

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

| Activity                   | FDA Form No. | No. of respondents | No. 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       |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

We have retained the currently approved burden estimate for this information collection and discuss the information collection activities 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 its Center for Veterinary Medicine and its Center for Food Safety and Applied Nutrition 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: December 5, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-26794 Filed 12-12-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0345]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Data To Support Drug Product Communications as Used by the Food and Drug Administration

**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 January 12, 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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0695. 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, 301-796-7729, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

**Data To Support Drug Product Communications as Used by the Food and Drug Administration**

*OMB Control Number 0910–0695—Extension*

This information collection supports Agency outreach efforts. Testing of communication messages in advance of a communication campaign provides an important role in improving FDA communications as they allow for an in-depth understanding of individuals’ attitudes, beliefs, motivations, and feelings. The methods to be employed include individual in-depth interviews, general public focus group interviews, intercept interviews, self-administered surveys, gatekeeper surveys, and professional clinician focus group interviews, all on a voluntary basis. The methods to be used serve the narrowly defined need for direct and informal opinion on a specific topic and, as a qualitative research tool, have two major purposes: To obtain information that is useful for developing variables and measures for formulating the basic objectives of risk communication campaigns, and to assess the potential effectiveness of messages and materials in reaching and successfully

communicating with their intended audiences.

FDA will use these methods to test and refine its ideas and to help develop messages and other communications but will generally conduct further research before making important decisions, such as adopting new policies and allocating or redirecting significant resources to support these policies. FDA will use this mechanism to test messages about regulated drug products on a variety of subjects related to consumer, patient, or health care professional perceptions and about use of drug products and related materials, including but not limited to, direct-to-consumer prescription drug promotion, physician labeling of prescription drugs, medication guides, over-the-counter drug labeling, emerging risk communications, patient labeling, online sale of medical products, and consumer and professional education. Annually, FDA projects about 45 communication studies using the variety of test methods listed in this document. FDA is requesting an extension of these burden hours so as not to restrict the Agency’s ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

In the **Federal Register** of June 19, 2017 (82 FR 27840), we published a 60-

day notice requesting public comment on the proposed extension of the collection of information. One comment was received requesting that FDA publish an annual list of its planned drug product communication studies and strive to reflect an overall work plan. The comment also noted the rather broad topic areas included in the information collection and suggested that perhaps additional notice regarding individual studies would allow for more meaningful feedback on whether that particular study would be necessary. FDA appreciates this comment. In determining which drug product communications it will undertake, we first consider those we believe will best address current or immediate public health issues. We also note that, in accordance with the PRA, any proposed study under this information collection request must first be submitted to and approved by OMB to determine whether it falls within the scope of the collection. At the same time, as resources are available, we will make every effort to communicate to our stakeholders anticipated studies so that ongoing or related research can be coordinated.

We therefore estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

| Activity                 | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response (in hours) | Total hours |
|--------------------------|-----------------------|------------------------------------|------------------------|----------------------------------------|-------------|
| Interviews/Surveys ..... | 19,822                | 1                                  | 19,822                 | 0.24 (14 minutes) ....                 | 4,757       |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 5, 2017.  
**Leslie Kux,**  
*Associate Commissioner for Policy.*  
[FR Doc. 2017–26795 Filed 12–12–17; 8:45 am]  
**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Allergy and Infectious Diseases; 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 of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01).  
*Date:* January 17, 2018.  
*Time:* 11:00 a.m. to 4:00 p.m.  
*Agenda:* To review and evaluate grant applications.  
*Place:* National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).  
*Contact Person:* Eleazar Cohen, Ph.D., Scientific Review Officer, Scientific Review

Program, Division of Extramural Activities, Room 3G62A, National Institute of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20899–823, (240) 669–5081, [ecohen@niaid.nih.gov](mailto:ecohen@niaid.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 6, 2017.  
**Natasha M. Copeland,**  
*Program Analyst, Office of Federal Advisory Committee Policy.*  
[FR Doc. 2017–26799 Filed 12–12–17; 8:45 am]  
**BILLING CODE 4140–01–P**