international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based, harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify, and then reduce, differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency, European Federation of Animal Health, Committee on Veterinary Medicinal Products, FDA, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Six observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, one representative from the industry of Canada, one representative from the government of South Africa, and one representative from the industry of South Africa. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

In the **Federal Register** of March 5, 2013 (78 FR 14306), FDA published a notice of availability for a draft revised guidance document entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing'' (VICH GL23(R)) giving interested persons until May 6, 2013, to comment on the draft revised guidance. FDA received one comment on the draft revised guidance, and that comment, as well as those received by other VICH member regulatory agencies, were considered as the guidance was finalized. The guidance announced in this document finalizes the draft revised guidance dated March 5, 2013. The revised guidance is a product of the Safety Expert Working Group of the VICH.

This revised VICH guidance document recommends a second test to evaluate the potential of a chemical to produce chromosomal effects. The revised VICH guidance indicates that the potential of a chemical to produce chromosomal effects can be evaluated using one of the following three tests: (1) An *in vitro* chromosomal aberrations test using metaphase analysis, which detects both clastogenicity and aneugenicity; (2) an *in vitro* mammalian cell micronucleus test, which detects the activity of clastogenicity and aneugenicity; or (3) a mouse lymphoma test, which, with modification, can detect both gene mutation and chromosomal damage. This revised VICH guidance is intended to facilitate the mutual acceptance of safety data necessary for the establishment of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory authorities. The objective of this revised VICH guidance is to ensure international harmonization of genotoxicity testing.

II. Significance of Guidance

This guidance, developed under the VICH process, is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

IV. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

VI. Electronic Access

Persons with access to the Internet may obtain the revised guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: May 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11527 Filed 5–12–15; 8:45 am]

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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; 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 or Agency) is announcing a public meeting on the reauthorization of the Prescription Drug User Fee Act (PDUFA) for fiscal years (FYs) 2018 through 2022. PDUFA authorizes FDA to collect user fees for the process for the review of human drugs. The current legislative authority for PDUFA expires in September 2017. At that time, new legislation will be required for FDA to continue collecting user fees in future fiscal years. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA begin the PDUFA reauthorization process by publishing a notice in the **Federal Register** requesting public input and holding a public meeting where the public may present its views on the reauthorization. FDA invites public comment as the Agency begins the

process to reauthorize the program in FYs 2018–2022.

DATES: The public meeting will be held on July 15, 2015, from 9 a.m. to 2 p.m. Registration to attend the meeting must be received by June 30, 2015. See section III.B for information on how to register for the meeting. Submit either electronic or written comments by August 15, 2015.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Sections B and C of the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

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 on the FDA Web site (*http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM2005475.htm)* approximately 30 days after the meeting.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993, 301–796–5003, FAX: 301–847–8443.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing a public meeting to begin the reauthorization process of PDUFA, the legislation that authorizes FDA to collect user fees for the process for the review of human drugs by various components in FDA including the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of the Commissioner, and the Office of Regulatory Affairs. The current authorization of the program (PDUFA V) expires in September 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)(2) (21 U.S.C. 379h–2(d)(2)) of the FD&C Act requires that before FDA begins negotiations with the regulated industry on PDUFA reauthorization, we do the following: (1) Publish a notice in the **Federal Register** requesting public input on the reauthorization, (2) hold a public meeting where the public may present its views on the reauthorization, (3) provide a period of 30 days after the public meeting to obtain written comments from the public, and (4) publish the comments on the FDA Web site at *http://www.regulations.gov.* This notice, the public meeting, the 30-day comment period after the meeting, and the posting of the comments on the FDA Web site will satisfy these requirements. The purpose of the meeting is to hear stakeholder views on PDUFA as we consider the features to propose, update, and discontinue in the next PDUFA. FDA is interested in responses to the following three questions and welcomes any other pertinent information stakeholders would like to share:

- What is your assessment of the overall performance of PDUFA V thus far?
- What current features of PDUFA should be reduced or discontinued to ensure the continued efficiency and effectiveness of the human drug review process?
- What new features should FDA consider adding to the program to enhance the efficiency and effectiveness of the human drug review process?

The following information is provided to help potential meeting participants better understand the history and evolution of PDUFA and its current status.

II. What is PDUFA? What does it do?

PDUFA is a law that authorizes FDA to collect fees from drug companies that submit marketing applications for certain human drug and biological products. PDUFA was originally enacted in 1992 as the Prescription Drug User Fee Act (Pub. L. 102–571) for a period of 5 years. In 1997, Congress passed the FDA Modernization Act of 1997 (FDAMA, Pub. L. 105–115) which reauthorized the program (PDUFA II) for an additional 5 years. In 2002, Congress extended PDUFA again through FY 2007 (PDUFA III) in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188). In 2007, Title I of the Food and Drug Administration Amendments Act of 2007 (FDAAA, Pub. L. 110–85) reauthorized PDUFA through FY 2012 (PDUFA IV). Most recently, PDUFA was reauthorized through FY 2017 (PDUFA V) as Title I of the Food and Drug Administration Safety and Innovation Act (FDASIA, Pub. L. 112–144).

PDUFA's intent is to provide additional revenues so that FDA can hire more staff, improve systems, and establish a better managed human drug review process to make important therapies available to patients sooner without compromising review quality or FDA's high standards for safety, efficacy, and quality. As part of FDA's agreement with industry during each reauthorization, the Agency agrees to certain performance goals. These goals apply to the process for the review of original new human drug and biological product applications, resubmissions of original applications, and supplements to approved applications. During the first few years of PDUFA I, the additional funding enabled FDA to eliminate backlogs of original applications and supplements. Phased in over the 5 years of PDUFA I, the goals were to review and act on 90 percent of priority new drug applications (NDAs), biologics license applications (BLAs), and efficacy supplements within 6 months of submission of a complete application; to review and act on 90 percent of standard original NDAs, BLAs, and efficacy supplements within 12 months, and to review and act on resubmissions and manufacturing supplements within 6 months. Over the course of PDUFA I, FDA exceeded all of these performance goals and significantly reduced median review times of both priority and standard NDAs and BLAs.

Under PDUFA II, the review performance goals were shortened and new procedural goals were added to improve FDA's interactions with industry sponsors and to help facilitate the drug development process. The procedural goals, for example, articulated timeframes for scheduling sponsor-requested meetings intended to address issues or questions regarding specific drug development programs, as well as timeframes for the timely response to industry-submitted questions on special study protocols. FDA met or exceeded nearly all of the review and procedural goals under PDUFA II. However, concerns grew that overworked review teams often had to return applications as ''approvable'' because they did not have the resources and sufficient staff time to work with the sponsors to resolve issues so that applications could be approved in the first review cycle.

A sound financial footing and support for limited postmarket risk management were key themes of PDUFA III. Base user fee resources were significantly increased and a mechanism to account for changes in human drug review workload was adopted. PDUFA III also

expanded the scope of user fee activities to include postmarket surveillance of new therapies for up to 3 years after marketing approval. FDA committed to the development of guidance for industry on risk assessment, risk management, and pharmacovigilance as well as guidance to review staff and industry on Good Review Management Principles and Practices (GRMPs). Initiatives to improve application submission and Agency-sponsor interactions during the drug development and application review processes were also adopted.

With PDUFA's reauthorization under FDAAA Title I (PDUFA IV), FDA obtained a significant increase in base fee funding and committed to full implementation of GRMPs, which includes providing a planned review timeline for premarket review, development of new guidance for industry on innovative clinical trials, modernization of postmarket safety, and elimination of the 3-year limitation on fee support for postmarket surveillance. Additional provisions in FDAAA (Titles IV, V, and IX) gave FDA additional statutory authority that increased the pre- and postmarket review process requirements, added new deadlines, and effectively increased review workload. Specifically, the new provisions expanded FDA's drug safety authorities such as the authority to require risk evaluation mitigation strategies (REMS), order safety labeling changes, and require postmarket studies.

With the current authorization of PDUFA under Title I of FDASIA, FDA implemented a new review program (''the Program'') to promote greater transparency and increase communication between the FDA review team and the applicant on the most innovative products reviewed by the Agency. The Program applies to all new molecular entity (NME) NDAs and original BLAs received by the Agency from October 1, 2012 through September 30, 2017. The Program adds new opportunities for communication between the FDA review team and the applicant during review of a marketing application, including mid-cycle communications and late-cycle meetings, while adding 60 days to the review clock to provide for this increased interaction and to address review issues for these complex applications. PDUFA V also required two assessments of the impact of the Program. The first of these, the interim assessment, is available on FDA's Web site at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM436448.pdf.*

In addition to continued commitment to a significant set of review, processing, and procedural goals, PDUFA V also included commitments related to enhancing regulatory science and expediting drug development, enhancing benefit-risk assessment in regulatory decisionmaking, modernizing the FDA drug safety system, and improving the efficiency of human drug review by requiring electronic submissions and standardization of electronic drug application data. The PDUFA V Commitment Letter (available at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf)* requires that FDA report on the progress in satisfying these commitments in the annual PDUFA performance report. The FY 2014 report can be found at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm440180.htm.* More information about FDA's implementation of PDUFA V can also be found at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm.* Key **Federal Register** documents, PDUFA-related guidances, performance reports, and financial reports can also be found at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm.*

III. Public Meeting Information

A. Purpose and Scope of the Meeting

Through this notice, FDA is announcing a public meeting to hear stakeholder views on what features the Agency should propose in the reauthorization of PDUFA for FYs 2018–2022. In general, the meeting format most likely will include presentations by FDA and a series of panels representing different stakeholder groups. We will also provide an opportunity for other stakeholders to provide public comment at the meeting. FDA policy issues are beyond the scope of these reauthorization discussions. Accordingly, the presentations should focus on process enhancements and funding issues, and not focus on policy issues.

Please consider the following questions for this meeting:

- What is your assessment of the overall performance of PDUFA V thus far?
- What new features should FDA consider adding to the program to enhance the efficiency and effectiveness of the human drug review process?
- What current features of PDUFA should be reduced or discontinued to ensure the continued efficiency and effectiveness of the human drug review process?

B. Meeting Attendance and Participation

We will conduct the meeting on July 15, 2015, at Building 31 of the FDA White Oak Campus (see **ADDRESSES**). If you wish to attend this meeting, visit *http://pdufapublicmeeting.eventbrite.com.* Please register by June 30, 2015. If you are unable to attend the meeting in person, you can register to view a live Web cast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Web cast. Your registration must also contain your complete contact information, including name, title, affiliation, address, email address, and phone number. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once their registrations have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Graham Thompson (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

In addition, any person may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.* To ensure consideration, all comments must be received by August 15, 2015.

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM2005475.htm.*

Dated: May 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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