

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

Activity/21 CFR section	No. of recordkeepers	No. of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Record retention, § 801.150(a)(2) .....	90	20	1,800	0.5 *	900

\* (30 minutes)

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

Dated: April 1, 2013.

**Peter Lurie,**

*Acting Associate Commissioner for Policy and Planning.*

[FR Doc. 2013-07916 Filed 4-4-13; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0370]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Export of Medical Devices; Foreign Letters of Approval**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 reporting requirements for firms that intend to export certain unapproved medical devices.

**DATES:** Submit either electronic or written comments on the collection of information by June 4, 2013.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm.

1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [daniel.gittleson@fda.hhs.gov](mailto:daniel.gittleson@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.

**Export of Medical Devices; Foreign Letters of Approval—(OMB Control Number 0910-0264)—Extension**

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export. Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or agency of the United States. The respondents to this collection of information are companies that seek to export medical devices. FDA's estimate of the reporting burden is based on the experience of FDA's medical device program personnel.

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

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

Activity/section of FD&C Act	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating & maintenance costs
Foreign letter of approval—§ 801(e)(2) ....	38	1	38	3	114	\$9,500

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

Dated: April 1, 2013.  
**Peter Lurie**,  
*Acting Associate Commissioner for Policy and Planning.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2012-N-1093]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Additive Petitions and Investigational Food Additive Exemptions**

**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 6, 2013.

**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 0910-0546. Also include the FDA docket number found

in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, *Jonnalynn.capezzuto@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.

**Food Additive Petitions and Investigational Food Additive Exemptions—(OMB Control Number 0910-0546)—Extension**

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation which prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) of the FD&C Act specifies the information that must be submitted by a petitioner in order to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provisions of section 409 of the FD&C Act, procedural regulations have been issued under part 571 (21 CFR part 571). These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the FD&C Act. The regulations add no substantive requirements to those indicated in the FD&C Act, but attempt to explain these requirements and provide a standard format for submission to speed

processing of the petition. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in parts 501, 573, and 579 (21 CFR parts 501, 573, and 579). The labeling regulations are considered by FDA to be cross-referenced to § 571.1, which is the subject of this same OMB clearance for food additive petitions.

With regard to the investigational use of food additives, section 409(j) of the FD&C Act provides that any food additive or any food bearing or containing such an additive, may be exempted from the requirements of this section if intended solely for investigational use by qualified experts. Investigational use of a food additive is typically to address the safety and/or intended physical or technical effect of the additive.

To implement the provisions of section 409(j) of the FD&C Act, regulations have been issued under § 570.17 (21 CFR 570.17). These regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broad terms by the FD&C Act. Labeling requirements for investigational food additives are also set forth in various regulations contained in part 501. The labeling regulations are considered by FDA to be cross-referenced to § 570.17; which is the subject of this same OMB clearance for investigational food additive files. In the **Federal Register** of November 13, 2012, (75 FR 67655), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

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

21 CFR Section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
<b>Food Additive Petitions</b>					
571.1(c) moderate category .....	1	1	1	3,000	3,000
517.1(c) complex category .....	1	1	1	10,000	10,000
517.1(c) complex category .....	2	2	4	1,300	5,200