

domestic commerce unless its packaging complies with section 3 of the Smokeless Tobacco Act (Id.). Among the requirements in section 3(b)(3) is that the rotation of label statements on packaging and advertising for each brand of smokeless tobacco must be "in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer" to, and approved by, FDA (Id.).

At this time, as an exercise of enforcement discretion, FDA does not intend to commence or recommend enforcement of the requirement that a smokeless tobacco manufacturer, distributor, importer, or retailer must have an FDA-approved rotational warning plan, so long as a rotational warning plan has been submitted to FDA by July 22, 2010. FDA believes that allowing additional time for the review of rotational warning plans will permit an orderly transition of regulatory authority from FTC to FDA to review and approve rotational warning plans. During such transition between June 22, 2010, and July 22, 2010, affected companies may wish to contact FDA to discuss the submission of their rotational warning plans in order to make the subsequent approval process more orderly and efficient. FDA intends to provide further public notice prior to revising or rescinding this enforcement policy after the transition from FTC to FDA has been accomplished for the submission and review of rotational warning plans. This enforcement policy pertains only to the requirement that smokeless tobacco manufacturers, distributors, importers, or retailers must have an FDA-approved rotational warning plan. FDA expects compliance with regard to all other requirements of section 3 of the Smokeless Tobacco Act, including the requirements relating to size, formatting, location, and use of required warning statements.

## II. Significance of Guidance

FDA is issuing this guidance document as a level 1 guidance consistent with FDA's good guidance practices regulations (21 CFR 10.115). This guidance is being implemented immediately without prior public comment under 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate. This document provides guidance on statutory provisions that take effect June 22, 2010. It is important that FDA explain its enforcement policy concerning the submission and approval of rotational warning plans for smokeless tobacco products before that date.

## III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary 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.

## IV. Electronic Access

An electronic version of this guidance document is available on the Internet at <http://www.regulations.gov> and <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: June 4, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0247]

### Investigational New Drug Applications; Co-development of Investigational Drugs

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

**ACTION:** Notice; establishment of docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is establishing a public docket to obtain input on methods to co-develop two or more distinct investigational drugs intended to be used in combination to treat a disease or condition. FDA is planning to develop guidance for industry and other affected parties on the co-development of two or more novel drugs intended to be used in combination (but not as not fixed-dose combinations) and is seeking public input to identify the affected parties' information needs concerning such co-development. Accordingly, FDA is seeking comment on general methodologic and regulatory issues that arise in various scenarios when co-developing two or more investigational drugs intended to be used in combination. FDA is also seeking comment on methodologic and regulatory issues when co-developing two or more investigational drugs

intended to be used in combination for specific therapeutic areas, including oncology, anti-infectives, seizure disorders, cardiovascular diseases, and any other therapeutic category in which such co-development is likely to occur.

**DATES:** Submit either electronic or written comments by September 7, 2010.

**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.regulations.gov>.

### FOR FURTHER INFORMATION CONTACT:

Colleen L. Locicero, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4200, Silver Spring, MD 20993-0002, 301-796-2270.

### SUPPLEMENTARY INFORMATION:

#### I. Background

FDA is aware of growing interest in co-developing two or more distinct, novel investigational drugs intended to be used in combination to treat a disease or condition (but not as fixed-dose combinations under 21 CFR 300.50). At a September 2009 conference co-hosted by the "Friends of Cancer Research" in partnership with the Engelberg Center for Health Care Reform at the Brookings Institution, and supported by the American Society for Clinical Oncology (ASCO), the American Association for Cancer Research (AACR) Susan G. Komen for the Cure, and the Lance Armstrong Foundation (Brookings Conference), which was attended by FDA scientists, there was considerable interest in approaches to developing new oncology therapies intended to be used in combination. In addition, on April 30, 2010, FDA held a public hearing in accordance with part 15 (21 CFR part 15) devoted, in part, to obtaining information about study designs and appropriate populations for developing two or more novel, direct-acting antivirals intended to be used in combination for the treatment of chronic hepatitis C. FDA is also aware of efforts to try to develop two or more investigational drugs intended to be used in combination to treat tuberculosis. FDA is further aware of general uncertainty about the evidentiary requirements and regulatory criteria applicable to such co-development efforts. Accordingly, FDA is planning to develop generally applicable guidance (not restricted to oncology or any other specific therapeutic category) to address

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 necessary 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.*

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## 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](mailto: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