

70 percent of the PMAs are eventually approved with 75 percent of these having original clinical trial data. Therefore, approximately 34 PMAs a year (48 annual submissions x 70 percent), would be subject to these requirements. Also, because the requirements apply to all active PMAs, all holders of an active PMA application must maintain these records.

PMAs have been required since 1976, and there are 1,128 active PMAs that could be subject to these requirements, based on actual FDA data. Each study has approximately 200 subjects, and at an average of 5 minutes per subject, there is a total burden per study of 1,000 minutes, or 17 hours. The aggregate burden for all 1,128 holders of approved original PMAs, therefore, is 19,176 hours (1,127 approved PMAs with clinical data x 17 hours per PMA).

The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the current good manufacturing practices for medical devices regulation (part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions of approval to ensure the device's continuing safety and effectiveness.

Dated: June 21, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Request for Notification From Industry Organizations Interested in Participating in the Selection Process for a Nonvoting Industry Representative on the Allergenic Products Advisory Committee and Request for Nominations for a Nonvoting Industry Representative on the Allergenic Products 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 a nonvoting industry representative to serve on its Allergenic Products Advisory Committee for the Center for

Biologics Evaluation and Research (CBER) notify FDA in writing. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nomination will be accepted for current vacancies effective with this notice.

**DATES:** Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating the interest to FDA by July 30, 2007, for vacancies listed in the notice. Concurrently, nomination material for prospective candidates should be sent to FDA by July 30, 2007.

**ADDRESSES:** All letters of interest and nominations should be submitted in writing to Gail Dapolito (see **FOR FURTHER INFORMATION CONTACT**).

**FOR FURTHER INFORMATION CONTACT:** Gail Dapolito, Center for Biologics Evaluation and Research, Food and Drug Administration (HFM-71), 1401 Rockville Pike, Rockville, MD 20892, 301-827-1289, [gail.dapolito@fda.hhs.gov](mailto:gail.dapolito@fda.hhs.gov)

**SUPPLEMENTARY INFORMATION:** Section 120 of the FDA Modernization Act of 1997 (FDAMA) (21 U.S.C. 355) requires that newly formed FDA advisory committees include representatives from the biologic manufacturing industries. Although not required for existing committees, to keep within the spirit of FDAMA, the agency intends to add nonvoting industry representatives to its CBER advisory committee identified below.

#### I. CBER 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 disease, and makes appropriate recommendations to the Commissioner of Food and Drugs of its findings regarding the affirmation or revocation of biological product licenses, on the safety, effectiveness, and labeling of the products, on clinical and laboratory studies of such products, on amendments or revisions to regulations governing the manufacture, testing and licensing of allergenic biological products, and on the quality and relevance of FDA's research programs which provide the scientific support for regulating these agents.

#### II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **ADDRESSES**) within 30 days of publication of this document. Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the Allergenic Products Advisory Committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

#### III. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. A current curriculum vitae and the name of the committee of interest should be sent to the FDA contact person within the 30 days. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

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, and therefore, encourages, nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the allergenic product manufacturing industry.

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: June 21, 2007.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

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