disputes related to an application for a user fee product under any of the available regulatory mechanisms (*i.e.,* 21 CFR 10.75, 312.48(c), 314.103(c)), through the formal dispute resolution process.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on formal dispute resolution requests for appeals above the division level. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This revised draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction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 The collections of information in this draft guidance have been approved under OMB control number 0910–0430. This draft guidance is a revision of an earlier version of the guidance. The revised version contains no additional information collections; therefore, it continues to be covered under OMB control number 0910–0430.

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, 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 *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: September 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22678 Filed 9–8–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0908]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees

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 October 9, 2015.

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 0910–0581. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees

OMB Control Number 0910–0581—Extension

Sponsors are required to monitor studies evaluating new drugs, biologics, and devices (21 CFR 312.50 and 312.56 for drugs and biologics and 21 CFR 812.40 and 812.46 for devices). Various individuals and groups play different roles in clinical trial monitoring. One such group is a data monitoring committee (DMC), appointed by a sponsor to evaluate the accumulating outcome data in some trials. A clinical trial DMC is a group of individuals with pertinent expertise that reviews on a regular basis accumulating data from one or more ongoing clinical trials. The DMC advises the sponsor regarding the continuing safety of current trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial.

The guidance document referenced in this document is intended to assist sponsors of clinical trials in determining when a DMC is needed for monitoring a study, and how such committees should operate. The guidance addresses the roles, responsibilities, and operating procedures of DMCs, describes certain reporting and recordkeeping responsibilities, including the following: (1) Sponsor reporting to FDA on DMC recommendations related to safety; (2) standard operating procedures (SOPs) for DMCs; (3) DMC meeting records; (4) sponsor notification to the DMC regarding waivers; and (5) DMC reports based on meeting minutes to the sponsor.

1. Sponsor Reporting to FDA on DMC Recommendations Related to Safety

The requirement of the sponsor to report DMC recommendations related to serious adverse events in an expedited manner in clinical trials of new drugs (21 CFR 312.32(c)) would not apply when the DMC recommendation is related to an excess of events not classifiable as serious. Nevertheless, the Agency recommends in the guidance that sponsors inform FDA about all recommendations related to the safety of the investigational product whether or not the adverse event in question meets the definition of ''serious.''

2. SOPs for DMCs

In the guidance, FDA recommends that sponsors establish procedures to do the following things:

- Assess potential conflicts of interest of proposed DMC members;
- Ensure that those with serious conflicts of interest are not included in the DMC;
- Provide disclosure to all DMC members of any potential conflicts that are not thought to impede objectivity and, thus, would not preclude service on the DMC;

- Identify and disclose any concurrent service of any DMC member on other DMCs of the same, related, or competing products;
- Ensure separation, and designate a different statistician to advise on the management of the trial, if the primary trial statistician takes on the responsibility for interim analysis and reporting to the DMC; and
- Minimize the risks of bias that are associated with an arrangement under which the primary trial statistician takes on the responsibility for interim analysis and reporting to the DMC, if it appears infeasible or highly impractical for any other statistician to take over responsibilities related to trial management.

3. DMC Meeting Records

The Agency recommends in the guidance that the DMC or the group preparing the interim reports to the DMC maintain all meeting records. This information should be submitted to FDA with the clinical study report (21 CFR 314.50(d)(5)(ii)).

4. Sponsor Notification to the DMC Regarding Waivers

The sponsor must report to FDA certain serious and unexpected adverse events in drugs and biologics trials (§ 312.32) and unanticipated adverse device effects in the case of device trials (21 CFR 812.150(b)(1)). The Agency recommends in the guidance that sponsors notify DMCs about any waivers granted by FDA for expedited reporting of certain serious events.

5. DMC Reports of Meeting Minutes to the Sponsor

The Agency recommends in the guidance that DMCs should issue a written report to the sponsor based on the DMC meeting minutes. Reports to the sponsor should include only those data generally available to the sponsor. The sponsor may convey the relevant information in this report to other interested parties, such as study investigators. Meeting minutes or other information that include discussion of confidential data would not be provided to the sponsor.

Description of Respondents: The submission and data collection recommendations described in this document affect sponsors of clinical trials and DMCs.

Burden Estimate: Table 1 provides the burden estimate of the annual reporting burden for the information to be submitted in accordance with the guidance. Table 2 provides the burden estimate of the annual recordkeeping burden for the information to be maintained in accordance with the guidance. Table 3 provides the burden estimate of the annual third-party disclosure burden for the information to be submitted in accordance with the guidance.

Reporting, Recordkeeping, and Third-Party Disclosure Burdens: Based on information from FDA review divisions, FDA estimates there are approximately 740 clinical trials with DMCs regulated by the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health. FDA estimates that the average length of a clinical trial is 2 years, resulting in an annual estimate of 370 clinical trials. Because FDA has no information on which to project a change in the use of DMCs, FDA estimates that the number of clinical trials with DMCs will not change significantly. For purposes of this information collection, FDA estimates that each sponsor is responsible for approximately 10 trials, resulting in an estimated 37 sponsors that are affected by the guidance annually.

Based on information provided to FDA by sponsors that have typically used DMCs for the kinds of studies for which this guidance recommends them, FDA estimates that the majority of sponsors have already prepared SOPs for DMCs, and only a minimum amount of time is necessary to revise or update them for use for other clinical studies. FDA receives very few requests for waivers regarding expedited reporting of certain serious events; therefore, FDA has estimated one respondent per year to account for the rare instance a request may be made. Based on FDA's experience with clinical trials using DMCs, FDA estimates that the sponsor on average would issue two interim reports per clinical trial to the DMC. FDA estimates that the DMCs would hold two meetings per year per clinical trial resulting in the issuance of two DMC reports of meeting minutes to the sponsor. One set of both of the meeting records should be maintained per clinical trial.

The ''Average Burden per Response'' and ''Average Burden per Recordkeeping'' are based on FDA's experience with comparable recordkeeping and reporting provisions applicable to FDA regulated industry. The ''Average Burden per Response'' includes the time the respondent would spend reviewing, gathering, and preparing the information to be submitted to the DMC, FDA, or the sponsor. The ''Average Burden per Recordkeeping'' includes the time to record, gather, and maintain the information.

The information collection provisions in the guidance for 21 CFR 312.30, 312.32, 312.38, 312.55, and 312.56 have been approved under OMB control number 0910–0014; § 314.50 has been approved under OMB control number 0910–0001; and 21 CFR 812.35 and 812.150 have been approved under OMB control number 0910–0078.

In the **Federal Register** of March 27, 2015 (80 FR 16402), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section of guidance/reporting activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
5. Sponsor reporting to FDA on DMC recommendations related to safety.	37	1	37	0.5 (30 min.)	18.5

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Section of guidance/recordkeeping activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
4.1. and 6.4 SOPs for DMCs	37	1	37	8	296
4.4.3.2. DMC meeting records	370	1	370	2	740
Total					1,036

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Section of guidance/disclosure activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
4.4.1.2. Sponsor notification to the DMC regarding waivers.	1	1	1	0.25 (15 minutes)	0.25
4.4.3.2. DMC reports of meeting minutes to the sponsor.	370	2	740	1	740
Total					740.25

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

Dated: September 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22680 Filed 9–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Nominations to the Presidential Advisory Council on HIV/AIDS

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: The Office of the Assistant Secretary for Health (OASH) is seeking nominations of qualified individuals to be considered for appointment as members of the Presidential Advisory Council on HIV/AIDS (PACHA). The PACHA is a federal advisory committee within the Department of Health and Human Services (HHS). Management support for the activities of this Council is the responsibility of the OASH. The qualified individuals will be nominated to the Secretary of Health and Human Services for consideration for appointment as members of the PACHA. Members of the Council, including the Chair, are appointed by the Secretary. Members are invited to serve on the Council for up to four-year terms. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention and care of HIV disease and AIDS. The functions of the Council are solely advisory in nature.

DATES: All nominations must be received no later than 5:00 p.m. (ET) on October 9, 2015 at the address listed below.

ADDRESSES: All nominations should be mailed or delivered to Ms. B. Kaye Hayes, Executive Director, PACHA, Department of Health and Human Services, Office of HIV/AIDS and Infectious Disease Policy, 200 Independence Avenue SW., Room 443–H, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, Department of Health and Human Services, 200 Independence Avenue SW., Room 443–H, Hubert H. Humphrey Building, Washington, DC 20201; (202) 205–1178. More detailed information about PACHA can be obtained by accessing the Council's page at the AIDS.gov Web site at *www.aids.gov/pacha.*

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention and care of HIV disease and AIDS. The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House Office on National AIDS Policy. Pursuant to advance written agreement, Council members shall receive no stipend for the advisory service they render as members of PACHA. However, as authorized by law and in accordance with federal travel regulations, PACHA members may receive per diem and reimbursement for travel expenses incurred in relation to performing duties for the Council.

This announcement is to solicit nominations of qualified candidates to fill current vacancies on the PACHA.

Nominations: In accordance with the PACHA charter, persons nominated for appointment as members of the PACHA should be among prominent community leaders and authorities with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. The following information should be included in the package of material submitted for each individual being nominated for consideration of appointment:

- Name, return address, daytime telephone number, and affiliation(s) of