By order of the Board of Governors of the Federal Reserve System, October 31, 2002.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 02–28116 Filed 11–6–02; 8:45 am]

<FNP>

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 Joddy Garner on (202) 501–4857, Per Diem Program Manager, General Services Administration. Also, inquiries may be sent to *robl.miller@gsa.gov.*

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

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.

Place: Hubert H. Humphrey Building, 200 Independence Avenue, SW., Room 705A, Washington, DC 20201.

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: October 29, 2002.

James Scanlon,

Acting Director, Office of Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 02–28293 Filed 11–6–02; 8:45 am]

BILLING CODE 4151–05–M

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 Diseases 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.

Dated: October 29, 2002.

Julie Louise Gerberding,

Administrator.

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

BILLING CODE 4160–70–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01P–0350]

Determination That Sodium Tetradecyl 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 tetradecyl sulfate injection (Sotradecol) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new

drug applications (ANDAs) for sodium tetradecyl sulfate injection.

FOR FURTHER INFORMATION CONTACT: J. Kenneth Borgerding, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness, before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)). FDA may not approve an ANDA that does not refer to a listed drug.

Sodium tetradecyl sulfate injection is the subject of NDA 5–970. On August 13, 1946, Elkins Sinn received approval to market sodium tetradecyl sulfate injection. During 2000, Elkins Sinn discontinued manufacture of this product.

On August 13, 2001, Bennett and Company submitted a citizen petition (Docket No. 01P–0350/CP1) under § 10.30 (21 CFR 10.30) to FDA requesting that the agency determine whether sodium tetradecyl 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 tetradecyl 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 tetradecyl 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 tetradecyl sulfate injection may be approved by the agency.

Dated: October 28, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–28400 Filed 11–6–02; 8:45 am]

BILLING CODE 4160–01–S

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, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. 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,