
Jennifer J. Johnson,
Secretary of the Board.
[FR Doc. 02–28116 Filed 11–6–02; 8:45 am]

GENERAL SERVICES ADMINISTRATION

Governmentwide Per Diem Advisory Board

AGENCY: Office of Governmentwide Policy, GSA.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given that the Governmentwide Per Diem Advisory Board will hold an open meeting from 2:00 p.m. to 4:00 p.m. on Thursday, November 14, 2002. The meeting will be held at The Crystal City Marriott, 1999 Jefferson Davis Highway, Arlington, VA 22202. This meeting is open to the public. Members of the public who wish to file a written statement with the Board may do so in writing c/o Rob Miller, Designated Federal Officer (MTT), General Services Administration, 1800 F St., NW, Room G–219, Washington, DC 20405, or via e-mail at robl.miller@gsa.gov. Due to critical mission and schedule requirements, there is insufficient time to provide the full 15 calendar days’ notice in the Federal Register prior to this meeting, pursuant to the final rule on Federal Advisory Committee management codified at 41 CFR 102–3.150.

Purpose: To review the current process and methodology that is used by GSA’s Office of Governmentwide Policy to determine the per diem rates for destinations within the continental United States (CONUS). The Board will receive recommendations for improvements to the current process and methodology used to establish the federal per diem rates within CONUS, and receive best practice recommendations for developing a Governmentwide lodging program.

For security and building access: (1) ADA accessible facility; (2) Public seating may be limited.

FOR FURTHER INFORMATION CONTACT: Rob Miller, Designated Federal Officer, on (202) 501–4621, or Jody Garner on (202) 501–4857, Per Diem Program Manager, General Services Administration. Also, inquiries may be sent to robl.miller@gsa.gov.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS).

Time and Date: November 19, 2002—9 a.m.–6 p.m. November 20, 2002—9 a.m.–4 p.m.


Status: Open.

Purpose: At this meeting the Committee will hear presentations and hold discussions on several health data policy topics. On the first day the full Committee will hear updates and status reports from the Department on several topics including the implementation of the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). There will also be a discussion of the Committee’s proposed recommendations to the Department on privacy and code sets for medical records. There will be Subcommittee breakout sessions late in the afternoon of the first day and prior to the full Committee meeting on the second day. Agendas for these breakout sessions may be found on the NCVHS website (URL below). On the second day the Committee will hear presentations on data issues on minority health and population-based health. Each of the NCVHS Subcommittees will report on their breakout sessions and other activities. Finally, the agendas for future NCVHS meetings will be discussed.

Contact Person for More Information: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS Web site: http://www.ncvhs.hhs.gov/, where further information including an agenda will be posted when available.

Dated: November 4, 2002.

Becky Rhodes,
Deputy Associate Administrator, Office of Transportation and Personal Property.

[FR Doc. 02–28510 Filed 11–6–02; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Statement of Organization, Functions, and Delegations of Authority

Part T (Agency for Toxic Substances and Disease Registry) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (50 FR 25129–25130, dated June 17, 1985, as amended most recently at 62 FR 1119–1120, dated January 8, 1997) is amended to abolish the Office of Federal Programs, Office of the Assistant Administrator, Agency for Toxic Substances and Disease Registry. Section T–B, Organization and Functions, is hereby amended as follows:

Delete the title and functional statement for the Office of Federal Program (TBB) in their entirety.


Julie Louise Gerberding,
Administrator.

[FR Doc. 02–28320 Filed 11–6–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01P–0350]

 Determination That Sodium Tetradeyl Sulfate Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that sodium tetradeyl sulfate injection (Sotradecol) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new
requesting that the agency determine whether sodium tetracetyl sulfate injection was withdrawn from sale for reasons of safety or effectiveness. In addition, on December 6, 2001, Omega Laboratories, Ltd., submitted a citizen petition (Docket No. 01P–0350/CP2) under § 10.30 to FDA making the same request. FDA has reviewed its records and has found no information to indicate that sodium tetracetyl sulfate injection was withdrawn from the market for safety or efficacy reasons. Therefore, FDA concludes that the decision to not manufacture and market the product was not due to safety or efficacy concerns. Accordingly, the agency will maintain sodium tetracetyl sulfate injection in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to sodium tetracetyl sulfate injection may be approved by the agency.

Margaret M. Dotzel,
Associate Commissioner for Policy.

Food and Drug Administration

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0439]

Medical Devices; Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System; Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System; Guidance for Industry and FDA.” This document describes a means by which transcutaneous air conduction hearing aid systems (TACHAS) may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the Federal Register, FDA is publishing a final rule classifying TACHAS into class II (special controls).

DATES: Submit written or electronic comments on this guidance by February 5, 2003.

ADDRESSES: Submit written requests for single copies on a 3.5” diskette of the guidance document entitled “Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System; Guidance for Industry and FDA” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1234 Piccadilly Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443– 8000. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Eric M. Mann, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080.

SUPPLEMENTARY INFORMATION:

I. Background

The TACHAS is intended to compensate for impaired hearing without occluding the ear canal. It consists of an air conduction hearing aid attached to a surgically fitted tube system, which is placed through the soft tissues between the post auricular region and the outer ear canal. This special control guidance document lists the risks to health identified by FDA and describes measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these devices.

Elsewhere in this issue of the Federal Register, FDA is publishing a final rule classifying TACHAS into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for the TACHAS device. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may,