

available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its labeling or in its labeling. This estimate is based on the average number of notification submissions received by the agency in the preceding 18 months.

Dated: October 19, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-26885 Filed 10-24-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Participants at the Process Analytical Technologies Subcommittee of the Advisory Committee for Pharmaceutical Science

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting names of qualified persons to participate on the Process Analytical Technologies Subcommittee (the Subcommittee) of the Advisory Committee for Pharmaceutical Science. The Subcommittee will identify and report to the Advisory Committee for Pharmaceutical Science on scientific issues related to application and validation of online process technologies such as near infrared and Raman spectroscopy and imaging methods for application in the manufacture of drug substances and drug products. The Subcommittee will also report on the potential benefits and risks associated with the application of these new technologies to public health and, as part of this analysis, evaluate the feasibility of the parametric release concept.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented and, therefore encourages recommendations of qualified candidates from these groups. Final selections from among qualified candidates will be based on the expertise demonstrated and previous experience with online process technologies.

DATES: All applications should be received by November 30, 2001.

ADDRESSES: Submit applications to David Morley (address below).

FOR FURTHER INFORMATION CONTACT: David Morley, Office of Testing and

Research (HFD-900), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5186, FAX 301-827-3787, e-mail: morleyd@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is seeking qualified persons to participate on the Process Analytical Technologies Subcommittee being formed under the Advisory Committee for Pharmaceutical Science. The Subcommittee will identify and report on the current state of technology, validation procedures, and the mechanistic basis of online process controls in both drug development and scaleup. These participants are not members of the Subcommittee and will not be voting on any issues, but they are encouraged to participate in the discussion of the issues. The Subcommittee will evaluate the potential for enhancing product quality and providing public health benefit.

II. Selection Criteria

Persons from government, industry, academia, and other organizations (such as research institutes) applying to participate on the Subcommittee should have exceptional accomplishments and be leading technical experts in the appropriate fields. In particular, expertise in application of the following scientific disciplines to pharmaceutical development and pharmaceutical manufacturing processes is desired: Process analytical chemistry, pharmaceuticals, industrial pharmacy, chemical engineering, pharmaceutical analysis, chemometrics, pattern recognition, computer expert systems, information technology, and statistics.

III. Application Procedures

Any interested person should submit appropriate biographical material and a list of scientific publications relevant to the Subcommittee to the contact person listed above.

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: October 17, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Organ Procurement and Transplantation Network

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of meeting of the Advisory Committee on Organ Transplantation.

SUMMARY: Pursuant to Public Law 92-463, the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the first meeting of the Advisory Committee on Organ Transplantation (ACOT), Department of Health and Human Services (HHS). The meeting will be held from approximately 8:15 a.m. to 6 p.m. on December 3, 2001, and from 8 a.m. to 5:15 p.m. on December 4, 2001, at the Hyatt Dulles, at Dulles International Airport, 2300 Dulles Corner Boulevard, Herndon, Virginia 20171. The meeting will be open to the public; however, seating is limited and pre-registration is encouraged (see below).

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. section 217a, section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), the ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, and, thereby, increasing public confidence in the integrity and effectiveness of the transplantation system. The ACOT is composed of 41 members, including the Chair. Members are non-governmental individuals with diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

The ACOT will consider a number of subjects relating to the means of expanding the donor pool and increasing organ donation; and it will also review the organ allocation policies submitted by the Organ Procurement