a larger number of submissions under the provisions discussed as follows:

Section 814.102 estimate assumes that 20 sponsors per year will submit a request for HUD designation. It is estimated to require 40 staff hours to complete each HUD designation request.

Section 814.104 estimate assumes that 15 sponsors per year will submit an HDE application after receiving HUD designation. FDA estimates that it will require an average of 320 staff hours to complete each HDE application.

Section 814.110(a) requires that a new indication for use of an HUD approved under this part be submitted as a new HDE application complying with § 814.104. All burden under this section is included under the estimate for § 814.104.

Section 814.106 estimate assumes that 4 times per year FDA will request or the sponsor will submit additional information or resubmit an HDE or HDE supplement for approximately 15 of the submitted HDE applications. FDA estimates that it will require the respondents to take an average of 50 staff hours to complete each amendment or resubmitted application. If FDA refuses to file the HDE application, requests for an informal conference (under § 814.112(b)) will be processed as an HDE amendment. Responses to approvable and not approvable letters (§ 814.116(b), (c), and (d)) will be processed as HDE amendments. A request for an opportunity for an informal hearing, prior to FDA issuing an order withdrawing approval, under § 814.118(d), will be processed as an HDE amendment. Because FDA only tracks amendments, and not the reasons for the amendment, the burden estimates for the sections listed in Tables 1 and 2 of this document are included in the burden estimate for § 814.106.

Section 814.108 estimate assumes that it will receive approximately 12 supplements for the submitted HDE applications. It is estimated that it will take approximately 80 staff hours to complete each supplemental application.

Section 814.116(d)(3) estimate assumes that it will receive approximately one request to withdraw an HDE application per year, based on withdrawals submitted in FY 1997 and FY 1998. FDA estimates it will take no longer than 1 staff hour to complete each written withdrawal notice.

Section 814.124(a) estimate assumes that five physicians will use HUD's in emergency situations before obtaining institute and review board (IRB) approval. FDA estimates that notification under this section will take an average of 1 hour per response.

Section 814.124(b) estimate assumes that one holder of an approved HDE will notify FDA of IRB withdrawal of approval. FDA estimates that it will take an average of 2 staff hours to notify FDA of IRB withdrawal.

Section 814.126(b)(1), following the implementation of the FDA Modernization Act, was amended to incorporate section 520(m)(5) of the act, which provides FDA the authority to require an HDE applicant to demonstrate continued compliance with the HDE requirements, if the agency believes that such a demonstration is necessary to protect the public health or has reason to believe that the criteria for the HDE exemption are no longer met. FDA amended this section to delete the requirement of an annual report and to include instead a periodic reporting requirement that will be established by the approval order for the HDE. This provision permits the agency to obtain sufficient information for it to determine whether there is reason to question the continued exemption of the device from the act's effectiveness requirements.

FDA anticipates that because of this amendment, the 15 HDE holders will remain active and therefore, estimates that 15 periodic reports will be received. FDA also estimates that it will take an average of 120 staff hours to complete a periodic report as a result of this amendment.

II. Explanation of Recordkeeping Burden Estimate

Section 814.126(b)(2) estimate assumes that 15 HDE holders per year will maintain records of certain required information. It is estimated that it will take an average of 2 staff hours to maintain this information.

Dated: October 18, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–27756 Filed 10–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4282]

Biotechnology in the Year 2000 and Beyond; Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing three public meetings on issues within FDA's jurisdiction related to foods (both human and animal) derived from plants developed using bioengineering techniques. The purpose of these public meetings is for the agency to share its current approach and experience over the past 5 years regarding safety evaluation and labeling of food products derived from bioengineered plant varieties, to solicit views on whether FDA's policies or procedures should be modified, and to gather information to be used to assess the most appropriate means of providing information to the public about bioengineered products in the food supply. These meetings will afford consumers, industry, and academia an opportunity to provide focused comment on these issues in a manner that will assist FDA in evaluating and refining its existing policies and procedures.

DATES: The meetings are scheduled as follows:

1. Thursday, November 18, 1999, 9 a.m. to 6 p.m., Chicago, IL.
2. Tuesday, November 30, 1999, 10 a.m. to 7 p.m., Washington, DC.
3. Monday, December 13, 1999, 9 a.m. to 6 p.m., Oakland, CA.

Submit written comments by January 13, 2000.

ADDRESSES: The meetings will be held at the following locations:

1. Chicago—One Prudential Plaza, Plaza Club, 40th floor,130 East Randolph St., Chicago, IL 60601.
2. Washington, DC— Grand Hyatt Washington, 1000 H St. NW., Washington, DC 20001.
3. Oakland—Elihu Harris State Office Building, 1515 Clay St., Oakland, CA 94612.

Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or via e-mail to www.fda.gov/ohrms/dockets. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For general information:

Nega Beru, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3090, FAX 202–418–3131, e-mail nberu@bangate.fda.gov.

For information about and registration for the public meeting in Chicago, IL:

Darlene Bailey, Chicago District (HFR–CE 645), Food and Drug Administration, 300 S. Riverside

Plaza, Suite 550–South, Chicago, IL 60606, 312–353–7126, FAX 312–886–3280, e-mail dbailey@ora.fda.gov.

For information about and registration for the public meeting in Washington, DC:

Patricia Alexander, Office of Consumer Affairs (HFE–40), Food and Drug Administration, Rockville, MD 20857, 301–827–5006, FAX 301–827–3052, e-mail palexand@oc.fda.gov.

For information about and registration for the public meeting in Oakland, CA:

Janet McDonald, San Francisco District (HFR–PA100), Food and Drug Administration, 1431 Harbor Bay Pkwy., Alameda, CA 94502–7070, 510–337–6845, FAX 510–337–6708, e-mail jmcdonal@ora.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA published a notice in the **Federal Register** of May 29, 1992 (57 FR 22984), entitled ''Statement of Policy: Foods Derived from New Plant Varieties'' (the 1992 policy) that clarified the agency's interpretation of the Federal Food, Drug, and Cosmetic Act (the act) with respect to foods derived from new plant varieties, including foods derived from plants developed through recombinant DNA techniques. The 1992 policy was issued in response to inquiries from developers and the public regarding food safety and labeling issues related to foods derived from bioengineered plants. The 1992 policy discussed how such foods would be regulated within the existing legal framework of the act and provided comprehensive guidance to developers for the safety and nutritional assessment of such foods. The agency's guidance, based on the agency's understanding of bioengineering advances in food and agriculture research then current, was intended to assist developers in meeting their legal duty under the act to ensure that relevant scientific, safety, and regulatory issues are resolved prior to commercial distribution of such foods. A basic principle of the 1992 policy is that the critical consideration in evaluating the safety of such foods should be the objective characteristics of the food product or its components rather than the fact that new development methods were used. Consistent with the 1992 policy, FDA believes that it is in the best interests of the public, the regulated industry, and the agency for developers to inform FDA about foods derived from new plant varieties developed through bioengineering prior to commercial distribution. Thus, FDA established procedures through which developers can consult with the agency, and through which these consultations can be brought to closure. FDA prepared guidance on the consultation procedures and made it available on its home page on the World Wide Web (http://www.fda.gov/cfsan under ''Biotechnology'').

FDA considers a consultation to be completed when all safety and regulatory issues have been resolved. Since 1994, when FDA completed its evaluation of the first food product developed using bioengineering (the Flavr Savr™ tomato), private firms have completed consultations with FDA on food safety, nutritional, and labeling issues for foods derived from over 40 different bioengineered plants.

The 1992 policy also addressed the labeling of foods derived from new plant varieties, including plants developed by genetic engineering. Under this policy and applicable law, FDA requires special labeling if the composition of a food developed through genetic engineering or any other method differs significantly from its conventional counterpart. For example, if a new food contains a protein derived from a food that commonly causes allergic reactions (and the developer cannot demonstrate that the protein is not an allergen), labeling would be necessary to alert sensitive consumers because they would not expect to be allergic to that food. Likewise, a new food that has a decrease in nutrients from the food's traditional counterpart would be required to contain that additional information on its label. In addition, the agency requires that the name of a new food be revised when that food is derived from a bioengineered plant that differs from its traditional counterpart such that the customary common or usual name no longer applies to the new food. FDA is not aware of information that would distinguish genetically engineered foods as a class from foods developed through other methods of plant breeding and, thus, the agency does not require that such foods be specially labeled to disclose the method of development. FDA believes that it would be useful to the public, the regulated industry, and the agency to conduct a series of public meetings to share the agency's current approach and experience over the past 5 years regarding its oversight of food products developed through bioengineering, to solicit views on whether FDA's process should be modified, and to gather information to be used to assess the most appropriate means of providing information to the public about bioengineered products in the food supply.

As part of the meetings, FDA will describe its current approach to regulating foods from bioengineered plants as well as the agency's experience over the past 5 years regarding safety testing and labeling of these products. FDA also intends to invite representatives from consumer groups, industry, and academia to make presentations on scientific and safety issues and to invite representatives of these same groups to make presentations on public information and labeling. Finally, there will be opportunities for oral presentations by preregistered members of the public.

II. Scope of Discussion

The scope of these three public meetings will be limited to the issues discussed in this document. A brief discussion on each of the issues with specific questions on which FDA seeks comment follows.

A. Scientific/Safety Issues

1. Has FDA's consultation process achieved its intended purpose? Based on experience to date, should this regulatory approach ''sunset,'' continue in its current state, be made mandatory, or otherwise be revised?

2. What newly emerging scientific information related to the safety of foods derived from bioengineered plants is there, if any? Are there specific tests which, if conducted on such foods, would provide increased assurance of safety for man or animals consuming these foods?

3. What types of food products derived from bioengineered plants are planned for the future? Will these foods raise food safety issues that would require different approaches to safety testing and agency oversight? If so, what are those approaches?

B. Public Information Issues

1. Should FDA's policy requiring labeling for significant changes, including changes in nutrients or the introduction of allergens, be maintained or modified? Should FDA maintain or revise its policy that the name of the new food be changed when the common or usual name for the traditional counterpart no longer applies? Have these policies regarding the labeling of these foods served the public?

2. Should additional information be made available to the public about foods derived from bioengineered plants? If so, what information? Who should be responsible for communicating such information?

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. 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

Opthalmic 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: Opthalmic 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.

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 HCI), Glaxo-Wellcome Pharmaceuticals, to be indicated for treatment of irritable bowel in female patients with diarrhea predominance.