enumerated through their CMS Certification Number (CCN). State Medicaid agencies and CMS use the provider's tax identification number and NPI or CCN combination in order to make payment, validate payment eligibility and detect and prevent duplicate payments for EPs, eligible hospitals and CAHs. *Form Number:* CMS–10336 (OMB Control Number: 0938–1158); *Frequency:* Occasionally; *Affected Public:* Private sector; *Number of Respondents:* 214,694; *Total Annual Responses:* 214,694; *Total Annual Hours:* 2,034,740. (For policy questions regarding this collection contact Steven Johnson at (410) 786–3332).

Dated: March 22, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–06081 Filed 3–26–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0073]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Consultation Procedures: Foods Derived From New Plant Varieties

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 26, 2018.

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 0910–0704. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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 on Consultation Procedures: Foods Derived From New Plant Varieties

OMB Control Number 0910–0704—Extension

This information collection supports the above captioned Agency guidance document. FDA recommends that producers who use biotechnology in the manufacture or development of foods and food ingredients work cooperatively with FDA to ensure that products derived through biotechnology are safe and comply with all applicable legal requirements and has instituted a voluntary consultation process with industry. To facilitate this process the Agency has issued a guidance entitled, ''Guidance on Consultation Procedures: Foods Derived From New Plant Varieties,'' which is available on our website at *https://www.fda.gov/FoodGuidances.* The guidance describes FDA's consultation process for the evaluation of information on new plant varieties provided by developers. The Agency believes this consultation process will help ensure that human food and animal feed safety issues or other regulatory issues (*e.g.,* labeling) are resolved prior to commercial distribution. Additionally, such communication will help to ensure that any potential food safety issues regarding a new plant variety are resolved during development, and will help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the standards of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

In the **Federal Register** of December 13, 2017 (82 FR 58619), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. Two comments were received in response to the notice. Overall, the comments supported FDA's need for the information collection and neither comment suggested revising our estimate of the associated burden. However, both comments reminded us that significant resources were invested into developing data upon which respondents rely to bring information to FDA regarding the development of foods derived from new plant varieties. All the more reason, the comments said, FDA should identify mechanisms by which it can better incorporate its experience over time and, where possible, implement more efficient, streamlined review processes for those products similar to those the Agency has reviewed in the past. The comments recommended FDA compare efficiencies with a process at the U.S. Department of Agriculture regarding the review of agricultural biotechnology products. We appreciate this suggestion. FDA strives to allocate its limited resources in ways that maximize protection to the public health and facilitate compliance with existing regulatory requirements implemented to do so. We also look for ways in which we might coordinate our efforts with those by other agencies who share these objectives.

Both comments also included the suggestion that FDA develop a less redundant review process (such as reciprocity if no material differences are identified) that better coordinates expertise across the Center for Food Safety and Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) into a single, efficient review. We appreciate this suggestion as well and, as discussed in the guidance, note the following:

[FDA's] Office of Premarket Approval of the CFSAN and the Office of Surveillance and Compliance of the CVM have established a Biotechnology Evaluation Team (BET) to facilitate, and to ensure consistency in the process by which firms consult under the 1992 policy and inform FDA regarding the marketing of bioengineered foods and food ingredients derived from new plant varieties including those developed using rDNA techniques. The BET oversees the consultation process, identifies regulatory and scientific issues that need to be addressed, and once all relevant issues have been adequately addressed, brings the consultation to closure.

At the same time, we have shared the comments received in response to this notice under the PRA with the BET. Consistent with our Good Guidance Practice regulations (21 CFR 10.115), FDA welcomes comments on our guidance documents at any time.

In consideration of these comments, we have retained the currently approved burden estimated associated with the information collection, which is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial consultation	None	20	2	40	4	160
Final consultation	3665	12	1	12	150	1,800
Total						1,960

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

Our estimate is based on the information collection activities discussed below.

Initial Consultations

Initial consultations are generally a one-time burden, although a developer might return more than once to discuss additional issues before submitting a final consultation. As noted in the guidance, FDA encourages developers to consult early in the development phase of their products, and as often as necessary. Historically, firms developing a new bioengineered plant variety intended for food use have generally initiated consultation with FDA early in the process of developing such a variety, even though there is no legal obligation for such consultation. These consultations have served to make FDA aware of foods and food ingredients before these products are distributed commercially, and have provided FDA with the information necessary to address any potential questions regarding the safety, labeling, or regulatory status of the food or food ingredient. As such, these consultations have provided assistance to both industry and the Agency in exercising their mutual responsibilities under the FD&C Act.

FDA estimates that CVM and CFSAN jointly received an average of 40 initial consultations per year in the last 3 years via telephone, email, or written letter. Based on this information, we expect to receive no more than 40 annually in the next 3 years.

Final Consultations

Final consultations are a one-time burden. At some stage in the process of research and development, a developer will have accumulated the information that the developer believes is adequate to ensure that food derived from the new plant variety is safe and that it demonstrates compliance with the relevant provisions of the FD&C Act. The developer will then be in a position to conclude any ongoing consultation with FDA. The developer submits to FDA a summary of the safety and nutritional assessment that has been conducted about the bioengineered food that is intended to be introduced into commercial distribution. FDA evaluates the submission to ensure that all potential safety and regulatory questions have been addressed. FDA has developed a form that prompts a developer to include certain elements in the final consultation in a standard format: Form FDA 3665 entitled, ''Final Consultation for Food Derived From a New Plant Variety (Biotechnology Final Consultation).'' The form, and elements that would be prepared as attachments to the form, can be submitted in electronic format.

We base our estimate of the average time to prepare a submission on informal contact with firms that made one or more biotechnology consultation submission under the voluntary biotechnology consultation process. As such, we estimate the average time to prepare a submission for final consultation to be 150 hours.

Dated: March 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06069 Filed 3–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0965]

Request for Nominations for Voting Members on a Public Advisory Committee; Pharmacy Compounding Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Pharmacy Compounding Advisory Committee (Committee), Division of Advisory Committee Consultant Management, Center for Drug Evaluation and Research. The Committee provides advice on scientific, technical, and medical issues concerning human drug compounding under the Federal Food, Drug, and Cosmetic Act (FD&C Act), and, as required, any other product for which FDA has regulatory responsibility, and makes appropriate recommendations to the Commissioner of Food and Drugs.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before May 29, 2018, will be given first consideration for membership on the Pharmacy Compounding Advisory Committee. Nominations received after May 29, 2018, will be considered for nominations to the Committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: *Regarding all nomination questions for membership, the primary contact is:* Cindy Chee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002; 301–796–9001, Fax: 301–847–8533, email: *PCAC@fda.hhs.gov.*

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website by using the following link: *https://www.fda.gov/AdvisoryCommittees/default.htm.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members on the Pharmacy Compounding Advisory Committee.