public conduct during advisory committee meetings.

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

Dated: September 6, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–23130 Filed 9–9–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0128]

Prescription Drug User Fee Act; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA), which authorizes FDA to collect user fees and use them for the process for the review of human drug applications for fiscal years (FYs) 2013 through 2017. The legislative authority for PDUFA expires in September 2012. At that time, new legislation will be required for FDA to collect prescription drug user fees for future fiscal years. Following discussions with the regulated industry and periodic consultations with public stakeholders, the Federal Food, Drug, and Cosmetic Act (FD&C Act) directs FDA to publish the recommendations for the reauthorized program in the **Federal Register**, hold a meeting at which the public may present its views on such recommendations, and provide for a period of 30 days for the public to provide written comments on such recommendations. FDA will then consider such public views and comments and revise such recommendations as necessary.

DATES: The public meeting will be held on October 24, 2011, from 9 a.m. to 5 p.m. Registration to attend the meeting must be received by October 10, 2011. See section IV.B of this document for information on how to register for the meeting. Submit either electronic or written comments by October 24, 2011.

ADDRESSES: The meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503, Silver Spring, MD, 20993.

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. All comments should be identified with the docket number found in brackets in the heading of this document.

Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 30 days after the public meeting (see section IV.C of this document).

FOR FURTHER INFORMATION CONTACT: Sunanda Bahl, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 1168, Silver Spring, MD 20993, 301–796–3584, *fax:* 301–847–8443, *PDUFAReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing a public meeting to discuss proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA), which authorizes FDA to collect user fees and use them for the process of the review of human drug applications for FYs 2013 through 2017. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human drug review process. Section 736B(d)(4) (21 U.S.C. 379h–2(d)(4)) of the FD&C Act requires that after FDA holds negotiations with regulated industry and periodic consultations with stakeholders, we do the following: (1) Present recommendations to congressional committees, (2) publish recommendations in the **Federal Register**, (3) provide a period of 30 days for the public to provide written comments on the recommendations, (4) hold a meeting at which the public may present its views, and (5) after consideration of public views and comments, revise the recommendations as necessary.

This notice, the 30-day comment period, and the public meeting will satisfy some of these requirements. After the public meeting, we will revise the recommendations as necessary and present our proposed recommendations to the congressional committees.

The purpose of the meeting is to hear the public's views on the proposed recommendations for the reauthorized program (PDUFA V). The following information is provided to help potential meeting participants better understand the history and evolution of the PDUFA program and the current status of the proposed PDUFA V recommendations.

II. The PDUFA Program

A. What is PDUFA? What does it do?

FDA considers the timely review of the safety and effectiveness of new drug applications (NDAs) and biologics license applications (BLAs) to be central to the Agency's mission to protect and promote the public health. Prior to enactment of PDUFA in 1992, FDA's drug review process was not very predictable and was relatively slow compared to other countries. As a result of concerns expressed by both industry and patients, Congress enacted PDUFA, which provided the added funds through user fees that enabled FDA to hire additional reviewers and support staff and upgrade its information technology systems. At the same time, FDA committed to complete reviews in a predictable timeframe. These changes revolutionized the drug approval process in the United States and enabled FDA to speed the application review process for new drugs and biologics without compromising the Agency's high standards for demonstration of safety, efficacy, and quality of new drugs prior to approval.

B. PDUFA Achievements

PDUFA has produced significant benefits for public health, providing patients faster access to over 1,500 new drugs and biologics since enactment in 1992, including treatments for cancer, infectious diseases, neurological and psychiatric disorders, and cardiovascular diseases. The United States now leads the world in the first introduction of new active drug substances.[1] Since PDUFA was enacted, the median approval time of original NDAs and BLAs has been reduced by about 50 percent for standard applications (25.6 months in FY 1992 versus 13 months in FY 2009) and 55 percent for priority applications (19.9 months in FY 1992 versus 9 months in 2009).

Increased resources provided by user fees have also enabled FDA to provide a large body of technical guidance to industry that has clarified the drug development pathway for many diseases. These resources have also enhanced FDA's ability to meet with companies during drug development to

[1] Scrip NCE Review/Scrip Yearbook/Scrip Magazine (1982–2005), PharmaProjects R&D Annual Review (2006–2009).

provide critical advice on specific development programs. In the past 5 years alone, FDA has held over 7,000 meetings within a short time after a sponsor's request. Innovations in drug development are being advanced by many new companies as well as more established ones, and new sponsors may need, and often seek, more regulatory guidance during development. In FY 2009, more than half of the meetings FDA held with companies at the early investigational stage and midway through the clinical trial process were with companies that had no approved product on the U.S. market.

1. Application Review

PDUFA provides FDA with a source of stable, consistent funding that has made possible our efforts to focus on promoting innovative therapies and help bring to market critical products for patients. As part of the PDUFA agreement, FDA agrees to certain review performance goals, such as reviewing and acting on standard applications within 10 months and on priority applications within 6 months. Priority application reviews are for drugs that generally represent advances in public health, often targeted at severe illnesses where few or no therapeutic options exist.

PDUFA funds help support the use of existing mechanisms in place to expedite the approval of certain promising investigational drugs and also to make them available to the very ill as early in the development process as possible, without unduly jeopardizing the patients' safety.

One such program is the accelerated approval process, instituted by FDA in 1992. Accelerated approval allows earlier approval of drugs that treat serious diseases and that fill an unmet medical need. One pathway for accelerated approval is based on a surrogate endpoint—a marker used as substitute measurement to represent a clinically meaningful outcome, such as survival or symptom improvement—that is reasonably likely to predict clinical benefit; the other pathway bases approval on a clinical endpoint other than survival or irreversible morbidity. This program allows drugs to be approved before measures of effectiveness that would normally be required for approval are available. In these cases, approval is given on the condition that postmarketing clinical trials verify the anticipated clinical benefit. Over 100 critical products, including most HIV therapies and many cancer treatments, have been approved under accelerated approval since the program was established.

2. Drug Safety

In parallel with improvements in the drug review process, PDUFA funds have enabled FDA to increase its focus on drug safety, including implementing the Food and Drug Administration Amendments Act of 2007 (FDAAA). In FDAAA, Congress authorized additional user fees totaling $225 million for the 5 years of PDUFA IV reauthorization to enhance drug safety activities. FDAAA also provided FDA with important postmarket safety authorities. Under FDAAA, FDA was given the authority to require postmarketing studies and clinical trials to address important drug safety questions. Between the enactment of FDAAA on September 27, 2007, and June 1, 2011, FDA has required applicants to conduct approximately 375 postmarketing studies or trials to address important drug safety questions that could not be addressed before the drug was approved. FDAAA also gave FDA the authority to require safety labeling changes based on new safety information identified after a drug is on the market. FDA has used its new authority to require applicants to place important new safety information onto their drug labels quickly, in some cases using this authority to require changes to the labeling of all members of a class of drugs. FDAAA also provided FDA with authority to manage risks associated with marketed drug products through required risk evaluation and mitigation strategies (REMS). FDA has been using this new authority judiciously to ensure that drugs that could not otherwise be approved because the risks without a REMS would outweigh the benefits, are available to patients.

FDA has implemented other important drug safety initiatives under FDAAA including, for example, initiating systematic reviews of the safety of marketed drugs 18 months after approval; conducting regular screening of the adverse event reporting system database and posting quarterly reports of new safety information or potential signals of serious risks identified from that screening; and developing an active post-market drug safety surveillance capability under the ''Sentinel'' initiative (*http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm2007250.htm*).

III. Proposed PDUFA V Recommendations

In preparing the proposed recommendations to Congress for PDUFA reauthorization, we have conducted discussions with the regulated industry, and we have consulted with stakeholders as required by the law. We began the PDUFA reauthorization process with a public meeting held on April 12, 2010 (75 FR 12555, March 16, 2010). The meeting included presentations by FDA and a series of panels representing different stakeholder groups, including patient advocates, consumer groups, regulated industry, health professionals, and academic researchers. The stakeholders were asked to respond to the following questions:

1. What is your assessment of the overall performance of the PDUFA IV program thus far?

2. What aspects of PDUFA should be retained, changed, or discontinued to further strengthen and improve the program?

Following the April 2010 public meeting, FDA conducted negotiations with regulated industry and continued monthly consultations with public stakeholders from July 2010 through May 2011. As directed by Congress, FDA posted minutes of these discussions on its Web site at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm117890.htm*. The proposed enhancements for PDUFA V address many of the top priorities identified by public stakeholders, the top concerns identified by regulated industry, and the most important challenges identified within FDA. These include a new review program for new molecular entity NDAs and original BLAs, proposals to enhance regulatory science and expedite drug development, enhanced benefit-risk assessment, modernization of FDA's drug safety system, requirements for electronic submissions with standardized application data, a technical correction related to discontinued products, and modifications to the PDUFA inflation adjuster with continued evaluation of the workload adjuster. The full descriptions of these proposed enhancements can be found in the draft PDUFA V commitment letter (draft commitment letter) posted on FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm149212.htm*. Each enhancement is briefly described below with reference to the section of the draft commitment letter where more detailed information can be found.

A. A Review Program for New Drug Applications (NDA), New Molecular Entities (NME), and Original Biologics License Applications (BLA)

FDA's existing review performance goals for priority and standard

applications, 6 and 10 months respectively, were established in 1997. Since that time, additional requirements in the drug review process have made those goals increasingly challenging to meet, particularly for more complex applications like NME NDAs and original BLAs. FDA also recognizes that increasing communication between the Agency and sponsors or applicants during the application review has the potential to increase efficiency in the review process. To address the desire for increased communication and efficiency, FDA proposes a new review program for NME NDAs and original BLAs in PDUFA V that will include presubmission meetings, mid-cycle communications, and late-cycle meetings between FDA and sponsors for these applications. FDA's review clock will begin after the 60-day administrative filing review period to accommodate this increased interaction during regulatory review. The impact of these modifications on the efficiency of drug review for this subset of applications would be assessed during PDUFA V.

B. Enhancing Regulatory Science and Expediting Drug Development

The following five enhancements focus on enhancing regulatory science and expediting drug development. Regulatory science is the science of developing and applying new tools, standards, and approaches to assess the safety, effectiveness, quality, and performance of FDA-regulated products. The details of these enhancements can be found in section IX of the draft commitment letter.

1. Promoting Innovation Through Enhanced Communication Between FDA and Sponsors During Drug Development

FDA recognizes that timely interactive communication with sponsors can help foster efficient and effective drug development. In some cases, a sponsor's questions may be complex enough to require a formal meeting with FDA, but in other instances, a question may be relatively straightforward such that a response can be provided more quickly. However, our review staff's workload and other competing public health priorities can make it challenging to develop an Agency response to matters outside of the formal meeting process.

This enhancement involves a dedicated drug development communication and training staff, focused on improving communication between FDA and sponsors during development. This staff will be responsible for identifying best practices for communication between the Agency and sponsors, training review staff, and disseminating best practices through published guidance.

2. Methods for Meta-Analysis

A meta-analysis typically attempts to combine the data or findings from multiple completed studies to explore drug benefits and risks and, in some cases, uncover what might be a potential safety signal in a premarket or postmarket context. However, there is no consensus on best practices in conducting a meta-analysis. With the growing availability of clinical trial data, an increasing number of meta-analyses are being conducted based on varying sets of data and assumptions. If such studies conducted outside FDA find a potential safety signal, FDA will work to try to confirm—or correct—the information about a potential harm that will create uncertainty for patients and health professionals. To do this, FDA must work quickly to conduct its own meta-analyses of publicly available data and the raw clinical trial data submitted by drug sponsors that would typically not be available to outside researchers. This is resource-intensive work that often exceeds the Agency's current scientific and computational capacity, causing delays in FDA findings that prolong public uncertainty.

This proposed recommendation includes the development of a dedicated staff to evaluate best practices and limitations in meta-analysis methods. Through a rigorous public comment process, FDA will develop guidance on best practices and the Agency's approach to meta-analysis in regulatory review and decision-making.

3. Biomarkers and Pharmacogenomics

Pharmacogenomics and the application of qualified biomarkers have the potential to decrease drug development time by helping to demonstrate benefits, to recognize unmet medical needs, and to identify patients who are predisposed to adverse events. FDA provides regulatory advice on the use of biomarkers to facilitate the assessment of human safety in early phase clinical studies to support claims of efficacy and to establish the optimal dose selection for pivotal efficacy studies. This is an area of new science where the Agency has seen a marked increase in sponsor submissions to FDA. In the 2008 to 2010 period, the Agency experienced nearly a four-fold increase in this type of review work.

In PDUFA V, FDA will augment the Agency's clinical, clinical pharmacology, and statistical capacity to adequately address submissions that propose to utilize biomarkers or pharmacogenomic markers. The Agency will also hold a public meeting to discuss potential strategies to facilitate scientific exchanges on biomarker issues between FDA and drug manufacturers.

4. Use of Patient-Reported Outcomes (PRO)

Assessments of study endpoints known as patient-reported outcomes (PROs) are increasingly an important part of successful drug development. PROs measure treatment benefit or risk in medical product clinical trials from the patients' point of view. PROs are critical in understanding the drug benefits and harm from the patients' perspective. However, PROs require rigorous evaluation and statistical design and analysis to ensure reliability to support claims of clinical benefit. Early consultation between FDA and drug sponsors can ensure that endpoints are well-defined and reliable. However, the Agency does not have the capacity to meet the current demand from industry.

This initiative will improve FDA's clinical and statistical capacity to address submissions involving PROs and other endpoint assessment tools, including providing consultation to sponsors during the early stages of drug development. In addition, FDA will convene a public meeting to discuss standards for PRO qualification, new theories in endpoint measurement, and the implications for multinational trials.

5. Development of Drugs for Rare Diseases

FDA's oversight of rare disease drug development is complex and resource intensive. Rare diseases are a highly diverse collection of disorders, their natural histories are often not well-described, only small population sizes are often available for study, and the diseases do not usually have well-defined outcome measures. This makes the design, execution, and interpretation of clinical trials for rare diseases difficult and time consuming, requiring frequent interaction between FDA and drug sponsors. If recent trends in orphan designations are any indication, FDA can expect an increase in investigational activity and marketing applications for drug products for rare diseases in the future.

This PDUFA V enhancement includes FDA facilitation of rare disease drug development by issuing relevant guidance, increasing the Agency's outreach efforts to the rare disease patient community, and providing specialized training in rare disease drug

development for sponsors and FDA staff.

C. Enhancing Benefit-Risk Assessment

FDA has been exploring how to develop an enhanced structured approach to benefit-risk assessments that accurately and concisely describes the benefit and risk considerations in the Agency's drug regulatory decision-making. Part of FDA's decision-making lies in thinking about the context of the decision, including gaining a strong understanding of the condition treated and the nature and extent of the unmet medical need. Patients who live with a disease have a direct stake in the outcome of the drug review process. The FDA drug review process could benefit from a more systematic and expansive approach to obtaining the patient perspective on disease severity and the potential gaps or limitations in available treatments in a therapeutic area.

During PDUFA V, FDA will expand its use of a benefit-risk framework in the drug review process, including holding public workshops to discuss the application of frameworks for considering benefits and risks that are most appropriate for the regulatory setting. FDA will also conduct a series of public meetings with the relevant patient advocacy communities to review the medical products available for use in specific therapeutic areas. The therapeutic areas to be discussed will be chosen through a public process. This enhancement is discussed in section X of the draft commitment letter.

D. Enhancement and Modernization of the FDA Drug Safety System

The drug safety enhancements in PDUFA V focus on FDA's use of REMS and the Sentinel Initiative. Additional information on these proposals is found in section XI of the draft commitment letter.

1. Standardizing REMS

FDAAA gave FDA authority to require a REMS when FDA finds that a REMS is necessary to ensure that the benefits of a drug outweigh its risks. Some REMS are more restrictive types of risk management programs that include elements to assure safe use (ETASU). These programs can require such tools as prescriber training or certification, pharmacy training or certification, dispensing only in certain health care settings, documentation of safe use conditions, patient monitoring, and patient registries. ETASU REMS can be challenging to implement and evaluate, involving cooperation of all segments of the health care system. Our experience with REMS to date suggests that the development of multiple individual programs has the potential to create burdens on the health care system and, in some cases, could limit appropriate patient access to important therapies.

FDA will initiate a public process in PDUFA V to explore strategies and initiate projects to standardize REMS programs with the goal of reducing burden on practitioners, patients, and others in the health care setting. In addition, FDA will conduct public workshops and develop guidance on methods for assessing the effectiveness of REMS and the impact on patient access and burden on the health care system.

2. Using the Sentinel Initiative To Evaluate Drug Safety Issues

FDA's Sentinel Initiative is a long-term program designed to build and implement a national electronic system for monitoring the safety of FDA-approved medical products. FDAAA required FDA to collaborate with Federal, academic, and private entities to develop methods to obtain access to disparate data sources and validated means to link and analyze safety data to monitor the safety of drugs after they reach the market, an activity also known as ''active postmarket drug safety surveillance.'' FDA will conduct a series of activities during PDUFA V to determine the feasibility of using Sentinel to evaluate drug safety issues that may require regulatory action (*e.g.,* labeling changes, post-marketing requirements, or postmarketing commitments). This may shorten the time it takes to better understand new or emerging drug safety issues. By leveraging public and private health care data sources to quickly evaluate drug safety issues; this proposal may reduce the Agency's reliance on required postmarketing studies and clinical trials.

E. Required Electronic Submissions and Standardization of Electronic Application Data

The predictability of the FDA review process relies heavily on the quality of sponsor and applicant submissions. The Agency currently receives submissions of original applications and supplements in formats ranging from paper-only to electronic-only, as well as hybrids of the two media. The variability and unpredictability of submitted formats and clinical data layout present major obstacles to conducting a timely, efficient, and rigorous review within current PDUFA goal time frames. A lack of standardized data also limits FDA's ability to transition to more standardized approaches to benefit-risk assessment and impedes conduct of safety analyses that inform FDA decisions related to REMS and other postmarketing requirements. The PDUFA V enhancements in this area include a phased-in requirement for standardized, fully electronic submissions for all marketing and investigational applications. Through partnership with open standards development organizations, the Agency will also conduct a public process to develop standardized terminology for clinical and nonclinical data submitted in marketing and investigational applications. More information on this initiative can be found in section XII of the draft commitment letter.

F. Technical Change to Section 736(a)(3)(B) of the FD&C Act Related to Discontinued Products

FDA proposes to amend section 736(a)(3)(B) of the FD&C Act, which provides for an exception in assessing a product fee if the same product is approved as an NDA or ANDA. This amendment will clarify FDA's long-standing policy to use the active portion of the Prescription Drug Product List in the ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (generally know as the ''Orange Book'') to identify fee-eligible prescription drug products. FDA will assess a product fee on a prescription drug product when there are no other products on the Prescription Drug Product List that are the same as that product.

G. PDUFA V Enhancements for a Modified Inflation Adjuster and Additional Evaluations of the Workload Adjuster

In calculating user fees for each new fiscal year, FDA adjusts the base revenue amount by inflation and workload as specified in the statute. PDUFA V financial enhancements include a modification to the inflation adjuster to more accurately account for changes in FDA's costs related to payroll compensation and benefits as well as changes in non-payroll costs through use of the Consumer Price Index (CPI). This new weighted composite inflation adjuster will help ensure that increases in fees more closely mirror the inflationary pressures that have an impact on FDA's costs. FDA will also continue evaluating the workload adjuster that was developed during the PDUFA IV negotiations to ensure that it continues to adequately capture changes in FDA's workload during PDUFA V. These evaluations will include options to discontinue,

modify, or retain any element of the workload adjuster.

H. Impact of PDUFA V Enhancements on User Fee Revenue

Implementing the proposed enhancements discussed in the previous sections of this document will add $40.4 million to the PDUFA user fee revenue amount in FY 2012. The fee revenue amount for FY 2012 is $652,709,000 as published by notice in the **Federal Register** of August 1, 2011 (76 FR 45831). This amount includes the additional user fee revenues for drug safety in FY 2012 totaling $65 million as specified in the statute. The additional user fee revenue for the PDUFA V enhancements translates to a 6-percent increase, and a total base of $693.1 million in FY 2013. The following table summarizes the FY 2013 baseline and added resources to support the new PDUFA V enhancements:

Financial baseline	Dollars
FY 2012 Baseline [1]	$499,412,000
Cumulative Inflation Adjustment for FY 2012	104,277,000
Cumulative Workload Adjustment for FY 2012	49,020,000
Fee Revenue Amount for FY 2012 [2]	652,709,000
PDUFA V Enhancements	
Increased Staff Capacity (129 FTE)	36,120,000
Other Direct Costs	4,270,000
Total Statutory Revenue Amount for FY 2013 [3]	693,099,000

[1] In determining the fee revenue amount for FY 2012, sections 736(b)(4)(A) and 736(b)(4)(B) of the FD&C Act direct the Secretary of Health and Human Services (Secretary) to substitute $392,783,000 plus $65,000,000 (for FY 2012) for the amount in paragraph (1)(A). Furthermore, paragraph (1)(B) directs the Secretary to add the amount of the modified workload adjustment for FY 2007 to the amount in paragraph (1)(A) to determine the total revenue amount in FY 2012. This total is $499,412,000.

[2] As published in the **Federal Register** of August 1, 2011 (76 FR 45831).

[3] Of this amount, $652,709,000 will be further adjusted according to the new statutory provisions to account for inflation and workload adjustments in determining fees for FY 2013. These adjustments must be captured in calculations of user fee revenue for FYs 2014–2017.

IV. What information should you know about the meeting?

A. When and where will the meeting occur? What format will FDA use?

We will convene a public meeting to hear the public's views on the proposed recommendations for reauthorization of PDUFA. We will conduct the meeting on October 24, 2011, at FDA's White Oak Campus (see **ADDRESSES**). The meeting will include a presentation by FDA and a series of panels representing different stakeholder groups identified in the statute (such as patient advocacy groups, consumer advocacy groups, health professionals, and regulated industry). We will also provide an opportunity for other organizations and individuals to make presentations at the meeting or to submit written comments to the docket before the meeting.

B. How do you register for the meeting or submit comments?

If you wish to attend this meeting, please register by e-mail at: *PDUFAReauthorization@fda.hhs.gov* by October 10, 2011. Your e-mail should contain complete contact information for each attendee, including: Name, title, affiliation, address, e-mail address, and phone number. Registration is free and will be on a first-come, first-served basis, with the exception below. 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. On-site registration on the day of the meeting will be based on space availability. We will try to accommodate all persons who wish to make a presentation. If you need special accommodations because of disability, please contact Sunanda Bahl (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

In addition, 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. To ensure consideration, all comments must be received by October 31, 2011.

C. Will meeting transcripts be available?

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov* and *http://www.fda.gov*. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be made available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: September 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–23251 Filed 9–9–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that industry organizations interested in participating in the selection of nonvoting industry representatives to serve on its Tobacco Products Scientific Advisory Committee, notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on the Tobacco Products Scientific Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for upcoming vacancies effective with this notice.

DATES: Send letters stating interest in participating in the selection process to FDA by October 12, 2011 (see sections I and II of this document for details). Concurrently, nomination material for prospective candidates should be sent to FDA by October 12, 2011.

ADDRESSES: All letters of interest and nominations should be submitted in writing to *TPSAC@fda.hhs.gov,* or by mail to Caryn Cohen, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Caryn Cohen, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373 (choose Option 4), FAX: 240–276–3761, e-mail: *TPSAC@fda.hhs.gov.*