

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
200	30	6,000	.5	3,000

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

FDA projects 30 emergency risk related surveys per year with a sample of between 50 and 200 respondents per survey. FDA also projects a response time of 0.5 hours per response. These estimates are based on the maximum sample size per questionnaire that FDA can analyze in a timely manner. The annual frequency of response was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only one time per year, while other respondents may be contacted several times annually, depending on the human drug, biologic, or medical device under evaluation. It is estimated that, given the expected type of issues that will be addressed by the surveys, it will take 0.5 hours for a respondent to gather the requested information and fill in the answers.

Dated: March 15, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0527]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles

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 April 23, 2007.

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: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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.

Threshold of Regulation for Substances Used in Food-Contact Articles (OMB Control Number 0910-0298)—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless one of the following is applicable: (1) It conforms to an exemption for investigational use under section 409(j) of the act, (2) it conforms to the terms of a regulation prescribing its use, or (3) in the case of a food additive which meets the definition of a food-contact substance in section 409(h)(6) of the act, there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B).

The regulations in § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing

regulation or an effective notification. The agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion (ppb). The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical composition of the substance for which the request is made, (2) detailed information on the conditions of use of the substance, (3) a clear statement of the basis for the request for exemption from regulation as a food additive, (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance, (5) results of a literature search for toxicological data on the substance and its impurities, and (6) information on the environmental impact that would result from the proposed use.

FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves.

In the **Federal Register** of January 8, 2007 (72 FR 792), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

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21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.39	15	1	15	48	720

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

In compiling these estimates, FDA consulted its records of the number of regulation exemption requests received in the past 3 years. The annual hours per response reporting estimate is based on information received from representatives of the food packaging and processing industries and agency records.

FDA estimates that approximately 15 requests per year will be submitted under the threshold of regulation exemption process of § 170.39. The threshold of regulation process offers one advantage over the premarket notification process for food-contact substances established by section 409(h) of the act (OMB control number 0910–0495) in that the use of a substance exempted by the agency is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food-contact articles as long as the conditions of use (e.g., use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both the agency and the regulated industry would be significantly less in that other manufacturers and suppliers would not have to prepare, and FDA would not have to review, similar submissions for identical components of food-contact articles used under identical conditions. Manufacturers and other interested persons can easily access an up-to-date list of exempted substances which is on

display at FDA’s Division of Dockets Management and on the Web site at <http://www.cfsan.fda.gov>. Having the list of exempted substances publicly available decreases the likelihood that a company would submit a food additive petition or a notification for the same type of food-contact application of a substance for which the agency has previously granted an exemption from the food additive listing regulation requirement.

Dated: March 15, 2007.
Jeffrey Shuren,
Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting Members on Public Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Allergenic Products Advisory Committee, Blood Products Advisory Committee, Cellular, Tissue and Gene Therapies Advisory Committee, Transmissible Spongiform Encephalopathies Advisory Committee,

and the Vaccines and Related Biological Products Advisory Committee in the Center for Biologics Evaluation and Research (CBER). Nominations will be accepted for vacancies that will or may occur through January 31, 2008.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees, and therefore, encourages nominations of qualified candidates from these groups.

DATES: Because scheduled vacancies occur on various dates throughout each year, no cutoff date is established for the receipt of nominations. However, when possible, nominations should be received 6 months before the date of scheduled vacancies for each year, as indicated in this notice.

ADDRESSES: All nominations and curricula vitae should be sent to the contact person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

FOR FURTHER INFORMATION CONTACT: Donald Jehn, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0314, e-mail: donald.jehn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations of voting members with appropriate expertise for vacancies listed below:

TABLE 1.

Advisory Committee and Expertise Needed to Fill Vacancies	No. of Vacancies	Approximate Date Members are Needed
Allergenic Products Advisory Committee—allergy, immunology, pediatrics, internal medicine, biochemistry, statistics, and related scientific fields	2 2	As soon as possible August 31, 2007
Blood Products Advisory Committee—clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, statistics, biological and physical sciences, biotechnology, computer technology, epidemiology, consumer advocacy, sociology/ethics, clinical trials, behavioral science, risk communication and other related professions	2	September 30, 2007