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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Nominations for Membership on the Board of Directors of the Reagan-Udall Foundation From Consumer Advocacy Groups, Professional Scientific and Medical Societies, and Industry Trade Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opportunity for patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations to nominate candidates to serve on the Board of Directors (the Board) of a new non-profit foundation, the Reagan-Udall Foundation for the Food and Drug Administration (the Foundation). The Foundation will be dedicated to modernizing medical, veterinary, food, food ingredient, and cosmetic product development, accelerating innovation, and enhancing product safety.

DATES: Submit written or electronic nominations on or before October 15, 2007.

ADDRESSES: Submit written nominations either by fax to Lisa Rovin or Nancy Stanisic at 301-443-9718 or by e-mail to *Reagan-Udall-Board@FDA.HHS.GOV*.

FOR FURTHER INFORMATION CONTACT:

Lisa Rovin, Office of Policy and Planning (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1443; or

Nancy Stanisic, Office of Critical Path Programs (HF-18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-

1660.

SUPPLEMENTARY INFORMATION:**I. Background**

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA). The law reauthorizes the Prescription Drug User Fee Act, the Medical Device User Fee Act, the Best Pharmaceuticals for Children Act, and the Pediatric Research Equity Act of 2007, and enacts the Pediatric Medical Device Safety and Improvement Act of 2007 as well as additional requirements and authorities for FDA. Title VI of FDAAA creates the Foundation. The purpose of the Foundation is to “advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.”

The duties of the Foundation include the identification of unmet needs in the development, manufacture, and evaluation (including postmarket evaluation) of the safety and effectiveness of FDA-regulated products, and the establishment of scientific and other projects and programs to meet those needs.

II. Criteria for Board Membership

The statute mandates a 14-member Board of Directors, composed of the following:

- Four representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries;
- Three representatives of academic research organizations;
- Two representatives of patient or consumer advocacy organizations;
- One representative of health care providers; and

- Four at-large representatives with expertise or experience relevant to the purpose of the Foundation.

The Board must include individuals with expertise in areas including the sciences of developing, manufacturing, and evaluating the safety and effectiveness of devices, including diagnostics, biological products, and drugs, and the safety of food, food ingredients, and cosmetics.

The Foundation's Board will be responsible for governing the organization and ensuring that it succeeds in its mission. To that end, the Board members will oversee the mission and operations of the Foundation, including: Approving programs and monitoring their effectiveness, coordinating Foundation activities with federal research programs, awarding grants, and ensuring financial solvency and raising resources.

The initial Board is to be appointed no later than 30 days after enactment, September 27, 2007, by the *ex officio* board members designated in the statute: The Commissioner of Food and Drugs, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Director of the Agency for Healthcare Research and Quality. Nine Board members are to be appointed from a list of candidates provided by the National Academy of Sciences. Five Board members are to be appointed from lists of candidates provided by "patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations."

III. Process and Criteria for Nominations

To facilitate nomination of candidates from patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations, FDA is publishing this notice and accepting nominations by fax or e-mail submission (see **ADDRESSES**). We welcome nominations from

any such organization, and are not limiting the number of nominations each organization may submit. We will accept joint nominations from multiple organizations.

Each nomination should include the following information:

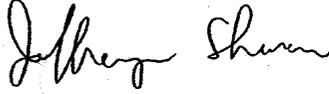
(1) Name, affiliation, and contact information for each nominating organization, and a statement indicating to which of the following categories the nominating organization belongs: Patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations.

(2) Name, title, affiliation (if any), resume or curriculum vitae, and contact information for each nominee. In addition, please include no more than one paragraph describing the individual's qualifications in relation to the mission of the Foundation and the statutory criteria for Board membership, described in section II of this document. A nominee may qualify in more than one of the statutory categories for Board membership; please list all categories for which each nominee qualifies.

IV. Electronic Access

Persons with access to the Internet may obtain the FDAAA statute at: <http://www.fda.gov/oc/initiatives/advance/fdaaa.html>.

Dated: 9-27-07
September 27, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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