data submitted in appropriately formatted datasets are critical components in the review of investigational antiviral products for the treatment of HIV. The information in this guidance will facilitate the development of anti-HIV products. This draft guidance revises the guidance for industry entitled ''Attachment to Guidance on Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HIV Resistance Data'' issued on June 5, 2006.

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 April 29, 2014.

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: Lisa K. Naeger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 22, rm. 6366, Silver Spring, MD 20993–0002, 301–796–0771.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Attachment to Guidance on Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HIV–1 Resistance Data.'' The purpose of this guidance is to assist sponsors in submitting HIV clinical virology data that are important for supporting clinical trials of products in development for the treatment of HIV. This guidance revises and replaces the guidance on submitting HIV resistance data published in June 2006. The revised guidance provides the format, recommended definitions, standardization of column headings and variables, and recommended data for submission of HIV resistance datasets.

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 submitting HIV clinical virology data. 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 (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.

III. 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.

IV. 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: February 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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