

3. How should additional information be made available to the public: e.g., on the Internet, through food information phone lines, on food labels, or by other means?

### III. Registration and Requests to Make Oral Presentations

If you would like to attend the meetings, you must register with the appropriate contact person (addresses above) 15 days prior to the meeting you wish to attend by providing your name, title, business affiliation, address, telephone, and fax number. To expedite processing, this registration information also may be faxed to the appropriate contact person (fax number above). If you need special accommodations due to disability, please inform the contact person when you register. If, in addition to attending, you wish to make an oral presentation during the meeting, you must so inform the contact person when you register and submit: (1) A brief written statement of the general nature of the views you wish to present; (2) the names and addresses of all persons who will participate in the presentation; and (3) an indication of the approximate time that you request to make your presentation. Depending upon the number of people who register to make presentations, FDA may have to limit the time allotted for each presentation.

### IV. Comments

Interested persons may, on or before January 13, 2000, submit written comments to the Dockets Management Branch (address above). You may also send comments to the Dockets Management Branch via e-mail to [www.fda.gov/ohrms/dockets](http://www.fda.gov/ohrms/dockets). 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.

### V. Transcripts

A transcript of each meeting will be made. You may request a copy of any transcript 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 transcripts of the meetings at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday

through Friday, as well as on the FDA web site, <http://www.fda.gov>.

Dated: October 18, 1999.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning and Legislation.*

[FR Doc. 99-27694 Filed 10-20-99; 8:49 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Ophthalmic Drugs Subcommittee of the Dermatologic and Ophthalmic Drugs 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:* Ophthalmic Drugs Subcommittee of the Dermatologic and Ophthalmic Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on November 17, 1999, 8:30 a.m. to 5 p.m.

*Location:* Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

*Contact:* Tracy Riley or Angie Whitacre, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting. Current information may also be accessed on the Internet at FDA's website at [www.fda.gov](http://www.fda.gov).

*Agenda:* The subcommittee will discuss new drug application 21-119 Visudyne™ (verteporfin for injection, QLT Therapeutics, Inc.), for treatment of age-related macular degeneration in patients with predominantly classic subfoveal choroidal neovascularization.

*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 November 12, 1999. Oral presentations from the public will be scheduled between approximately 8:30

a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before November 12, 1999, 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.

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

Dated: October 14, 1999.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 99-27757 Filed 10-22-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Gastrointestinal Drugs 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:* Gastrointestinal Drugs 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 November 16, 1999, 9 a.m. to 5 p.m.

*Location:* Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person:* Joan C. Standaert, Center for Drug Evaluation and Research (HFD-180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419-259-6211, or John M. Treacy (HFD-21), 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12538. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The committee will discuss new drug application 21-107, Lotronex™ (alosteron HCl), Glaxo-Wellcome Pharmaceuticals, to be indicated for treatment of irritable bowel in female patients with diarrhea predominance.

*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 November 9, 1999. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 9, 1999, 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.

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

Dated: October 12, 1999.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 99-27758 Filed 10-22-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98N-0222]

#### Notice of Appeal of Order Granting Summary Judgment and Permanent Injunction

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration is issuing this notice to inform interested parties that the United States is appealing the Order of the United States District Court for the District of Columbia, in *Washington Legal Foundation v. Henney*, Civ. No. 94-1306 (D.D.C. July 28, 1999). This order, entitled "Final Amended Order Granting Summary Judgment and Permanent Injunction," was previously published in the **Federal Register** at the court's direction (August 12, 1999, 64 FR 44025).

**FOR FURTHER INFORMATION CONTACT:** Bradford W. Stone, Office of Public Affairs (HFI-2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6250.

Dated: October 13, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 99-27697 Filed 10-22-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[HCFA-1105-N]

#### Medicare Program; November 9, 1999, Meeting of the Competitive Pricing Demonstration Area Advisory Committee, Maricopa County, AZ

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

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Competitive Pricing Demonstration Area Advisory Committee (AAC), Maricopa County, AZ on November 9, 1999.

The Balanced Budget Act of 1997 (BBA) requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology. The BBA requires the Secretary to appoint an AAC in each designated demonstration area to advise on implementation of the project, including the marketing and pricing of the plan and other factors. The AAC meetings are open to the public.

**DATES:** The meeting is scheduled for November 9, 1999, from 9:30 a.m. until 5 p.m., m.s.t.

**ADDRESSES:** The meeting will be held at the YWCA of the USA, Leadership Development Conference Center, 9440 North 25th Avenue, Phoenix, AZ 85021, (602) 944-0569.

**FOR FURTHER INFORMATION CONTACT:** Joseph Tilghman, Acting Regional Administrator, Health Care Financing Administration, 75 Hawthorne Street, 4th Floor, San Francisco, CA 94105, (415) 744-3501.

**SUPPLEMENTARY INFORMATION:** Section 4011 of the Balanced Budget Act of 1997 (BBA) requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology.

Section 4012(a) of the BBA requires the Secretary to appoint a Competitive Pricing Advisory Committee (the CPAC) to make recommendations to the Secretary concerning the designation of areas for inclusion in the project and

appropriate research designs for implementing the project. Once an area is designated as a demonstration site, section 4012(b) of the BBA requires the Secretary to appoint an Area Advisory Committee (AAC) to advise on the marketing and pricing of the plan in the area and other factors. Thus far, the Kansas City, MO Metropolitan Area and Maricopa County, AZ have been designated as demonstration sites.

The Maricopa County AAC has previously met on March 31, 1999, April 20, 1999, May 18 and 19, 1999, June 7 and 8, 1999, and June 30 and July 1, 1999, and September 23, 1999. The Maricopa County AAC is composed of representatives of health plans, providers, employers, and Medicare beneficiaries in the area. The members are: Joseph Anderson, Schaller Anderson Inc.; Rick Badger, Pacificare of Arizona; Reginald Ballantyne III, PMH Health Resources, Inc.; Donna Buelow, Arizona State Retirement System; Charles Cohen, Arizona Department of Insurance; John Hensing, M.D., Samaritan Health Systems; Mary Lynn Kasunic, Area Agency on Aging; Anne Lindeman, Governor's Advisory Council on Aging; Ben Lopez, Honeywell Corp.; Thomas Marreel, William M. Mercer Associates; Anthony Mitten, Maricopa County Medical Society; Edward Munno, Jr., Intergroup of Arizona; Erik Olsen, D.D.S., American Association of Retired Persons; Leland Peterson, Sun Health Corp.; Donna Redford, Arizona Bridge to Independent Living; Herb Rigberg, M.D., Health Services Advisory Group; Martha Taylor, Arizona SHIP; Clyde Wright, M.D., Cigna of Arizona; Arthur Pelberg, M.D., Schaller Anderson Inc.; Joseph Hanss, M.D., Physician; and Phyllis Biedess, Director, AHCCCS. Susan Navran of Blue Cross Blue Shield of Arizona has resigned from the Committee. In accordance with section 4012(b) of the BBA, the AAC will exist for the duration of the project in the area.

This notice announces the November 9, 1999, meeting of the Maricopa County AAC. This meeting will be held from 9:30 a.m. to 5 p.m., m.s.t. at the YWCA of the USA, Leadership Development Conference Center in Phoenix, AZ.

The agenda for the November 9, 1999, meeting will include the following:

- A discussion of the draft bid package for the competitive pricing demonstration.
- A discussion of a proposed plan for beneficiary education and outreach.
- Reports from the AAC subcommittees.
- A discussion of any outstanding issues.