DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0021]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Generally Recognized as Safe: Notification Procedure

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 March 21, 2016.

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 0910–0495. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Substances Generally Recognized as Safe: Notification Procedure—21 CFR 170.36 and 570.36 (OMB Control Number 0910–0342)—Extension

Section 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348) establishes a premarket approval requirement for ''food additives''; section 201(s) of the FD&C Act (21 U.S.C. 321(s)) provides an exclusion to the definition of ''food additive'' and thus from the premarket approval requirement, for uses of substances that are generally recognized as safe (GRAS) by qualified experts. In the **Federal Register** of April 17, 1997 (62 FR 18938) (the 1997 proposed rule), we published a proposed rule that would establish a voluntary procedure whereby manufacturers would notify us about a view of a particular use (or uses) of a substance that is not subject to the statutory premarket approval requirements based on a determination that such use is GRAS. Under an interim policy announced in the proposed rule, we invited manufacturers to submit notices of their independent determinations for review under the framework of the proposed rule during the period between issuance of the proposal and any final rule based on the proposal. The proposed regulations (proposed 21 CFR 170.36 and 21 CFR 570.36) provide a standard format for the voluntary submission of a notice.

To assist respondents in submissions to our Center for Food Safety and Applied Nutrition (CFSAN), we developed Form FDA 3667 entitled ''Generally Recognized as Safe (GRAS) Notice.'' The form, and elements prepared as attachments to the form, may be submitted in electronic format via the Electronic Submission Gateway (ESG), or may be submitted in paper format, or as electronic files on physical media with paper signature page. While we do not expect Form FDA 3667 to reduce reporting time for respondents, use of the form helps to expedite our review of the information being submitted. For submissions to our Center for Veterinary Medicine (CVM), respondents may continue to send GRAS notices in letter format to the Agency, as instructed in our **Federal Register** notice of June 4, 2010 (75 FR 31800).

Presently, we have committed to issuing a final rule regarding ''Substances Generally Recognized as Safe'' in 2016, as part of a settlement agreement with the Center for Food Safety, which filed a lawsuit in 2014 seeking to vacate our 1997 proposed rule.

Description of Respondents: The respondents to this collection of information are manufacturers of substances used in food and feed.

In the **Federal Register** of September 17, 2015 (80 FR 55857), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received a number of comments in support of the information collection generally. We also received one comment suggesting that the names, credentials, and affiliations of ''qualified experts'' associated with GRAS determinations be included on the form. We received a second comment suggesting that information submitted by manufacturers be reviewed by independent scientists. We appreciate this input. As discussed previously, rulemaking is underway that will necessitate a revision to the information collection provisions associated with our GRAS program and we continue to consider all comments.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Form No.[2]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
170.36 (CFSAN)	3667 [3]	40	1	40	150	6,000
570.36 (CVM)	N/A	20	1	20	150	3,000
Total						9,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Only CFSAN uses Form FDA 3667.
[3] Form FDA 3667 may be submitted electronically via the ESG.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
170.36(c)(v) (CFSAN)	40	1	40	15	600
570.36(c)(v) (CVM)	20	1	20	15	300
Total					900

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

For purposes of this extension request, we are retaining our 2012 estimates. The PRA analysis for the GRAS final rule will take into account any changes to the GRAS notification procedure as set forth in the final rule and we will revise the collection accordingly.

Dated: February 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Request for Nominations on Public Advisory Panels of the Medical Devices Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on certain panels of the Medical Devices Advisory Committee (MDAC) in the Center for Devices and Radiological Health (CDRH) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on certain device Panels of the MDAC in the CDRH. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current and upcoming vacancies effective with this notice. 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: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by March 21, 2016, (see sections I and II for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by March 21, 2016.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership 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. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5215, Silver Spring, MD 20993, 301–796–5960, Fax: 301–847–8505, *margaret.ames@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency is requesting nominations for nonvoting industry representatives to certain panels identified in the following paragraphs:

I. Medical Devices Advisory Committee

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner of Food and Drugs regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of Food and Drugs on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices. The Committee also provides recommendations to the Commissioner or designee on complexity categorization of in vitro diagnostics under the Clinical Laboratory Improvement Amendments of 1988.

A. Anesthesiology and Respiratory Therapy Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in anesthesiology and respiratory therapy and makes appropriate recommendations to the Commissioner of Food and Drugs.

B. Ear, Nose and Throat Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational ear, nose and throat devices and makes appropriate recommendations to the Commissioner of Food and Drugs.