manufacturers of biological products other than human blood and blood components, licensed manufacturers of blood and blood components including Source Plasma, unlicensed registered blood establishments, transfusion services, and establishments that manufacture non-reproductive HCT/Ps regulated solely under section 361 of the PHS Act as described in § 1271.10. The number of respondents and total annual responses are based on the BPD reports and HCT/P deviation reports FDA received in fiscal year 2012. The number of licensed manufacturers and total annual responses under § 600.14 include the estimates for BPD reports submitted to both CBER and CDER. Based on the information from industry, the estimated average time to complete a deviation report is 2 hours. The availability of the standardized report form, Form FDA 3486, and the ability to submit this report electronically to CBER (CDER does not currently accept electronic filings) further streamlines the report submission process.

CBER has developed an addendum to Form FDA 3486. The Web-based addendum (Form FDA 3486A) provides additional information when a BPD report has been reviewed by FDA and evaluated as a possible recall. The additional information requested includes information not contained in the Form FDA 3486 such as: (1) Distribution pattern; (2) method of consignee notification; (3) consignee(s) of products for further manufacture; (4) additional product information; (5) updated product disposition; and (6) industry recall contacts. This information is requested by CBER through email notification to the submitter of the BPD report. This information is used by CBER for recall classification purposes. At this time, Addendum 3486A is being used only for those BPD reports submitted under § 606.171. CBER estimates that 5 percent of the total BPD reports submitted to CBER under § 606.171 would need additional information submitted in the addendum. CBER further estimates that it would take between 10 to 20 minutes to complete the addendum. For calculation purposes, CBER is using 15 minutes.

Activities such as investigating, changing standard operating procedures or processes, and followup are currently required under 21 CFR parts 211, (approved under OMB control number 0910–0139), part 606 (approved under OMB control number 0910–0116), part 820 (approved under OMB control number 0910–0073) and part 1271 (approved under OMB control number 0910–0543) and, therefore, are not included in the burden calculation for the separate requirement of submitting a deviation report to FDA.

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

ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR section	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
600.14	3486	91	7.71	702	2.0	1,404
606.171	3486	1,679	32.73	54,954	2.0	109,908
1271.350(b)	3486	94	2.66	250	2.0	500
	[2]3486A	84	32.70	2,747	0.25	687
Total						112,499

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Five percent of the number of respondents (1,679 × 0.05 = 84) and total annual responses to CBER (54,954 × 0.05 = 2,748).

Dated: May 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13279 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–0172]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 5, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0622. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application—(OMB Control Number 0910–0622)—Reinstatement

Under § 312.120 (21 CFR 312.120), FDA accepts foreign clinical studies not conducted under an investigational new drug application (IND) as support for an IND or application for marketing approval for a drug or biological product if the studies are conducted in accordance with good clinical practices (GCP), including review and approval by an independent ethics committee (IEC).

Under § 312.120(a), FDA accepts as support for an IND or application for marketing approval a well-designed and well-conducted foreign clinical study not conducted under an IND if the study is conducted in accordance with GCP, and we are able to validate the data from the study through an onsite inspection if necessary. GCP includes review and

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