

form, as well as in a Portable Document Format (PDF) viewable and downloadable electronic image on OGE's Internet Web site (Uniform Resource Locator address: <http://www.usoge.gov>, under the Ethics Resource Library section) and in future editions of The Ethics CD-ROM. The Office of Government Ethics also will permit departments and agencies to photocopy or have copies printed of the form as well as to develop or utilize, on their own, electronic versions of the form, provided that they precisely duplicate the paper original to the extent possible. As noted above, agencies can also develop their own access forms, provided all the information required by the Ethics Act and OGE regulations is placed on the form, along with the appropriate Privacy Act and paperwork notices with any attendant clearances being obtained therefor.

Public comment is invited on each aspect of the proposed slightly modified OGE Form 201 as set forth in this notice, including specifically views on the need for and practical utility of this proposed modified collection of information, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology).

The Office of Government Ethics, in consultation with OMB, will consider all comments received, which will become a matter of public record.

Approved: June 14, 1999.

**Stephen D. Potts,**

*Director, Office of Government Ethics.*

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BILLING CODE 6345-01-U

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99N-0791]

#### Agency Information Collection Activities; Announcement of OMB Approval; Survey of Medical Device Manufacturers for Year 2000 Compliance of Manufacturing Systems

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Survey of Medical Device Manufacturers for Year 2000 Compliance of Manufacturing Systems"

has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**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:** In the **Federal Register** of May 10, 1999 (64 FR 25045), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0405. The approval expires on November 30, 1999. A copy of the supporting statement for this information collection is available on the Internet at "<http://www.fda.gov/ohrms/dockets>".

Dated: June 11, 1999.

**William K. Hubbard,**

*Acting Deputy Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99N-1174]

#### Dietary Supplements; Center for Food Safety and Applied Nutrition Strategy; Public Meeting

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a second public meeting to solicit comments that will assist the Center for Food Safety and Applied Nutrition (CFSAN) to develop an overall strategy for achieving effective regulation of dietary supplements under the Dietary Supplement Health and Education Act (DSHEA). This meeting is intended to give the public an opportunity to comment on the development of the strategy.

**DATES:** The public meeting will be held on July 20, 1999, from 9 a.m. to 5 p.m. Submit written comments by August 20, 1999.

**ADDRESSES:** The public meeting will be held at the Oakland Federal Bldg., third

fl. auditorium, north tower, 1301 Clay St., Oakland, CA.

**FOR FURTHER INFORMATION CONTACT:** Janet B. McDonald, Office of Regulatory Affairs (HFR-PA-145), Food and Drug Administration, 1431 Harbor Bay Pkwy., Alameda, CA 94502-7070, 510-337-6845, FAX 510-337-6708, "e-mail [jmcdonal@ora.fda.gov](mailto:jmcdonal@ora.fda.gov)."

## SUPPLEMENTARY INFORMATION:

### I. Introduction

This public meeting is the second of two meetings to seek stakeholder comments on the development of an overall strategy for achieving effective regulation of dietary supplements under the Federal Food, Drug, and Cosmetic Act, as amended by DSHEA. The first meeting was held on June 8, 1999, in Washington, DC. These two meetings build upon themes that emerged from a broader stakeholder meeting sponsored by CFSAN in June 1998. That meeting addressed the nonfood safety initiative programs that are managed by CFSAN and identified some basic themes including: (1) The need to maintain a credible FDA program, including compliance, enforcement, and consumer outreach activities that will help ensure consumer confidence in FDA regulated products; (2) the need to maintain a solid, science based program staffed with highly qualified scientists; and (3) the recognition that FDA's assistance to consumers and the regulated industry is important.

### II. Registration and Requests for Oral Presentations

If you would like to attend the public meeting, you must register with the contact person (address above) by July 9, 1999, by providing your: Name, title, business affiliation, address, telephone, and fax number. To expedite processing, registration information may also be faxed to 510-337-6708. If you need special accommodations due to disability, please inform the contact person when you register.

If you wish to make an oral presentation during the meeting, you must inform the contact person of that desire when you register to attend and submit: (1) A brief written statement of the general nature of the evidence or arguments that you wish to present, (2) the names and addresses of the persons who will give the presentation, and (3) the approximate length of time that you are requesting for your presentation. Depending on the number of people who register to make presentations, we may have to limit the time allotted for each presentation.

### III. CFSAN's 1999 Program Priorities Document

The meeting announced in this notice, as well as the meeting that took place on June 8, 1999, in Washington, DC, are in response to CFSAN's 1999 Program Priorities document that calls for the development of an overall dietary supplement strategy in conjunction with other agency units and stakeholders. A copy of the priorities document is available on the Internet on FDA's Website at "<http://vm.cfsan.fda.gov/~dms/cfsan199.html>".

The priorities document states that the overall strategy should address all elements of the dietary supplement program including: (1) Boundaries between dietary supplements and conventional foods, between dietary supplements and drugs, and between dietary supplements and cosmetic products; (2) claims; (3) good manufacturing practices; (4) adverse event reporting; (5) laboratory capability; (6) research needs; (7) enforcement; and (8) resource needs. FDA's objective in developing this strategy is to ensure consumer access to safe dietary supplements that are truthfully and not misleadingly labeled. FDA intends to develop this strategy by following a process of openness, flexibility, efficiency, and commitment to public health.

FDA has identified four criteria for priority ranking the tasks encompassed in the strategy. These criteria are: (1) Enhancement of consumer safety, (2) development of health-related product labeling regulation, (3) improvement in efficiency of operation, and (4) closure on unresolved regulatory issues.

This meeting also addresses activity undertaken by the agency to solicit comments in accordance with section 406(b) of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) (21 U.S.C. 393(b)).

### IV. Agenda and Goals

To help focus comments for the July 20, 1999, meeting, FDA requests that oral and written input regarding an overall strategy for achieving effective regulation of dietary supplements address the following questions:

1. In addition to ensuring consumer access to safe dietary supplements that are truthfully and not misleadingly labeled, are there other objectives that an overall dietary supplement strategy should include?

2. Are the criteria for prioritizing the tasks within the supplement strategy appropriate? Which specific tasks should FDA undertake first?

3. What factors should FDA consider in determining how best to implement a task (i.e., use of regulations, guidance, etc.)?

4. What tasks should be included under the various dietary supplement program elements in the CFSAN 1999 Program Priorities document?

5. Are there current safety, labeling, or other marketplace issues that FDA should address quickly through enforcement actions to ensure, for example, that consumers have confidence that the products on the market are safe, truthful, and not misleadingly labeled?

6. Toward what type or area of research on dietary supplements should FDA allocate its research resources?

7. Given FDA's limited resources, what mechanisms are available, or should be developed, to leverage FDA's resources to meet effectively the objective of the strategy?

### V. Comments

Interested persons may, on or before August 20, 1999, submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may also send comments to the Dockets Management Branch via e-mail to "[FDA.Dockets@bangate.fda.gov](mailto:FDA.Dockets@bangate.fda.gov)" or via the FDA Website "<http://www.fda.gov>". You should annotate and organize your comments to identify the specific issues to which they refer. You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document, except that you may submit one copy if you are an individual. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

### VI. Transcripts

You may request transcripts of the meeting in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. You may also examine the transcript of the meeting at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA Website "<http://www.fda.gov>", "<http://vm.cfsan.fda.gov/dms/cfsan199.html>".

Dated: June 11, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy Coordination.*

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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Health Care Financing Administration

[HCFA-2039-FN]

RIN 0938-AJ41

#### Medicare Program; Recognition of the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) for Hospices

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Final notice.

**SUMMARY:** This notice recognizes the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) as a national accreditation organization for hospices that request participation in the Medicare program. We believe that accreditation of hospices by JCAHO demonstrates that all Medicare hospice conditions of participation are met or exceeded. Thus, we grant deemed status to those hospices accredited by JCAHO. The proposed notice included the application from the Community Health Accreditation Program, Inc. (CHAP). The final notice recognizing CHAP as a national accreditation organization for hospices was published on April 20, 1999 at 64 FR 19376.

**EFFECTIVE DATE:** This final notice is effective June 18, 1999, through June 18, 2003.

**FOR FURTHER INFORMATION CONTACT:** Joan C. Berry, (410) 786-7233.

#### SUPPLEMENTARY INFORMATION:

#### I. Background

##### A. Laws and Regulations

Under the Medicare program, eligible beneficiaries may receive covered palliative services in a hospice provided certain requirements are met. The regulations specifying the Medicare conditions of participation for hospice care are located in 42 CFR part 418. These conditions implement section 1861(dd) of the Social Security Act (the Act), which specifies services covered as hospice care and the conditions that a hospice program must meet in order to participate in the Medicare program.

Generally, in order to enter into an agreement with Medicare, a hospice must first be certified by a State survey