methodologic and regulatory issues related to the co-development of two or more investigational drugs intended to be used in combination.

II. Issues on Which FDA is Seeking Comment

All material submitted to this docket will be publicly available. To facilitate development of guidance that meaningfully addresses the concerns of those who may co-develop drugs intended to be used in combination, FDA is seeking input on the following issues, and any other issues relevant to developing FDA guidance:

1. General methodologic and regulatory issues that arise in the co-development of two or more drugs intended to be used in combination where the drugs are directed at providing a therapeutic effect on the same symptom or manifestation of the disease or condition of interest, including relevance and utility of clinical or animal findings for either drug alone;
2. General methodologic and regulatory issues that arise in the co-development of two or more drugs intended to be used in combination where the drugs are directed at providing a therapeutic effect for the same disease or condition, but act on different symptoms or manifestations of that disease or condition, including relevance and utility of clinical or animal findings for either drug alone;
3. General methodologic and regulatory issues that arise in the co-development of two or more drugs intended to be used in combination where one or more of the drugs is intended to enhance the effectiveness of the other, but one or more of the drugs does not or may not have an independent therapeutic effect, including relevance and utility of clinical or animal findings for either drug alone; and
4. Methodologic and regulatory issues that arise in the co-development of two or more drugs intended to be used in combination for specific therapeutic categories, including oncology, anti-infectives, seizure disorders, cardiovascular diseases, and any other therapeutic category in which such co-development is likely to occur.

III. Submission of Comments

Interested parties may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necesary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13769 Filed 6–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0128]

Prescription Drug User Fee Act; Meetings on Reauthorization; Request for Notification of Stakeholder Intention to Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice to request that public stakeholders—including patient and consumer advocacy groups, health care professionals, and scientific and academic experts—notify FDA of their intent to participate in periodic consultation meetings on reauthorization of the Prescription Drug User Fee Act (PDUFA). The statutory authority for PDUFA expires in September 2012. At that time, new legislation will be required for FDA to continue collecting user fees for the prescription drug program. The Federal Food, Drug, and Cosmetic Act (the act) requires that FDA consult with a range of stakeholders in developing recommendations for the next PDUFA program. The act also requires that FDA hold continued discussions with patient and consumer advocacy groups at least monthly during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate by June 25, 2010. The first stakeholder meeting will be held on July 1, 2010, from 9 a.m. to 11 a.m. Stakeholder discussions will continue at least monthly during reauthorization negotiations with the regulated industry.

ADDRESSES: Submit notification of intention to participate in monthly stakeholder meetings by e-mail to *PDUFAReauthorization@fda.hhs.gov*. The first stakeholder meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503C, Silver Spring, MD 20993.

FOR FURTHER INFORMATION CONTACT: Patrick Frey, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, rm. 1174, Silver Spring, MD 20993, 301–796–3844, FAX: 301–847–8443.

SUPPLEMENTARY INFORMATION:

I. Introduction

The authority for PDUFA expires in September 2012. Without new legislation to reauthorize the program, FDA will no longer be able to collect user fees to fund the human drug review process. Section 736B(d)(1) (21 U.S.C. 379h-2(d)(1)) of the act requires that FDA consult with a range of groups in developing recommendations for the next PDUFA program, including scientific and academic experts, health care professionals, and representatives from patient and consumer groups. FDA initiated this process of consultation on April 12, 2010, by holding a public meeting where stakeholders and other members of the public were given an opportunity to present their views on reauthorization (75 FR 12555, March 16, 2010). This meeting and written comments submitted to the docket have provided critical input as the Agency prepares for reauthorization discussions. Section 736B(d)(3) of the act further requires that FDA continue meeting with these stakeholders at least once every month during negotiations with the regulated industry to continue discussions of their views on the reauthorization, including suggested changes to the PDUFA program.

FDA is issuing this **Federal Register** notice to request that stakeholders—including patient and consumer advocacy groups, health care professionals, and scientific and academic experts—notify FDA of their intent to participate in periodic consultation meetings on reauthorization of PDUFA. FDA believes that consistent stakeholder representation at these meetings will be important to ensuring progress in these discussions. If you wish to participate in this part of the reauthorization process, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions as needed. Stakeholders who identify themselves through this notice will be included in all future stakeholder discussions while FDA

negotiates with the regulated industry. If a stakeholder decides to participate in these monthly meetings at a later time, they may still participate in remaining monthly meetings by notifying FDA (see **ADDRESSES**). These stakeholder discussions will satisfy the requirement in section 736B(d)(3) of the act.

II. Additional Information on PDUFA

There are several sources of information on FDA's Web site that may serve as useful resources for stakeholders participating in the periodic consultation meetings:

- Information on the April 2010 public meeting on PDUFA Reauthorization, the **Federal Register** notice announcing the meeting, and the transcript of the meeting are available at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm117890.htm.* The slide presentations from the meeting can be found at *http://www.regulations.gov* using Docket No. FDA–2010–N–0128.
- FDA created a webinar on the PDUFA program, drug development, and FDA's drug review in PDUFA IV. These presentations are available at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm207597.htm.*
- Key **Federal Register** documents, PDUFA-related guidances, legislation, performance reports, and financial reports and plans are posted at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm.*
- The Food and Drug Administration Amendments Act of 2007 (FDAAA)-specific information is available at: *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm*

III. Notification of Intent to Participate in Periodic Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding PDUFA Reauthorization, please provide notification by e-mail to *PDUFAReauthorization@fda.hhs.gov* by June 25, 2010. Your e-mail should contain complete contact information, including name, title, affiliation, address, e-mail address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting once FDA receives their notification.

Dated: June 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13671 Filed 6–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0259]

Array-Based Cytogenetic Tests: Questions on Performance Evaluation, Result Reporting and Interpretation; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: Array-Based Cytogenetic Tests: Questions on Performance Evaluation, Result Reporting and Interpretation. The purpose of the public meeting is to seek input on challenges related to performance evaluation, determination of clinical significance, result reporting, and interpretation for array-based cytogenetic tests.

Date and Time: The meeting will be held on June 30, 2010, from 1:30 p.m. to 5 p.m.

Location: The meeting will be held at Hyatt Regency Bethesda, 7400 Wisconsin Ave., 1 Bethesda Metro Center, Bethesda, MD.

Contact: Susan Monahan, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4321, Silver Spring, MD 20903, 301–796–5661, e-mail: *Susan.Monahan@fda.hhs.gov*; or Zivana Tezak, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5668, Silver Spring, MD 20903, 301–796–6206, e-mail: *Zivana.Tezak@fda.hhs.gov*.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by June 21, 2010. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the public meeting will be provided on a space-available basis beginning at 7 a.m.

If you wish to make an oral presentation during the open comment session at the meeting, you must indicate this at the time of registration. FDA has included general discussion topics and specific questions for comment in section III of this document, Topics for Input. You should also identify which discussion topic you wish to address in your presentation. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

If you need special accommodations due to a disability, please contact Susan Monahan or Zivana Tezak (see *Contact*) at least 7 days in advance.

Comments: FDA is holding this public meeting to obtain input on a number of questions regarding review and interpretation issues for array-based cytogenetic testing.

Regardless of attendance at the meeting, interested persons may submit either electronic or written comments on any discussion topic(s) to the open docket. The deadline for submitting comments to the docket is July 30, 2010. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section III of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

Many human genetic disorders are a result of the gain or loss of human genetic material, which may manifest as congenital anomalies, dysmorphic features, developmental disabilities, etc. Traditionally, chromosomes were analyzed using a method called karyotyping. In addition, molecular methods such as fluorescence in situ hybridization (FISH) provide the information about chromosome abnormalities at specific loci. The recent