unforeseeable'' events for purposes of BPD reporting (see § 606.171(b)(1)(ii)). Accordingly, establishments have been submitting BPD reports regarding PDI that may affect the safety, purity, or potency of a distributed product. PDI events continue to be reported, and the numbers have increased over time. Reports of PDI events have consistently been the highest number of reports received from blood establishments, representing a significant burden to industry and FDA. For example, from FYs 2000 through 2017, FDA has received approximately 18,000 to 40,000 PDI reports each year. The total number of PDI reports submitted by blood establishments in FY 2017 was 37,265 of 51,434 total BPD reports, representing approximately 72 percent of all BPD reports submitted by blood establishments. In reviewing the data for the past 18 years, based on the extraordinarily high number of PDI reports, FDA has concluded that PDI events are no longer ''unexpected or unforeseeable,'' and will likely continue to occur. Because PDI events are no longer ''unexpected or unforeseeable,'' and also do not represent deviations from CGMP, applicable regulations, applicable standards, or established specifications, such events are not reportable under § 606.171.

FDA is issuing this guidance for immediate implementation in accordance with § 10.115(g)(3) (21 CFR 10.115(g)(3)) without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate (see § 10.115(g)(2)). Specifically, we made this determination because this guidance presents a less burdensome policy for reporting BPDs that is consistent with public health. It eliminates the reporting of PDI events as BPD reports because these reports are no longer unexpected or unforeseeable based on PDI data for the past 18 years, without compromising public health protections.

This guidance is expected to significantly reduce the BPD reporting burden on industry and the burden on FDA to review these reports. Based on the above FY 2017 PDI data, FDA expects that the elimination of PDI reports will result in a 72 percent reduction in total BPD reports received (elimination of 37,265 of 51,434 total reports in FY 2017). FDA anticipates that this will substantially and proportionally reduce the blood industry's estimated annual reporting burden under § 606.171, which FDA recently estimated to be 92,384 total annual hours (84 FR 70979 at 70981; December 26, 2019). The revised recommendations are also consistent with public health.

Given the substantial number of PDI reports FDA has received, the Agency is aware that these events occur, and the submission of additional PDI reports to FDA is unlikely to facilitate the identification of manufacturing or safety issues. PDI events are not associated with deviations from CGMP or other requirements, and blood establishments generally have no control over information provided by donors or third parties subsequent to a donation. Eliminating PDI reports will enable blood establishments and FDA to prioritize resources on BPD reports that are more likely to inform corrective actions to protect the public health. Additionally, blood establishments are required to comply with applicable regulations regarding, among other things, establishing, maintaining, and following standard operating procedures (SOPs) (see § 606.100(b) (21 CFR 606.100(b)) and maintaining records (see § 606.160 (21 CFR 606.160)). FDA will continue to assess SOPs and records associated with PDI events during routine inspections of blood establishments. Thus, this revised guidance presents a less burdensome policy for reporting PDI events that is consistent with public health.

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). FDA is issuing this guidance for immediate implementation in accordance with § 10.115(g)(3) without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate. The guidance represents the current thinking of FDA on biological product deviation reporting for blood and plasma establishments. 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information under §§ 600.14 and 606.171 were approved under OMB control number 0910–0458; the collections of information under §§ 606.100 and 606.160 were approved under OMB control number 0910–0116; the collections of information under 21 CFR 211.192 and 211.198 were approved under OMB control number 0910–0139; and the collections of information under 21 CFR 601.12 were approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics* or *https://www.regulations.gov.*

Dated: March 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05103 Filed 3–12–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4711]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Nonbinding Feedback After Certain Food and Drug Administration Inspections of Device Establishments

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 (PRA).

DATES: Fax written comments on the collection of information by April 13, 2020.

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–NEW and title ''Nonbinding Feedback After Certain FDA Inspections of Device Establishments.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations,

Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Requests for Nonbinding Feedback After Certain FDA Inspections of Device Establishments

OMB Control Number 0910–NEW

The guidance document entitled ''Nonbinding Feedback After Certain FDA Inspections of Device Establishments'' explains how the owner, operator, or agent in charge of a device establishment may submit a request for nonbinding feedback to FDA regarding actions the firm has proposed to take to address certain kinds of inspectional observations that have been documented on an FDA Inspectional Observations Form (Form FDA 483) and issued to the firm upon completion of an inspection of the firm's establishment. The guidance also identifies a standardized method for communicating and submitting requests for nonbinding feedback and describes how FDA evaluates and responds to such requests.

In the **Federal Register** of February 19, 2019 (84 FR 4823), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received comments on the following PRA related topics:

FDA received several comments regarding whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.

(Comment 1) One commenter requested that FDA clarify the benefits of requesting nonbinding feedback (*e.g.,* whether nonbinding feedback, and a subsequent reaction to that feedback) could prevent a Warning Letter from being issued.

(Response) FDA believes that the benefits of requesting nonbinding feedback are clear. Specifically, timely nonbinding feedback could help firms determine whether proposed actions to address inspectional observations are adequate, possibly avoiding unnecessary investment in potential solutions not likely to satisfactorily address an inspectional observation. FDA's considerations and procedures for determining whether a Warning Letter should be issued are identified in other documents (*e.g.,* FDA's Regulatory Procedures Manual).

(Comment 2) Multiple commenters felt that the guidance applies narrow criteria that forecloses meaningful access to Agency feedback. For example, some commenters felt that FDA should provide feedback on any emerging safety issue, not just those that are likely to cause death or serious injury.

(Response) Section 704(h)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 374(h)(2)) sets forth eligibility criteria for a request for nonbinding feedback. FDA's guidance describes situations involving significant observations that the Agency believes meet the statutory criteria. In addition, we note that firms have other options to engage with FDA.

FDA received several comments related to ways to enhance the quality, utility, and clarity of the information to be collected.

(Comment 3) Multiple commenters asked whether findings from Medical Device Single Audit Program (MDSAP) audits are eligible to receive nonbinding feedback.

(Response) The Medical Device Single Audit Program is a voluntary program that allows an MDSAP-recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program. MDSAP audits do not meet the definition of an inspection set forth in section 704 of the FD&C Act; therefore, findings from MDSAP audits are not eligible to receive nonbinding feedback.

(Comment 4) One commenter stated that the guidance contradicts least burdensome principles.

(Response) FDA disagrees with the comment. As stated in FDA's guidance, ''The Least Burdensome Provisions: Concepts and Principles,'' [1] FDA defines ''least burdensome'' to be ''the minimum amount of information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time.'' FDA believes that the nonbinding feedback program is fundamentally ''least burdensome,'' because it strives to help firms avoid unnecessary investment in potential solutions not likely to satisfactorily address an inspectional observation. By providing a mechanism in which firms can, voluntarily, seek nonbinding feedback on proposed actions to address certain inspectional observations, the program seeks to help firms resolve regulatory issues through the most efficient manner at the right time, using the minimum amount of information necessary.

(Comment 5) One commenter asked whether outputs of the draft guidance, such as requests for nonbinding feedback or FDA's responses to requests for nonbinding feedback, will be placed in a public database.

(Response) The FD&C Act does not require requests for nonbinding feedback or FDA's responses to requests for nonbinding feedback to be placed in a public database. However, FDA may take additional actions (*e.g.,* issue Warning Letters or safety communications) in response to significant inspectional observations, some of which may be posted publicly.

(Comment 6) Multiple commenters requested that FDA extend the ''deadline'' for requesting nonbinding feedback beyond 15 days after issuance of a Form FDA 483. For example, some commenters felt that imposing a 15 day ''deadline'' for requesting nonbinding feedback would result in rushed remediations without a sufficient understanding of the root-cause of the underlying quality system deviations.

(Response) Firms are not required to submit requests for nonbinding feedback. To be eligible for nonbinding feedback, a request for nonbinding feedback must involve a public health priority, implicate systemic or major actions, or relate to emerging safety issues. FDA believes that a corrective action should be taken as expeditiously as possible in response to an observation that meets one or more of the statutory criteria. In situations where a firm is unable to submit a timely request for nonbinding feedback, the firm has other options to engage with FDA.

(Comment 7) Multiple commenters requested that FDA allow multiple chances to seek nonbinding feedback. For example, some commenters stated that a firm's initial corrective action plan may change over time and that remediation may take months; therefore, firms may need feedback more than once and more than 15 days after issuance of a Form FDA 483.

(Response) FDA believes that inspectional observations that involve a public health priority, implicate systemic or major actions, or relate to emerging safety issues should be corrected as expeditiously as possible. FDA acknowledges that in some situations, firms may desire feedback more than once. If multiple requests for nonbinding feedback are timely and

[1] The guidance is available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles.*

meet the other statutory requirements, FDA is required to respond to each request within 45 days. If multiple requests for nonbinding feedback are not timely, then these requests will not be subject to a response from FDA within 45 days.

Finally, FDA acknowledges that when the inspectional observations involve a public health priority, implicate a systemic or major action, or relate to an emerging safety issue, continued communication between FDA and the firm may be needed after issuance of the nonbinding feedback to ensure adequate protection of public health. In such cases, FDA may continue communication with the firm and/or take any action necessary to ensure adequate protection of public health.

FDA received one comment regarding ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

(Comment 8) One commenter requested that FDA develop templates for manufacturers to submit when requesting nonbinding feedback.

(Response) At this time, FDA does not believe that providing a template would be appropriate since the content of the request for nonbinding feedback is expected to be situationally dependent and different firms may have different preferred formats for requesting nonbinding feedback. FDA believes that use of a template may be too restrictive and could result in pertinent information not being included in the request for nonbinding feedback. Nonetheless, FDA may choose to utilize a template at a later date if it determines it would be beneficial to firms to do so.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests for nonbinding feedback after certain FDA inspections of device establishments	220	1	220	500	110,000

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

Our estimate that 220 respondents per year will request nonbinding feedback is based on recent inspectional data. Based on the recommendations in the guidance and our experience with similar information collections, we believe it will take approximately 500 hours to complete a request for nonbinding feedback. Therefore, we estimate the burden of this information collection to be 110,000 hours.

Dated: March 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05131 Filed 3–12–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIDA.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE ON DRUG ABUSE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIDA.

Date: May 7–8, 2020.

Time: 8:00 a.m. to 3:15 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: Intramural Research Program, Biomedical Research Center, Johns Hopkins Bayview Campus, 251 Bayview Boulevard, Room BRC 03C219, Baltimore, MD 21224.

Contact Person: Joshua Kysiak, Program Specialist, Biomedical Research Center, Intramural Research Program, National Institute on Drug Abuse, NIH, DHHS, 251 Bayview Boulevard, Baltimore, MD 21224, 443–740–2465, *kysiakjo@nida.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: March 9, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05096 Filed 3–12–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Member Conflict SEP.

Date: April 14, 2020.

Time: 12:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ramesh Vemuri, Ph.D., Chief, Scientific Review Branch, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, (301) 402–7700, *rv23r@nih.gov*.