

DATES AND TIME: Tuesday, March 3, 1998 at 10:00 a.m.

PLACE: 999 E Street, N.W., Washington, D.C.

STATUS: This meeting will be closed to the public.

TIMES TO BE DISCUSSED:

Compliance matters pursuant to 2

U.S.C. § 437g.

Audits conducted pursuant to 2 U.S.C.

§ 437g, § 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

DATE AND TIME: Thursday, March 5, 1998 at 2:00 p.m.

PLACE: 999 E Street, N.W., Washington, D.C. (ninth floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes. Advisory Opinion 1997-28: W. Ben Bius.

Advisory Opinion 1998-02: Reform Party of the United States of America, by Russell J. Verney, Chairman.

Advisory Opinion 1998-03: Reform Party of Idaho, by Gary G. Allen, Chairman.

Audit: San Diego Host Committee/Sail to Victory '96 (continued from meeting of February 26, 1998).

Audit: Committee on Arrangements for the 1996 Republican National Convention (continued from meeting of February 26, 1998).

Legislative Recommendation—1998 (continued from Meeting of February 26, 1998).

Administrative Matters.

PERSON TO CONTACT FOR INFORMATION:

Mr. Ron Harris, Press Officer, Telephone: (202) 219-4155.

Marjorie W. Emmons,

Secretary of the Commission.

[FR Doc. 98-5083 Filed 2-24-98; 12:12 pm]

BILLING CODE 6715-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Dermatologic and Ophthalmic Drugs Subcommittee and the Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

Name of Committees: Joint meeting of the Dermatologic and Ophthalmic Drugs Subcommittee and the Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on March 11, 1998, 8 a.m. to 5 p.m.

Location: Holiday Inn, Walker Room, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Tracy Riley or Kathleen R. Reedy, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 12534 and 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss scientific clinical trial design for products intended for the treatment of diabetic retinopathy.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 4, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m., and between approximately 1 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 4, 1998, 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 joint meeting of the Dermatologic and Ophthalmic Drugs Subcommittee and the Endocrinologic and Metabolic Drugs Advisory Committee. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Dermatologic and Ophthalmic Drugs Subcommittee and the Endocrinologic and Metabolic

Drugs Advisory Committee were available at this time, the Commissioner 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: February 20, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-5050 Filed 2-24-98; 11:42 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on March 23, 1998, 7:45 a.m. to 6:20 p.m.

Location: Ramada Inn, Embassy Ballroom, 8400 Wisconsin Ave., Bethesda, MD.

Contact Person: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM-21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will: (1) Discuss scientific and ethical considerations of a human challenge model using virulent *Salmonella typhi* bacteria; (2) complete recommendations pertaining to the influenza virus vaccine formulation for 1998 and 1999; and (3) hear short briefings on research programs in the Laboratories of DNA Viruses, Hepatitis Viruses, and Bacterial Polysaccharides.

Procedure: On March 23, 1998, from 7:45 a.m. to 4:50 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 16, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. to 8:15 a.m. and between approximately 3:30 p.m. to 4:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 16, 1998, 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.

Closed Committee Deliberations: On March 23, 1998, from 4:50 p.m. to 6:20 p.m., the meeting will be closed to review data of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of this information.

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

Dated: February 20, 1998.

Michael A. Friedman,

Deputy Commissioner of Operations.

[FR Doc. 98-4964 Filed 2-25-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0040]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Food Safety Survey" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. 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 August 12, 1997 (62 FR 43169), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910-0345. The approval expires on October 31, 2000.

Dated: February 18, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-4846 Filed 2-25-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0046]

Comprehensive List of Current Guidance Documents at the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a comprehensive list of all guidance documents currently in use at the agency. FDA committed to publishing this list in its February 1997 "Good Guidance Practices" (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. This list is intended to inform the public of the existence and availability of all current guidance documents, including those documents that were issued prior to the adoption of the GGP's.

DATES: General comments on this list and on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFD-305), Food and Drug Administration, 12420 Parklawn Dr., rm 1-23, Rockville, MD 20857. Information on where to obtain single copies of a listed guidance document is provided for each agency center individually in the specific center's list of guidance documents.

FOR FURTHER INFORMATION CONTACT: Lisa L. Barclay, Office of Policy (HF-22), Food and Drug Administration, 5600

Fishers Lane, Rockville, MD 20857, 301-827-3360.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice announcing its "Good Guidance Practices" (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. The agency adopted the GGP's to ensure public involvement in the development of guidance documents and to enhance public understanding of the availability, nature, and legal effect of such guidance.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, the agency committed to publish a comprehensive list of all guidance documents that are currently in effect. This comprehensive list is maintained on the FDA World Wide Web home page. The list will be updated and published annually in the **Federal Register**. FDA also has committed to publish quarterly a **Federal Register** notice that lists all guidance documents that were issued and withdrawn during that quarter. FDA also has undertaken to publish, on a quarterly basis, a list of all new "Level 2" guidance documents issued by the agency under the GGP's. In a separate notice in a future issue of the **Federal Register**, FDA will publish its first quarterly update including a list of Level 2 guidance documents issued during that quarter.

The following list of guidance documents represents all guidances issued by FDA that are currently in effect. The documents are organized by the issuing Center or Office within FDA, and are further grouped by the intended users or regulatory activities to which they pertain. Dates provided in the following list refer to the date of issuance or, where applicable, the date of last revision of the document. Document numbers are provided where available, and guidance documents that are still in draft form and on which public comment has been requested are so identified.

This cumulative list includes guidance documents that were issued prior to the adoption of the GGP's. At the time such documents are substantively revised, FDA will update them to include the standard guidance elements and nomenclature described in the GGP's.

II. Guidance Documents Issued by the Center for Biologics Evaluation and Research (CBER)