

CDC expects to publish final Guidelines in 2005.

Dated: November 24, 2004.

James D. Seligman,

*Associate Director for Program Services,
Centers for Disease Control and Prevention
(CDC).*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0395]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Application for Participation in the Medical Device Fellowship Program

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 January 5, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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.

Application for Participation in the Medical Device Fellowship Program—(OMB Control Number 0910-0551)—Extension

Collecting applications for the Medical Device Fellowship Plan will allow FDA's Center for Devices and Radiological Health (CDRH) to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in CDRH activities. The process will reduce the time and cost of submitting written documentation to the agency and lessen the likelihood of applications being misrouted within the agency mail system. It will assist the agency in promoting and protecting the public health by encouraging outside persons to share their expertise with CDRH.

In the **Federal Register** of September 20, 2004 (69 FR 56228), 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:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA Form 3608	100	1	100	1	100

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

FDA based these estimates on the number of inquiries that have been received about the program and requests for application forms over the past year. We anticipate the number of interested individuals and universities, and subsequent number of applications, to increase as we continue to develop an outreach program and an alumni base.

In addition, we would expect applicants who are not selected for their preferred term of employment to reapply at a later date. For these reasons we would expect that the number of applications submitted in the second and third years would increase substantially. During the first year, we expect to receive 100 applications. We believe that we will receive approximately 100 applications the second year and 100 applications the third year. FDA believes it will take individuals 1 hour to complete the application. This is based on similar applications submitted to FDA.

Dated: November 26, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-26672 Filed 12-3-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for a Nonvoting Member Representing Industry Interests on a Public Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) requests nominations for a nonvoting industry representative to serve on the Cellular Tissue and Gene Therapies Advisory Committee (formerly the Biological Response Modifiers Advisory Committee) under the purview of the

Center for Biologics Evaluation and Research (CBER).

DATES: Industry organizations interested in participating in the selection of a nonvoting member to represent industry for the vacancy listed in this notice must send a letter to FDA by January 5, 2005.

Concurrently, nomination materials for prospective candidates should be sent to FDA by January 5, 2005. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative.

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

FOR FURTHER INFORMATION CONTACT: Gail Dapolito, Division of Scientific Advisors and Consultants (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20857-1448, 301-827-0314, e-mail: dapolito@cber.fda.gov.

SUPPLEMENTARY INFORMATION: The agency requests nominations for a nonvoting industry representative to the advisory committee identified below.

I. Function

The Cellular, Tissue and Gene Therapies Advisory Committee (formerly the Biological Response Modifiers Advisory 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 the reconstruction, repair or replacement of tissues for various conditions. The committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

II. Selection Procedure

Any organization in the biologics manufacturing industry wishing to participate in the selection of a nonvoting member to represent industry on the Cellular, Tissue and Gene Therapies Advisory Committee (formerly the Biological Response Modifiers Advisory Committee) should send a letter stating that interest to FDA contact identified above within 30 days of publication of this notice. Persons who nominate themselves as an industry representative for the advisory committee will not participate in the selection process. It is, therefore, recommended that nominations be made by someone within an organization, trade association, or firm who is willing to participate in the selection process. Within the subsequent 30 days, FDA will send a letter to each organization and a list of all nominees along with their resumes. The letter will state that the interested organizations are responsible for conferring with one another to select a candidate, within 60 days after receiving the letter, to serve as the nonvoting member representing industry interests on the advisory committee. If no individual is selected within the 60 days, the Commissioner of Food and Drugs may select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may nominate themselves or an organization representing the

biologics manufacturing industry may nominate one or more individuals to serve as nonvoting industry representatives. A current curriculum vitae (which includes the nominee's business address, telephone number, and e-mail address) and the name of the committee of interest should be sent to FDA contact person. FDA will forward all nominations to the organizations that have expressed interest in participating in the selection process for that committee.

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees. Therefore, the agency encourages nominations for appropriately qualified candidates from these groups.

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: November 29, 2004.

Sheila Dearybury Walcott,

Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Recruitment of Clinicians To Become Commissioned Officers; Recruitment of Sites for Assignment of Commissioned Officers

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: General notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that applications will be accepted from clinicians seeking to be hired as commissioned officers in the U.S. Public Health Service and from sites seeking the assistance of these commissioned officers. These commissioned officers will be primary care clinicians who are physicians, dentists, family nurse practitioners, physician assistants, clinical psychologists, clinical social workers and registered nurses (baccalaureate level) and will be considered for placement in ambulatory community-based systems of care. These officers will be assigned by the National Health Service Corps (NHSC) Ready Responder Program to the neediest Health Professional Shortage Areas throughout

the Nation. The NHSC will pay the salaries, moving expenses and benefits for these commissioned officers.

These officers will be part of a mobile cadre of health care professionals who, in addition to the services they will provide to patients at their assigned sites, may be called upon to respond to regional and/or national emergencies. The NHSC will assist the officers in acquiring, maintaining and enhancing emergency response skills. Their initial assignments will be up to three years in duration, after which, should these clinicians choose to stay in the U.S. Public Health Service, they will progress to new assignments.

Eligible Applicants

Clinicians—Applicants must file a U.S. Public Health Service Commissioned Corps application and meet the requirements for such commissioning. For example, all clinicians must be U.S. citizens under 44 years of age (age may be offset by prior active duty Uniformed Service time and/or civil service work experience in a Public Health Service (PHS) agency at a PHS site at a level commensurate with the duties of a commissioned officer), and have served less than 8 years of active duty if the clinician is/was a member of another Uniformed Service. Also, applicants must meet medical requirements, and pass an initial suitability investigation.

In addition, prior to the start of their assignment at an NHSC site, these clinicians must meet the following requirements:

(1) Physicians must have completed a residency in Family Practice, Internal Medicine, combined Internal Medicine and Pediatrics, General Psychiatry or Obstetrics and Gynecology and be a diplomate of their respective Allopathic or Osteopathic Specialty Boards;

(2) Family Nurse Practitioners must have national certification by the American Nurses Credentialing Center or the American Academy of Nurse Practitioners;

(3) Physician Assistants must have national certification by the National Commission on Certification of Physician Assistants;

(4) Clinical Psychologists must have a doctoral degree in clinical psychology, have a minimum of 1 year of postgraduate supervised clinical experience, have passed the Examination for Professional Practice in Psychology, and be able to practice independently and unsupervised as a clinical psychologist;

(5) Clinical Social Workers must have a masters degree in social work, have passed the Association of Social Work