provide for the safe use of Color Index (C.I.) Pigment Violet 19, C.I. Pigment Yellow 154, and C.I. Pigment Red 122 as color additives in contact lenses.

FOR FURTHER INFORMATION CONTACT:

Regarding CAPs 5C0278 and 5C0280: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1282.

Regarding CAP 5C0279: Harold Woodall, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1259.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that three color additive petitions (CAP 5C0278, Docket No. 2005C–0302; CAP 5C0279, Docket No. 2005C–0303; CAP 5C0280, Docket No. 2005C–0304) have been filed by CIBA Vision Corp., 11460 Johns Creek Pkwy., Duluth, GA 30097–1556. The petitions propose to amend the color additive regulations in 21 CFR part 73 to provide for the safe use of C.I. Pigment Violet 19 (CAP 5C0278), C.I. Pigment Yellow 154 (CAP 5C0279), and C.I. Pigment Red 122 (CAP 5C0280), as color additives in contact lenses.

The agency has determined under 21 CFR 25.32(l) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: July 22, 2005.

Laura M. Tarantino,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 05–16332 Filed 8–16–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting Consumer Representative Members on Public Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting consumer representatives to serve on the National Mammography Quality Assurance Advisory Committee (NMQAAC) in the Center for Devices and Radiological Health (CDRH). FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Nominations will be accepted through January 31, 2006.

ADDRESSES: All nominations should be sent to the contact person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

FOR FURTHER INFORMATION CONTACT: Michael Ortwerth, Advisory Committee Oversight and Management Staff (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, e-mail: *Michael.Ortwerth@fda.gov*.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting consumer representatives to serve on the NMQAAC.

I. Functions of NMQAAC

The functions of the committee are to advise FDA on the following topics: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

II. Criteria for Members

Persons nominated for membership on the committee as a consumer representative must meet the following criteria: (1) Must be from among national breast cancer or consumer health organization with expertise in mammography, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative must be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include use of organizations representing the public interest and consumer advocacy groups. The organizations have the responsibility of recommending candidates of the agency's selection.

IV. Nomination Procedures

All nominations must include a cover letter, a curriculum vita or resume (which should include nominee's office address, telephone number, and e-mail address), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Any interested person or organization may nominate one or more qualified persons for membership on the NMQAAC to represent consumer interests. Self-nominations are also accepted. Nominations shall include complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest. The term of office is up to 4 years, depending on the appointment date.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: August 10, 2005.

Scott Gottlieb,

Deputy Commissioner for Policy.

[FR Doc. 05–16330 Filed 8–16–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0137]

Levothyroxine Sodium Therapeutic Equivalence; Public Meeting; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until September 23, 2005, the comment period for the May 23, 2005, public meeting on the therapeutic equivalence of levothyroxine sodium drug products that was announced in the **Federal Register** of April 20, 2005 (70 FR 20574). The public meeting included FDA staff and representatives of three medical societies: The American Thyroid Association (ATA), the Endocrine Society, and the American Association of Clinical Endocrinologists (AACE). FDA is taking this action in response to a request for an extension.

DATES: Submit written or electronic comments on or before September 23, 2005.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Rose Cunningham, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–443–5595, e-mail: *cunninghamr@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On May 23, 2005, FDA cosponsored a public meeting on the therapeutic equivalence of levothyroxine sodium drug products. The meeting included FDA staff and representatives of three medical societies: The ATA, the Endocrine Society, and the AACE. The purpose of the meeting was to discuss FDA's regulatory standards and methodological approaches for determining therapeutic equivalence between levothyroxine sodium drug products. FDA asked interested constituencies, including patient advocacy and education groups, and pharmaceutical sponsors, to submit comments by July 23, 2005.

By letter dated July 6, 2005, Abbott Laboratories (Abbott) requested that FDA extend the date for submission of comments. Abbott requested the extension to give interested parties the opportunity to comment meaningfully on the matters discussed at the meeting. The transcript became available on July 12, 2005.

FDA has decided to reopen the comment period until September 23, 2005.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the topics discussed at the May 23, 2005, meeting. Submit two copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Transcript

The transcript of the May 23, 2005, meeting is available on FDA's Web site at *http://www.fda.gov/cder/meeting/levothyroxine2005.htm*.

Dated: August 10, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–16241 Filed 8–16–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic 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: Oncologic 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 September 13, 2005, from 8 a.m. to 5 p.m. and on September 14, 2005, from 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Johanna M. Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *cliffordj@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. When available, background materials for this meeting will be posted 1 business day before the meeting on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to Oncologic Drugs Advisory Committee.)

Agenda: On September 13, 2005, the committee will discuss the following: (1) New drug application (NDA) 21–491, proposed trade name XINLAY (atrasentan hydrochloride) Capsules, Abbott Laboratories, proposed indication for the treatment of men with metastatic hormone-refractory prostate cancer; and (2) NDA 21–743, S003, TARCEVA (erlotinib) Tablets, OSI Pharmaceuticals Inc., proposed indication for the first-line treatment, in combination with gemcitabine, of patients with locally advanced, unresectable or metastatic pancreatic cancer. On September 14, 2005, the committee will discuss the following: (1) NDA 21–880, proposed trade name REVLIMID (lenalidomide), Celgene Corp., proposed indication for the treatment of patients with transfusion-dependent anemia due to low-or intermediate–1–risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities; and (2) NDA 21–877, proposed trade name ARRANON (nelarabine) Injection, GlaxoSmithKline, proposed indication for the treatment of patients with T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma whose disease has not responded to, or has relapsed with, at least two chemotherapy regimens.

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 September 2, 2005. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 2:30 p.m. to 3 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 2, 2005, and