

that calcium would qualify as a food since it is an essential mineral nutrient.

HP&M articulates several other grounds for the action requested in the petition. HP&M also argues that the requirements of section 403(r)(6) of the act apply only to structure/function claims that fall within the health claims definition 21 CFR 101.14(a)(1). Moreover, HP&M argues that FDA's change in interpretation is not entitled to deference because it was issued more than 5 years after the Dietary Supplement Health and Education Act (DSHEA) was passed and, therefore, is not a "contemporaneous construction" of the statute. The petition also asserts that Congress intended DSHEA to reduce FDA requirements for dietary supplements. HP&M believes that FDA's new position is inconsistent with congressional intent since it imposes regulatory burdens that did not exist before DSHEA. Finally, the petition also raises an administrative law argument that FDA's reversal is effectively a substantive rule that must comply with the notice and comment rulemaking procedures of the Administrative Procedure Act in 5 U.S.C. 553.

Petitions filed by AHPA and jointly by CRN and CHPA on February 7, 2000, also requested a reversal of FDA's position on this issue. These petitions made arguments similar to those made by the HP&M petition.

III. Questions

The agency is interested in receiving comments on all three petitions. Moreover, there are several specific questions on which FDA would like comment.

1. The outcome of a reversal of FDA's position would be that dietary supplements that qualify for the "(other than food)" exception would not have to accompany the structure/function claim with a disclaimer while dietary supplements that do not qualify would. Would consumer confusion result from this outcome?

2. The outcome of maintaining the current position would be that dietary supplements making a structure/function claim would have to bear a disclaimer while conventional foods making the same claim would not. Is it better to have an inconsistency between dietary supplements and conventional foods or between dietary supplements that qualify for the "(other than food)" exception and dietary supplements that do not?

3. If FDA were to reverse its position as requested by the petitions, the agency would be notified of some structure/function claims for dietary supplements, but not others. Therefore, the agency

would not be aware of all the structure/function claims in the marketplace, including some that might be in fact disease claims rather than legitimate structure/function claims. To determine whether a dietary supplement could legitimately bear a structure/function claim without a disclaimer, FDA would have to investigate whether the claim was based on the nutritive value of the supplement. What would be the impact of this situation on enforcement?

IV. Comments

You may submit to the Dockets Management Branch (address above) written or electronic comments by December 22, 2000. Electronic comments may be submitted via the Internet to: www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm or via e-mail: fdadockets@oc.fda.gov. Groups or organizations must submit two copies of any comments. Individuals may submit one copy of their comments. Identify your written comments by placing the docket number at the top of your comment(s). If you base your comments on scientific evidence or data, please submit copies of the specific information along with your comments. Any comments submitted will be filed under the docket number identified in brackets in the heading of this document. The petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 13, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-27083 Filed 10-20-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

General Function of the Panel: To provide advice and recommendations to

the agency on scientific disputes between the Center for Devices and Radiological Health and sponsors, applicants, and manufacturers.

Date and Time: The meeting will be held on October 31, 2000, 1 p.m. to 4 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Les S. Weinstein, Center for Devices and Radiological Health (HFZ-5), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, e-mail: lsw@cdrh.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 10232. Please call the Information Line for up-to-date information on this meeting.

Agenda: The members of the newly established Medical Devices Dispute Resolution Panel will be introduced to the public and will hear presentations by FDA staff on the purpose of the panel and its role in dispute resolution.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues regarding resolving scientific disputes concerning medical devices and on the role of this panel. Written submissions may be made to the contact person by October 25, 2000. Oral presentations from the public will be scheduled between approximately 2 p.m. and 4 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 25, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the October 31, 2000, Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 18, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-27228 Filed 10-19-00; 12:06 pm]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of November 2000.

Name: Maternal and Child Health Research Grants Review Committee.

Date and Time: November 15-17, 2000; 8:00 a.m.-5 p.m.

Place: Ramada Inn Bethesda, 8400 Wisconsin Avenue, Bethesda, Maryland 20814.

The meeting is open to the public on Wednesday, November 15, 2000, from 9 a.m.-10:00 a.m., and closed for the remainder of the meeting.

Purpose: To review research grant applications in the program areas of maternal and child health, administered by the Maternal and Child Health Bureau, Health Resources and Services Administration.

Agenda: The open portion of the meeting will cover opening remarks by the Director, Division of Research, Training and Education, who will report on program issues, congressional activities, and other topics of interest to the field of maternal and child health. The meeting will be closed to the public on Wednesday, November 15, 2000, from 10:00 a.m. through the remainder of the meeting for the review of grant applications. The closing is in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., and the Determination by the Associate Administrator for Management and Program Support, Health Resources and Services Administration, pursuant to Public Law 92-463.

Anyone wishing to obtain a roster of members, minutes of meetings, or other relevant information should write or contact Gontran Lamberty, Dr. P.H., Executive Secretary, Maternal and Child Health Research Grants Review Committee, Room 18A-55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-2190.

Dated: October 16, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00-27084 Filed 10-20-00; 8:45 am]

BILLING CODE 4160-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Filing of Annual Report of Federal Advisory Committee

Notice is hereby given that pursuant to section 13 of Public Law 92-463, the annual report for the following Health Resources and Services Administration's Federal advisory committee has been filed with the Library of Congress: Maternal and Child Health Research Grants Review Committee.

Copies are available to the public for inspection at the Library of Congress Newspaper and Current Periodical Reading Room, James Madison Memorial Building, Room LM-133, First Street and Independence Avenue, SE., Washington, DC. Copies may be obtained from: Gontran Lamberty, Dr. P.H., Executive Secretary, Maternal and Child Health Research Grants Review Committee, Room 18A-55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-2190.

Dated: October 16, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00-27085 Filed 10-20-00; 8:45 am]

BILLING CODE 4160-15-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[(610-5101-01-B109) CACA-40467]

Cadiz Groundwater Storage and Dry-Year Supply Program Proposed Pipeline and Plan Amendment, San Bernardino County, California

AGENCY: Bureau of Land Management, California Desert District.

ACTION: Notice of availability (NOA) of supplement to the draft environmental impact statement for proposed Cadiz Groundwater Storage and Dry-Year Supply Program Pipeline Right-of-Way and plan amendment.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, notice is hereby given that the Bureau of Land Management has prepared a joint Supplement to the Draft Environmental Impact Statement (Supplement) and Draft Environmental Impact Report in conjunction with the Metropolitan Water District of Southern California (MWD). The Draft EIR/EIS,

published in November 1999, evaluates a range of alternatives for conveying water between the Colorado River Aqueduct and the aquifer underlying the Cadiz and Fenner Valleys across a proposed right-of-way for a pipeline. A plan amendment to the California Desert Conservation Area Plan (1980) is also proposed to allow for the proposed right-of-way for the pipeline outside of an existing utility corridor. This Supplement provides additional information regarding management of groundwater resources and related air quality issues in response to comments on the Draft EIR/EIS.

The aim of the Cadiz Project is to ensure the reliability of Metropolitan's existing water supply in the Colorado River Aqueduct. The project would achieve this goal by storing Colorado River water in the Cadiz/Fenner aquifer and withdrawing the stored water along with indigenous groundwater during dry years. The project area is located in the eastern Mojave Desert region of San Bernardino County in the Cadiz and Fenner valleys and crosses federal land administered by the BLM.

SUPPLEMENTARY INFORMATION: Copies of the Supplement will be available for 45-day public review from October 20, 2000, through December 4, 2000, at the following locations:

Needles Branch Library, 1111 Bailey Avenue, Needles, California 92363
Twentynine Palms Branch Library, 6078 Adobe Road, Twentynine Palms, California 92277

Barstow Branch Library, 304 East Buena Vista, Barstow, California 92311

Norman Feldheim Central Library, 555 West 6th Street, San Bernardino, California 92410

Bureau of Land Management, Riverside Office, 6221 Box Springs Boulevard, Riverside, California 92507

Bureau of Land Management, Needles Office, 101 West Spike's Road, Needles, California 92363

Metropolitan Water District of Southern California, 700 North Alameda Street, Los Angeles, California 90012

DATES: Comments must be received in writing by the Metropolitan Water District or by the Bureau of Land Management no later than December 4, 2000.

ADDRESSES: Written comments on the Supplement should be mailed to: Metropolitan Water District of Southern California, Post Office Box 54153, Los Angeles, California 90054-0153, Attention: Mr. Jack Safely, or U.S. Bureau of Land Management, 6221 Box Springs Boulevard, Riverside, California 92507, Attention: Mr. James Williams.