

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0196]

**Food and Drug Administration Prescription Drug User Fee Act V Benefit-Risk Plan; Request for Comments**

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

**ACTION:** Notice, request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft 5-year plan describing the Agency's approach to further developing and implementing a structured framework for benefit-risk assessment in the human drug and biologic review process and the opportunity for public comment on the draft plan. This plan is part of FDA's commitments that were made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). FDA has published the draft plan on its Web site at <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf>.

**DATES:** Submit either electronic or written comments by May 7, 2013.

**ADDRESSES:** Submit electronic comments to [www.regulations.gov](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.

**FOR FURTHER INFORMATION CONTACT:** Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1199, Silver Spring, MD 20993, 301-796-5003, FAX: 301-847-8443, Email: [Graham.Thompson@fda.hhs.gov](mailto:Graham.Thompson@fda.hhs.gov); or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA), (Pub. L. 112-144). Section 905 of FDASIA amends section 505(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by requiring

FDA to "implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs." Title I of FDASIA reauthorizes PDUFA and provides FDA with the user fee resources necessary to maintain an efficient review process for human drug and biological products. The reauthorization of PDUFA includes performance goals and procedures for the Agency that represent FDA's commitments during fiscal years 2013-2017. These commitments are fully described in the document entitled "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017" ("PDUFA Goals Document"), available on FDA's Web site at <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf>. Section X of the PDUFA Goals Document, titled "Enhancing Benefit-Risk Assessment in Regulatory Decisionmaking," addresses the development of a 5-year plan that describes the Agency's approach to further develop and implement a structured benefit-risk framework in its human drug and biologic review process. The publication and implementation of this plan are intended to fulfill the requirement in section 905 of FDASIA and the commitments described in Section X of the PDUFA Goals Document.

**II. Draft Plan Describing Structured Approach to Benefit-Risk Assessment**

Ensuring the safety, effectiveness, and quality of human drugs is a complicated regulatory task, requiring FDA's consideration of a multitude of complex factors. FDA's regulatory decision making process takes into consideration not only the data submitted in a marketing application, but also a broad set of additional factors, including the clinical context for the proposed product (such as the nature and severity of the disease or condition that the proposed product is intended to treat or prevent and the benefits and risks of other available therapies for that disease or condition) and any risk management tools that might be necessary to ensure that the benefits of the proposed product outweigh its risks.

FDA believes that implementing a standardized structure for the analysis of the various benefit and risk considerations that make up a regulatory decision will help to facilitate balanced and consistent

consideration of the benefit and risk factors during the review process and to enhance the transparency of regulatory review. FDA therefore has developed a draft plan describing a benefit-risk assessment framework that is designed to make explicit the consideration of the various benefit-risk factors and the role of those factors in the regulatory decision-making process for human drug and biological product marketing applications. It is important to note that, as specified in section 905 of FDASIA, this framework does not change the criteria for approval of a drug or biological product. All new drug applications and biological license applications must meet the requirements for approval under the FD&C Act and the Public Health Service Act, respectively.

By clearly articulating FDA's key considerations in a standard structure, this framework can serve as an important tool for the analysis and discussion of the relevant benefit and risk considerations during the review process. A second and equally important purpose of the benefit-risk framework is that it can serve as a tool to communicate the reasoning of FDA's regulatory decisions to the public. When FDA approves a new drug or biological product, it generally posts decisional memos on the Agency's Web site. These documents may be highly technical and may not be easily understandable to a broad audience with varying backgrounds. The benefit-risk framework aims to enhance FDA's communication of its decisions by making clear the important considerations in the Agency's decision-making process, and how they affected the final regulatory decision, in a clear, succinct summary.

With this notice, FDA is announcing the availability of a draft 5-year plan describing the Agency's approach to further developing and implementing the benefit-risk framework and the opportunity for the public to comment on the plan. FDA has published the plan on the Agency's Web site at <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf>. The comment period will remain open for 60 days following the publication of this notice. After consideration of public comments, FDA will finalize the plan. Throughout PDUFA V, the Agency will update the plan as necessary and post all updates on the FDA's Web site.

Dated: March 5, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Report on Carcinogens Webinar on Pentachlorophenol; Notice of Public Webinar and Registration Information

**SUMMARY:** The National Toxicology Program (NTP) announces a public webinar, "Human cancer studies on exposure to pentachlorophenol (PCP): Differentiating potential cancer effects of PCP exposure from effects due to occupational co-exposures or PCP contaminants." The Office of the Report on Carcinogens (ORoC), Division of the NTP (DNTP), National Institute of Environmental Health Sciences (NIEHS) will hold the webinar using Adobe® Connect™, and the public can register to attend.

**DATES:**

*Webinar:* April 11, 2013, 12:30 p.m. to approximately 5:00 p.m. Eastern Daylight Time (EDT).

*Pre-Registration for Webinar:* March 8, 2013 to April 8, 2013.

**ADDRESSES:**

*Webinar Web page:* The agenda, speaker abstracts, registration, and other meeting materials are at <http://ntp.niehs.nih.gov/go/pcpwebinar>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Ruth M. Lunn, Director, ORoC, DNTP, NIEHS, P.O. Box 12233, MD K2-14, Research Triangle Park, NC 27709. Phone: (919) 316-4637; Fax: (301) 480-2970, Email: [lunn@niehs.nih.gov](mailto:lunn@niehs.nih.gov). Hand Delivery/Courier: 530 Davis Drive, Room 2138, Morrisville, NC 27560.

**SUPPLEMENTARY INFORMATION:**

*Background:* The Report on Carcinogens (RoC) is a congressionally mandated, science-based, public health report that identifies agents, substances, mixtures, or exposures (collectively called "substances") in our environment that are cancer hazards for people living in the United States. The NTP prepares the RoC on behalf of the Secretary of Health and Human Services following an established, four-part process (<http://ntp.niehs.nih.gov/go/rocprocess>).

PCP, including its sodium salt, is a chlorinated aromatic compound that is used primarily as a wood preservative in the United States. It was selected as a candidate substance following solicitation of public comment and review by the NTP Board of Scientific

Counselors on June 21–22, 2012 (<http://ntp.niehs.nih.gov/go/9741>) (for more information on the status of NTP review of PCP see <http://ntp.niehs.nih.gov/go/37897>).

The objective of the webinar is to provide scientific input to the ORoC on issues related to its approach for evaluating the epidemiologic studies on exposure to PCP and not to receive recommendations from invited speakers or the public on whether or not PCP should be listed in the RoC. The webinar will consist of (1) four presentations, each of which will be followed by a short question and answer period specific for the presentation, and (2) a discussion session across presentations. The goals of the individual presentations are (1) to identify occupational co-exposures and PCP components or contaminants in human epidemiologic studies of exposure to PCP, (2) to identify which co-exposures should be considered as potential confounders, and (3) to discuss the methods used in the epidemiologic studies to evaluate confounding.

*Webinar and Registration:* The webinar is scheduled for April 11, 2013, from 12:30 to approximately 5 p.m. e.d.t. The webinar may end early if the presentations and general discussion period are finished. The public may register for the webinar beginning March 8, 2013, through April 8, 2013, at <http://ntp.niehs.nih.gov/go/pcpwebinar>. There will be 50 connections available on a first-come, first-served basis for registrants. Registrants will receive instructions by email to access the webinar (via Adobe® Connect™) on or before April 9, 2013.

The preliminary agenda, list of speakers, and abstracts of the presentations should be posted on the NTP Web site (<http://ntp.niehs.nih.gov/go/pcpwebinar>) by March 26, 2013. Registrants are encouraged to access the webinar Web page to stay abreast of the most current information regarding this event. Any updates will be posted to the Web site.

*Public Participation:* Time will be set aside following each presentation and during the general discussion period after the talks are finished for the public to ask questions or make brief remarks. Instructions for participating in the meeting via Adobe® Connect™ will be included in the information for accessing the webinar. Individuals with disabilities who need accommodation to participate in this event should contact Dr. Lunn. TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at least

five business days in advance of the event.

*Background Information on the RoC:* Published biennially, each edition of the RoC is cumulative and consists of substances newly reviewed in addition to those listed in previous editions. The 12th RoC, the latest edition, was published on June 10, 2011 (available at <http://ntp.niehs.nih.gov/go/roc12>). The 13th RoC is under development. For each listed substance, the RoC contains a substance profile, which provides information on: Cancer studies that support the listing—including those in humans, animals, and studies on possible mechanisms of action—information about potential sources of exposure to humans, and current Federal regulations to limit exposures.

Dated: March 4, 2013.

**John R. Bucher,**

*Associate Director, National Toxicology Program.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; Review K99 Grant Applications.

*Date:* April 3, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* John J. Laffan, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.18J, Bethesda, MD 20892, 301-594-2773, [laffanjo@mail.nih.gov](mailto:laffanjo@mail.nih.gov).