approval by an IEC before initiating a study, continuing review of an ongoing study by an IEC, and obtaining and documenting the freely given informed consent of the subject before initiating a study. Under § 312.120(b), a sponsor of a non-IND foreign study who wants to rely on that study as support for an IND or application for marketing approval must provide the following information to FDA: (1) The investigator's qualifications; (2) a description of the research facilities; (3) a detailed summary of the protocol and results of the study and, should FDA request, case records maintained by the investigator or additional background data such as hospital or other institutional records; (4) a description of the drug substance and drug product used in the study, including a description of the components, formulation, specifications, and, if available, bioavailability of the specific drug product used in the clinical study; (5) if the study is intended to support the effectiveness of a drug product, information showing that the study is adequate and well controlled under § 314.126; (6) the name and address of the IEC that reviewed the study and a statement that the IEC meets the definition in § 312.3; (7) a summary of the IEC's decision to approve or modify and approve the study, or to provide a favorable opinion; (8) a description of how informed consent was obtained; (9) a description of what incentives, if any, were provided to subjects to participate in the study; (10) a description of how the sponsor(s) monitored the study and ensured that the study was carried out consistently with the study protocol; and (11) a description of how investigators were trained to comply with GCP and to conduct the study in accordance with the study protocol, and a statement on whether written commitments by investigators to comply with GCP and the protocol were obtained.

Section 312.120(c) specifies how sponsors or applicants can request a waiver for any of the requirements under § 312.120(a)(1) and (b). Under § 312.120(c)(1), a waiver request must contain at least one of the following: (1) An explanation why the sponsor's or applicant's compliance with the requirement is unnecessary or cannot be achieved, (2) a description of an alternative submission or course of action that satisfies the purpose of the requirement, or (3) other information justifying a waiver. A waiver request may be submitted in an IND or in an information amendment to an IND, or in an application or in an amendment or supplement to an application submitted under 21 CFR part 314 or 601. Section 312.10 sets forth requirements for sponsors who request waivers from FDA for compliance with any of the provisions in part 312, and § 314.90 sets forth requirements for applicants who request waivers from FDA for compliance with §§ 314.50 through 314.81.

FDA has approval for the submission of these waiver requests under OMB control numbers 0910–0014 for part 312 and 0910–0001 for part 314. In addition to the reporting requirements set forth in table 1 of this document, there is also a recordkeeping provision in § 312.120(d) stating how long sponsors and applicants must retain records required by § 312.120. In addition, § 312.120(b) states that any signed written commitments by investigators must be maintained by the sponsor or applicant and made available for Agency review upon request, and also specifies sponsor recordkeeping of IEC-related information. Under § 312.120(d), if a study is submitted in support of an application for marketing approval, records must be retained for 2 years after an Agency decision on that application; if a study is submitted in support of an IND but not an application for marketing approval, records must be retained for 2 years after the submission of the IND. The retention requirements in § 312.57(c) for records and reports required under part 312 apply to these provisions, and are approved under OMB control number 0910–0014.

We estimate that 237 companies will submit a total of approximately 1,185 non-IND foreign clinical studies in support of an IND or application for marketing approval for a drug or biological product. Hour burden estimates vary due to differences in size, complexity, and duration across studies, and we estimate that complying with § 312.120 would take sponsors between 18 and 32 hours annually for each non-IND foreign clinical trial, totaling 37,920 hours ($32 \times 1{,}185$).

In the **Federal Register** of February 26, 2013 (78 FR 13067), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received that pertained to the collection of information.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
312.120	237	5	1,185	32	37,920

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13246 Filed 6–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0589]

Draft Guidance for Industry on Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment; 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 ''Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in all phases of development of antiretroviral drugs for the treatment of HIV. This draft guidance revises the guidance for industry entitled ''Antiretroviral Drugs Using Plasma HIV RNA Measurements—Clinical Considerations

for Accelerated and Traditional Approval'' issued in October 2002.

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 August 5, 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: Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6370, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment.'' This guidance revises the guidance for industry entitled ''Antiretroviral Drugs Using Plasma HIV–RNA Measurements—Clinical Considerations for Accelerated and Traditional Approval'' issued in October 2002. Significant changes from the 2002 version include: (1) More details on nonclinical development of antiretroviral drugs; (2) a greater emphasis on recommended trial designs for HIV–1 infected heavily treatment-experienced patients (those with multiple-drug, resistant virus and few remaining therapeutic options); (3) use of a primary endpoint evaluating early virologic changes for studies in heavily treatment-experienced patients; and (4) use of the traditional approval pathway for initial approval of all antiretrovirals with primary analysis time points dependent on the indication sought instead of an accelerated approval pathway followed by traditional approval. Longer term trials may be appropriate for patients who are treatment-naïve or have limited prior experience, whereas shorter term trials may be appropriate for patients with limited treatment options.

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 antiretroviral drugs for the treatment of HIV–1 infection. 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, the collections of information in 21 CFR part 314 have been approved under 0910–0001, and the collections of information referred to in the guidance for industry entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under 0910–0581.

III. Comments

Interested persons may submit either written comments regarding this document 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*.

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: May 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13288 Filed 6–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0580]

Battery-Powered Medical Devices Workshop: Challenges and Opportunities; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Battery-Powered Medical Devices Workshop: Challenges and Opportunities''. The purpose of this workshop is to create awareness of the challenges related to battery-powered medical devices and collaboratively develop solutions and best practices to improve the performance and reliability of these devices.

Date and Time: The public workshop will be held on July 30 and 31, 2013, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. All visiting public workshop participants (non-FDA employees) must enter through Building 1 for routine security check procedures. For parking and security information, please visit the following Web site: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

Contact: Iacovos Kyprianou, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 3609, Silver Spring, MD 20993–0002, 301–796–2601, email: *iacovos.kyprianou@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m., July 19, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the workshop will be available beginning at 7 a.m.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://*