

14. Can you determine the date the fastener was manufactured? (If yes, notify GAO of the date.)

15. Have there been any changes in fastener industry practice resulting from or apparently resulting from the small lot exemption? (Report all such changes in industry practice to the GAO address above.)

Document Submission

Do not send original documents, including photographs or graphics, in the mail because they cannot be returned.

Electronic Access and Filing

This notice is available on GAO's website at <http://www.gao.gov> under the Fastener Quality Act Amendments Act of 1999.

You may submit comments and data by sending electronic mail (email) to: fasteners@gao.gov. Please include the name and phone number of the person we should contact for clarification or additional information.

Email messages are encouraged but attachments to email messages are discouraged because of the possibility of transmitting computer viruses. If you believe such attached files are necessary to provide the requested information, please send them in ASCII or Microsoft Word format. No graphics should be sent through email, but copies of graphics may be sent to the address in the **ADDRESSES** section at the beginning of this document.

Authority: 15 U.S.C.A. 5402 note.

Dated: August 3, 2000.

Michael Brostek,

Associate Director, General Government Division.

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GENERAL SERVICES ADMINISTRATION

Notice of Intent To Prepare an Environmental Impact Statement

The United States General Services Administration intends to prepare an Environmental Impact Statement (EIS) on the following project:

U.S. Courthouse

Los Angeles, California

Proposed Action: The United States General Services Administration is planning the construction of a new U.S. Courthouse in downtown Los Angeles, California. The building will house the U.S. Courts and other Court related

agencies currently located in various facilities.

Alternatives to the proposed action include:

A. Construction of new facility on the site located within downtown Los Angeles and comprised of the southwest half of the city block bounded by West Temple Street, North Spring Street, West First Street, and North Broadway.

B. Construction of a new facility on the site located within downtown Los Angeles and comprised of a full city block bounded by West First Street, South Broadway, West Second Street, and South Hill Street. This action may entail demolition of existing structures.

C. Construction of a new facility on the site located within downtown Los Angeles and comprised of a full city block bounded by West First Street, South Olive Street, West Second Street, and South Grand Avenue. This action may entail demolition of existing structures.

D. No action: Space for the U.S. Courts' functions will continue to be provided in the current facilities. The impact to the community of maintaining the status quo will be analyzed.

The public is cordially invited to participate in the scoping process, review of the draft Environmental Impact Statement, and the public meeting. The scoping meeting will be held at the Los Angeles Downtown Marriott Hotel, located at 333 South Figueroa Street, Los Angeles, California, on Thursday, August 31, 2000 from 4:30 p.m. to 7:30 p.m.

At the scoping meeting, the public will be asked to identify any significant issues that they believe should be analyzed in the Environmental Impact Statement.

Release of the draft EIS for public comment and the public meeting will be announced in the local newspaper, as these dates are established.

FOR FURTHER INFORMATION CONTACT:

Javad Soltani, General Services Administration, Portfolio Management Division (9PT), 450 Golden Gate Avenue, San Francisco, California 94102, (415) 522-3493, Fax: (415) 522-3215. Email: javad.soltani@gsa.gov.

Dated: July 31, 2000.

Javad Soltani,

Asset Planner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Nonvoting Representatives of Consumer and Industry Interests on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for nonvoting consumer representatives and nonvoting industry representatives to serve on certain device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health (CDRH). Nominations will be accepted for current vacancies and for those that will or may occur through July 31, 2001.

FDA has a special interest in ensuring that women, minority groups, individuals with disabilities, and small businesses are adequately represented on advisory committees and, therefore, encourages nominations for appropriately qualified candidates from these groups, as well as nominations from small businesses that manufacture medical devices subject to the regulations.

DATES: Nominations should be received by September 8, 2000, for vacancies listed in this notice.

ADDRESSES: All nominations and curricula vitae (which includes nominee's office address, telephone number, and e-mail address) for consumer representatives should be submitted in writing to Mary C. Wallace (address below). All nominations and curricula vitae (which includes nominee's office address, telephone number, and e-mail address) for industry representatives should be submitted in writing to Kathleen L. Walker (address below).

FOR FURTHER INFORMATION CONTACT:

Regarding consumer representatives:

Mary C. Wallace, Office of Consumer Affairs (HFE-3), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4406, e-mail: MWALLACE@OC.FDA.GOV.

Regarding industry representatives:

Kathleen L. Walker, Office of Systems and Management (HFZ-17), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1283, ext. 114, e-mail: KLW@CDRH.FDA.GOV.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for nonvoting

members representing consumer and industry interests for the vacancies listed below:

Medical Devices Panels	Approximate Date Representative is Needed	
	Consumer	Industry
Circulatory System Devices Panel	NV ¹	July 1, 2001
Dental Products Panel	November 1, 2000	NV ¹
Ear, Nose & Throat Devices Panel	NV ¹	November 1, 2000
Immunology Devices Panel	NV ¹	March 1, 2001
Neurological Devices Panel	December 1, 2000	December 1, 2000
Obstetrics & Gynecology Devices Panel	February 1, 2001	February 2, 2001
Orthopaedic & Rehabilitation Devices Panel	NV ¹	September 1, 2000

¹ NV = No vacancy

I. Function

The functions of the medical device panels are to: (1) Review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation; (2) advise the Commissioner of Food and Drugs regarding recommended classification or reclassification of these devices into one of three regulatory categories; (3) advise on any possible risks to health associated with the use of devices; (4) advise on formulation of product development protocols; (5) review premarket approval applications for medical devices; (6) review guidelines and guidance documents; (7) recommend exemption to certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act (the act); (8) advise on the necessity to ban a device; (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices; and (10) make recommendations on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

II. Consumer and Industry Representation

Section 520(f)(3) of the act (21 U.S.C. 360j(f)(3)), as amended by the Medical Device Amendments of 1976, provides that each medical device panel include as members one nonvoting representative of consumer interests and one nonvoting representative of interests of the medical device manufacturing industry.

III. Nomination Procedures

A. Consumer Representatives

Any interested person may nominate one or more qualified persons as a member of a particular advisory committee or panel to represent

consumer interests as identified in this notice. Self-nominations are also accepted. To be eligible for selection, the applicant's experience and/or education will be evaluated against Federal civil service criteria for the position to which the person will be appointed.

Nominations shall include a complete curriculum vitae of each nominee and shall state that the nominee is aware of the nomination, is willing to serve as a member, 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. The nomination should state whether the nominee is interested only in a particular advisory committee or panel or in any advisory committee or panel. The term of office is up to 4 years, depending on the appointment date.

B. Industry Representatives

Any organization in the medical device manufacturing industry (industry interests) wishing to participate in the selection of an appropriate member of a particular panel may nominate one or more qualified persons to represent industry interests. Persons who nominate themselves as industry representatives for the panels will not participate in the selection process. It is, therefore, recommended that all nominations be made by someone with an organization, trade association, or firm who is willing to participate in the selection process.

Nominees shall be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers. Nominations shall include a complete curriculum vitae of each nominee. The term of office is up

to 4 years, depending on the appointment date.

IV. Selection Procedures

A. Consumer Representatives

Selection of members representing consumer interests is conducted through procedures which include use of a consortium of consumer organizations which has the responsibility for recommending candidates for the agency's selection. Candidates should possess appropriate qualifications to understand and contribute to the committee's work.

B. Industry Representatives

Regarding nominations for members representing the interests of industry, a letter will be sent to each person that has made a nomination, and to those organizations indicating an interest in participating in the selection process, together with a complete list of all such organizations and the nominees. This letter will state that it is the responsibility of each nominator or organization indicating an interest in participating in the selection process to consult with the others in selecting a single member representing industry interests for the panel within 60 days after receipt of the letter. If no individual is selected within 60 days, the agency will select the nonvoting member representing industry interests.

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: August 4, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

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