

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 20, 2001.

**John Burckhardt,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0459]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the regulation requiring manufacturers, packers, and distributors of dietary supplements to notify FDA that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in the Federal Food, Drug, and Cosmetic Act (the act).

**DATES:** Submit written or electronic comments on the collection of information by **DECEMBER 24, 2001.**

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of

the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Food Labeling; Notification Procedures for Statements on Dietary Supplements—21 CFR Part 101.93 (OMB Control Number 0910-0331)—Extension

*Description:* Section 403(r)(6) of the act (21 U.S.C. 343(r)(6)) requires that the agency be notified by manufacturers, packers, and distributors of dietary supplements that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the act. Section 403(r)(6) of the act requires that the agency be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented.

The agency established § 101.93 (21 CFR 101.93) as the procedural regulation for this program. Section 101.93 provides details of the procedures associated with the submission and identifies the information that must be included in order to meet the requirements of section 403 of the act.

*Description of Respondents:* Businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
101.93	2,500	1	2,500	.75	1,875

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

The agency believes that there will be minimal burden on the industry to generate information to meet the

requirements of section 403 of the act in submitting information regarding section 403(r)(6) of the act statements on

labels or labeling of dietary supplements. The agency is requesting only information that is immediately

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]

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## 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