

Mandell/IC 9000–0068, Economic Price Adjustment.

*Instructions:* Please submit comments only and cite Information Collection 9000–0068, Economic Price Adjustment, in all correspondence related to this collection. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check [www.regulations.gov](http://www.regulations.gov), approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

**FOR FURTHER INFORMATION CONTACT:** Mr. Michael O. Jackson, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA, 202–208–4949 or email [michaelo.jackson@gsa.gov](mailto:michaelo.jackson@gsa.gov).

**SUPPLEMENTARY INFORMATION:**

**A. Solicitation of Public Comment**

Written comments and suggestions from the public should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

**B. Purpose**

The FAR clause 16.203, Fixed-price contracts with economic price adjustment, and associated clauses at 52.216–2, 52.216–3, and 52.216–4, provide for upward and downward revision of the stated contract price upon occurrence of specified contingencies. In order for the contracting officer to be aware of price changes, the firm must provide pertinent information to the Government. The information is used to determine the proper amount of price adjustments required under the contract.

**C. Annual Reporting Burden**

*Respondents:* 3,550.

*Responses per Respondent:* 214.

*Annual Responses:* 759,700.

*Hours per Response:* 1.5.

*Total Burden Hours:* 1,139,550.

*Obtaining Copies of Proposals:*

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0068, Economic Price Adjustment, in all correspondence.

Dated: April 11, 2019.

**Janet Fry,**

*Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.*

[FR Doc. 2019–07646 Filed 4–16–19; 8:45 am]

**BILLING CODE 6820–EP–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2010–N–0414]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Manufactured Food Regulatory Program Standards**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the manufactured food regulatory program standards.

**DATES:** Submit either electronic or written comments on the collection of information by June 17, 2019.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 17, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time

at the end of June 17, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA–2010–N–0414 for “Manufactured Food Regulatory Program Standards.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food

and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

**Manufactured Food Regulatory Program Standards OMB Control Number 0910–0601—Extension**

In the **Federal Register** of July 20, 2006 (71 FR 41221), FDA announced the availability of a document entitled “Manufactured Food Regulatory Program Standards.” These program standards are the framework that States should use to design and manage their manufactured food programs. There are 43 State programs enrolled, which receive an average of \$230,000 (maximum of \$300,000) each year for a period of 5 years from the year they first enroll, provided there is significant conformance with and/or maintenance of the 10 standards.

In the first year of implementing the program standards, the State program conducts a baseline self-assessment to determine if it meets the elements of each standard. FDA suggests that the State program use the worksheets and forms contained in the draft program standards; however, it can use alternate forms that are equivalent. The State program maintains the documents and verifies records required for each standard. The information contained in the documents must be current and fit for use. If the State program fails to meet all program elements and documentation requirements of a standard, it develops a strategic plan which includes the following: (1) The individual element of documentation requirement of the standard that was not met, (2) improvements needed to meet the program element or documentation requirement of the standard, and (3) projected completion dates for each task.

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

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

Respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
State Departments of Agriculture or Health .....	43	1	43	569	24,467

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State Departments of Agriculture or Health .....	43	10	430	40	17,200

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

One additional State has enrolled in the program since 2016. The total estimated burden of this collection has increased to 41,667 hours among 43 respondents, from a previous total of 15,792 hours among 42 respondents. This increase is due to a change in the self-reported response times provided by the respondents. Because this is a long-term program, we believe this change is the result of more precise documentation by participating agencies as they have grown more experienced over time.

Dated: April 12, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-07706 Filed 4-16-19; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-3758]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Individual Patient Expanded Access Applications

**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 May 17, 2019.

**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](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0814. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, [PRAStaff@fda.hhs.gov](mailto: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 Industry on Individual Patient Expanded Access Applications: Form FDA 3926

*OMB Control Number 0910-0814—Extension*

This information collection supports Agency regulations, associated guidance, and Form FDA 3926 concerning individual patient expanded access. Individual patient expanded access allows an individual patient who has a serious or immediately life-threatening disease or condition and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition, the use of an investigational new drug (IND) outside of a clinical investigation, or the use of an approved drug where availability is limited by a risk evaluation and mitigation strategy. When applicable criteria in § 312.305(a) (21 CFR 312.305(a)) (which apply to all types of expanded access) and the criteria in § 312.310(a) (21 CFR 312.310(a)) (which apply specifically to individual patient expanded access, including for emergency use) are met, FDA may permit expanded access.

Section 312.305(b) sets forth the submission requirements for all types of expanded access requests. To assist respondents with requirements in § 312.305, we developed Form FDA 3926 (Individual Patient Expanded Access Investigational New Drug Application) and the guidance document entitled, “Individual Patient Expanded Access Applications: Form FDA 3926,” which are available at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> and <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm432717.pdf>, respectively.

The physician may satisfy some of the submission requirements by referring to information in an existing IND, ordinarily the one held by the investigational drug’s manufacturer, if the physician obtains permission from that IND holder. If permission is obtained, the physician should then provide to FDA a letter of authorization (LOA) from the existing IND holder that permits FDA to reference that IND.

One of the requirements under § 312.305(b)(2) is that a “cover sheet” must be included “meeting the requirements of § 312.23(a).” This provision applies to several types of

submissions under part 312 (21 CFR part 312), ranging from commercial INDs under § 312.23 that involve large groups of patients enrolled in clinical trials to requests from physicians to use an investigational drug for an individual patient. Sponsors currently use Form FDA 1571 for all types of IND submissions to meet the requirements in § 312.23(a).

Concerned that physicians requesting expanded access for an individual patient may encounter difficulty in completing Form FDA 1571 and the associated documents because the form is not tailored to requests for individual patient expanded access, we developed Form FDA 3926 to comply with the IND submission requirements in §§ 312.23, 312.305(b), and 312.310(b). Form FDA 3926 provides a streamlined means to request expanded access and is available for licensed physicians. FDA considers a completed Form FDA 3926 with the box in Field 10 checked and the form signed by the physician to be a request in accordance with § 312.10 for a waiver of any additional requirements in part 312 for an IND submission, including additional information currently provided in Form FDA 1571 and Form FDA 1572 (Statement of Investigator, which provides the identity and qualifications of the investigator conducting the clinical investigation).

Under § 312.310(d), in an emergency situation that requires the patient to be treated before a written submission can be made, the request to use the investigational drug for individual patient expanded access may be made by telephone (or other rapid means of communication) to the appropriate FDA review division. Authorization of the emergency use may be given by an FDA official over the telephone, provided the physician explains how the expanded access use will meet the requirements of §§ 312.305 and 312.310 and agrees to submit an expanded access application within 15 working days of FDA’s initial authorization of the expanded access use (§ 312.310(d)). The physician may choose to use Form FDA 3926 for the expanded access application.

As explained in the instructions for Form FDA 3926 and discussed in the guidance document, the following information is submitted to FDA:

- Initials for the patient and date of submission.
- Type of submission (initial or followup submission).
- Clinical information, including indication, brief clinical history of the patient (age, gender, weight, allergies, diagnosis, prior therapy, response to prior therapy), and the reason for