

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Guidance title: Custom device exemption	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Section VI. Annual Reporting	33	1	33	40	1,320

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

FDA estimates it will receive 33 reports for custom devices annually. The Agency reached this estimate by the number of pre-FDASIA manufacturers who qualified for custom devices and that percentage of current manufactures that qualify under post-FDASIA requirements. Only 10 percent of manufacturers would meet this qualification, which was calculated by adding the number of estimated old custom device manufactures with the estimated new manufacturers submitting annual reports of custom devices each year. FDA estimates it will take custom device manufacturers approximately 40 hours to complete the annual report described in section VI of the draft guidance. FDA reached this time estimate based on its expectation of the amount of information that should be included in the report.

Before the proposed information collection provisions contained in this draft guidance become effective, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it display a currently valid OMB control number.

This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). The collections of information in 21 CFR 814, subparts B and E have been approved under OMB control number 0910–0231; the collections of information in 21 part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 part 807, subpart E have been approved under OMB control number 0910–0120.

V. 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>.

Dated: January 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1622]

Draft Guidance for Industry: Submitting Food Canning Establishment Registration Form and Food Process Filing Forms to the Food and Drug Administration in Electronic or Paper Format; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance entitled “Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format.” The draft guidance is intended to alert stakeholders to changes we are planning for the administrative procedures currently used by commercial processors that manufacture, process, or pack acidified foods (AF) and/or thermally processed low-acid foods packaged in hermetically sealed containers (historically referred to as “low-acid canned foods” or “LACF”). These changes include new food process filing forms and a new “smart form” system for electronic submission of these forms. The draft guidance, when finalized, will supersede the July 2012 guidance entitled “Guidance for

Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541a and FDA 2541c (Food Process Filing Forms) to FDA in Electronic or Paper Format” when the new food process filing forms and the new “smart form” electronic system become operational.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the Agency considers your comments on the draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by March 17, 2014.

ADDRESSES: Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–302), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Susan Brecher, Center for Food Safety and Applied Nutrition (HFS–302), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1781.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled “Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format.” The draft guidance is intended to alert stakeholders to changes we are planning for the administrative procedures currently used by commercial processors that manufacture, process, or pack AF and/or LACF. These changes

include new food process filing forms and a new “smart form” system for electronic submission of these forms. The draft guidance, when finalized, will supersede the current guidance entitled “Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541a and FDA 2541c (Food Process Filing Forms) to FDA in Electronic or Paper Format” (Ref. 1) when the new food process filing forms and the new “smart form” electronic system become operational. We intend to update the process filing regulations in 21 CFR 108.25(c)(2) and 108.35(c)(2) to specify the new form numbers, and to provide information about how to access the online system for electronic submission of these forms, when the new system becomes operational, or as soon as possible thereafter.

The draft guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 publish notice in the **Federal Register** soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we published a 60-day notice on the proposed collection of information in the **Federal Register** of September 18, 2013 (78 FR 57391).

III. Comments

Interested persons may submit either electronic comments regarding the draft guidance 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 draft guidance at either <http://www.fda.gov/FoodGuidances> or at <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the draft guidance.

V. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>. (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA, 2012, Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541a and FDA 2541c (Food Process Filing Forms) to FDA in Electronic or Paper Format.

Dated: January 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1430]

Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics.” This draft

guidance responds to stakeholder requests for specific guidance on FDA’s current views on how manufacturers, packers, and distributors (firms), that may either be the applicant or acting on behalf of the applicant, of prescription human and animal drug and biological products (drugs) can fulfill regulatory requirements for postmarketing submissions of interactive promotional media for their FDA-approved products. This draft guidance clarifies FDA’s policies on what the Agency considers to be interactive promotional media.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 14, 2014. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; or to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding human prescription drugs: Barbara Chong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993, 301–796–1200.

Regarding prescription human biological products: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.