

TABLE 1. —ESTIMATED ANNUAL REPORTING BURDEN¹

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.
 [FR Doc. E7–5196 Filed 3–21–07; 8:45 am]
BILLING CODE 4160–01–S

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	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

TABLE 1.—Continued

Advisory Committee and Expertise Needed to Fill Vacancies	No. of Vacancies	Approximate Date Members are Needed
Cellular, Tissue, and Gene Therapies Advisory Committee—cellular therapies, tissue transplantation, gene transfer therapies and xenotransplantation including biostatistics, bioethics, hematology/oncology, human tissues and transplantation, reproductive medicine, general medicine and various medical specialties including surgery and oncology, immunology, virology, molecular biology, cell biology, developmental biology, tumor biology, biochemistry, rDNA technology, nuclear medicine, gene therapy, infectious diseases, and cellular kinetics	1	March 31, 2007
Transmissible Spongiform Encephalopathies Advisory Committee—clinical and administrative medicine, hematology, virology, neurovirology, neurology, infectious diseases, immunology, transfusion medicine, surgery, internal medicine, biochemistry, biostatistics, epidemiology, biological and physical sciences, consumer advocacy, sociology/ethics, and other related professions	4 3	As soon as possible January 31, 2008
Vaccines and Related Biological Products Advisory Committee—immunology, molecular biology, rDNA, virology, bacteriology, epidemiology, biostatistics, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, biochemistry, and other related scientific fields	3 5	As soon as possible January 31, 2008

I. Functions

A. Allergenic Products Advisory Committee

The committee reviews and evaluates available data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or treatment of allergies and allergic diseases.

B. Blood Products Advisory Committee

The committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood and products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases.

C. Cellular, Tissue and Gene Therapies Advisory Committee

The committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies and xenotransplantation products which are intended for transplantation, implantation, infusion and transfer in the prevention and treatment of a broad spectrum of human diseases and in reconstruction, repair, or replacement of tissues for various conditions.

D. Transmissible Spongiform Encephalopathies Advisory Committee

The committee reviews and evaluates available scientific data concerning the safety of products which may be at risk for transmission of spongiform encephalopathies having an impact on the public health.

E. Vaccines and Related Biological Products Advisory Committee

The committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases.

II. Qualifications

Persons nominated for membership on the committees shall have adequately diversified experience appropriate to the work of the committee in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the committee. The particular need for vacancies on each committee through January 31, 2008, is shown in Table 1 of this document. The term of office is up to 4 years, depending on the appointment date.

III. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory committees. Self-nominations are also accepted. Nominations shall include the name of the committee, a complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member (name of committee(s) must be specified), and appears to have no conflict of interest that would preclude membership. FDA

will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: March 14, 2007.

Randall W. Lutter,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pulmonary-Allergy Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 1, 2007, from 8 a.m. to 5:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.