

Xenobiotic and Nutrient Disposition and Action Study Section.

Date: October 6, 2010.

Time: 8 a.m. to 6 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: Patricia Greenwel, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2172, MSC 7818, Bethesda, MD 20892. 301-435-1169. greenwep@csr.nih.gov.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group, Myocardial Ischemia and Metabolism Study Section.

Date: October 6-7, 2010.

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

Agenda: To review and evaluate grant applications.

Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

Contact Person: Joseph Thomas Peterson, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892. 301-443-8130. peterstonjt@csr.nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group, Gene and Drug Delivery Systems Study Section.

Date: October 6-7, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Hotel Nikko San Francisco, 222 Mason Street, San Francisco, CA 94102.

Contact Person: Amy L Rubinstein, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5152, MSC 7844, Bethesda, MD 20892. 301-408-9754. rubinsteinal@csr.nih.gov.

Name of Committee: Cell Biology Integrated Review Group, Molecular and Integrative Signal Transduction Study Section.

Date: October 6-7, 2010.

Time: 8 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Sir Francis Drake Hotel, 450 Powell Street at Sutter, San Francisco, CA 94102.

Contact Person: Raya Mandler, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5134, MSC 7840, Bethesda, MD 20892. (301) 402-8228. rayam@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Neuroscience Education.

Date: October 6-7, 2010.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting.)

Contact Person: Jonathan Arias, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892. 301-435-2406. ariasj@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 23, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-21357 Filed 8-26-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Molecular Genetics B Study Section, October 3, 2010, 7 p.m. to October 4, 2010, 8 a.m., The Fairmont Hotel, 950 Mason Street, San Francisco, CA 94108 which was published in the **Federal Register** on August 19, 2010, 75 FR 51277-51278.

The meeting will be held October 4, 2010, 7 p.m. to October 5, 2010, 6 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: August 19, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-21352 Filed 8-26-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0437]

Development and Distribution of Patient Medication Information for Prescription Drugs; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comment.

SUMMARY: The Food and Drug Administration (FDA) is announcing a 2-day public hearing to obtain input on a new framework for development and distribution of patient medication information (PMI) to be provided to patients who are prescribed drug products. Under the current system, patients may receive several different

types of information, developed by different sources that may be duplicative, incomplete, or difficult to read and understand. FDA has determined that the current system is not adequate to ensure that patients receive the essential medication information that is needed to use the drug safely. Based on recommendations from FDA's Risk Communication Advisory Committee (RCAC) and other stakeholder input, FDA sees merit in adopting use of a single document that is standardized with respect to content and format. The purpose of this hearing is to solicit public input on processes and procedures for standardizing PMI using a quality system approach for monitoring development and distribution of PMI.

DATES: The public hearing will be held on September 27 and 28, 2010, from 8:30 a.m. to 4:30 p.m. Registration requests and requests to present at the public hearing should be received by September 13, 2010 (see section III of this document for details). Electronic or written comments will be accepted after the public hearing until October 29, 2010 (see section V of this document for details).

ADDRESSES: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD 20993. To register for the public hearing, email your registration information to PMIpublicmeeting@fda.hhs.gov. See section III of this document for registration details. 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Denise Hinton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6348, Silver Spring, MD 20993, 301-796-1090, FAX: 301-847-3529, email: PMIpublicmeeting@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Ensuring that patients who are prescribed medical products have access to quality information about those products is an important component of medical product safety. Currently, patients receive multiple types of written prescription drug information in varying formats, which

complicates information accessibility and comprehension. The types of written prescription drug information include:

- *Consumer Medication Information* (CMI) is written information about prescription drugs developed by organizations or individuals other than a drug manufacturer that is intended for distribution to consumers at the time of drug dispensing. The information is not FDA reviewed or approved and is voluntarily distributed by pharmacies to consumers (Ref. 1).

- A *Patient Package Insert* (PPI) is patient labeling that is part of the FDA-approved prescription drug labeling. PPIs are developed by the manufacturer, approved by FDA, and are required to be dispensed with specific products or classes of products (i.e., oral contraceptives and estrogen-containing products). Other PPIs are submitted to FDA voluntarily by the manufacturer and approved by FDA, but their distribution is not mandated.

- A *Medication Guide* is also patient labeling that is part of the FDA-approved prescription drug labeling. Medication Guides are required for certain drugs “that pose a serious and significant public health concern” (see 21 CFR part 208). Medication Guides are developed by the manufacturer, approved by FDA, and are required to be given to patients each time the medication is dispensed.

By objective measures, current systems for providing high quality, easily accessible prescription medication information to patients have failed. For example, an evaluation of CMI in 2008 showed that while 94 percent of consumers receive CMI with new prescriptions, only 75 percent of CMI received met even minimum criteria for usefulness (Ref 2.). FDA presented these concerns to the RCAC at a February 26 and 27, 2009 meeting. That committee recommended that FDA adopt a standard, single document for communicating essential information about prescription drugs to replace CMI, PPIs, and Medication Guides. FDA is engaged in a collaborative effort to explore this recommendation.

The major challenges in providing patients with quality prescription drug information are as follows: (1) Development of uniform, evidence-based content and format standards for PMI, including that the PMI contains the essential information about the drug, and is accurate, balanced, comprehensible, and accessible; (2) identification and assessment of mechanisms to ensure that PMI meets these standards; and (3) identification and assessment of mechanisms to

ensure that the PMI reaches its target audience. This public hearing is intended to focus primarily on issues 2 and 3, and related issues, while the first issue is being addressed separately, as discussed in the following paragraphs.

There are two key limitations that underpin FDA’s expectations for how improvements in providing patient information might be structured. First, although one approach could include FDA review and approval of all PMI prior to distribution, FDA recognizes that this may not be feasible given FDA’s resource constraints and the potential volume of products that will require PMI (perhaps as many 22,000 if counting all innovator and generic products). Second, based on FDA’s compliance and enforcement experience in a variety of program areas, including professional labeling, manufacturing, and clinical trials, FDA recognizes that relying primarily or exclusively on retrospective Agency evaluations and inspections may not be an optimal approach to providing assurance that PMI meets format and content standards prior to distribution to patients. For these reasons, FDA is interested in exploring an approach centered on effective processes for PMI development and distribution and process controls for a PMI implementation program. With a system in place that assures high quality PMI, FDA believes that development of PMI by the manufacturer would be more efficient and fulfill the information needs of patients.

Such an approach for PMI would provide manufacturers with a quality framework for developing, distributing, and amending PMI and would facilitate continual improvement of PMI. FDA envisions that this approach would provide assurance that manufacturers have implemented the following: (1) Effective procedures for developing PMI that reflect quality standards for PMI content and format, for ensuring appropriate distribution, and for ensuring PMI revision if necessary; (2) mechanisms to monitor whether these procedures are being followed; and (3) mechanisms to implement process changes as needed.

Because it will take a substantial amount of time to transition from the existing system to the use of a standard, single document for PMI, FDA is also seeking public input on a potential structure and challenges and solutions for a step-wise transition to a new PMI paradigm.

As described in the explanation of major challenges earlier in this document, FDA is also continuing its efforts and seeking additional

information to identify and assess the development of format and content standards for PMI as a standard, single document. With input from the following sources FDA has developed three draft PMI prototypes to be used in consumer testing:

- (1) FDA’s RCAC meeting (Ref. 3);
- (2) a public workshop held on September 24 and 25, 2009 (available at <http://www.fda.gov/Drugs/NewsEvents/ucm168106.htm>); and
- (3) an expert panel meeting convened by the Brookings Institute on July 21, 2010 (available at http://www.brookings.edu/events/2010/0721_CMI.aspx),¹

Based on public comment (75 FR 23775, May 4, 2010) and expert panel input, FDA is also finalizing the design of the consumer testing study for the prototypes (available on the Internet at <http://edocket.access.gpo.gov/2010/pdf/2010-10359.pdf>). Consumer testing will begin when the final study design is approved by the Office of Management and Budget. The results of this study will inform FDA of the usefulness and parameters of various format options for patient information documents. FDA is interested in any formal research conducted on this topic and encourages submission to this docket. See section III of this document for details on how to register and or participate in the meeting. See section V of this document for details on how to post comments to the docket.

II. Scope of the Hearing

FDA is particularly interested in seeking input on the following issues:

- (1) How can we best ensure PMI quality and compliance with content and format criteria?
 - What are the elements that should be addressed with a quality system approach, or other type of system, to ensure PMI quality?
 - What functions and procedures should be the responsibility of manufacturers (e.g., PMI development, consumer testing, marketplace surveillance)?
 - What functions and procedures should be FDA’s responsibility (e.g., surveillance, audit, enforcement)?
 - Are there a subset of products that should receive more regulatory scrutiny than would be provided by an approach that relies heavily on manufacturers implementing and monitoring the adequacy of procedures for generating PMI content (i.e., types of products for

¹ FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.

which PMI should be prospectively reviewed and approved by FDA before use)? If so, what categories of drugs might be included in this subset? What other approaches to ensuring quality should be considered for drugs in this subset?

- At what time-point should evaluation of the PMI be initiated and how often should it be repeated?

(2) *What are the components of an effective framework for ensuring patient access to PMI?*

- Who should be responsible for processes to ensure distribution of PMI?

- What types of processes are needed to ensure distribution of PMI? For example, should there be a process or system to monitor patient receipt of PMI?

- How can we ensure adequate distribution of PMI while minimizing disruption to health care delivery processes (e.g., medical practice, pharmacy practice)?

- Are there situations where the distribution of PMI would not be appropriate (e.g., for medications administered by a health care professional in an inpatient or outpatient setting, dialysis unit, oncology setting, or operating room)?

- Should there be a centralized repository for all PMI? If so, how might a repository be implemented and maintained to ensure the integrity and sustainability of the repository? Are there relevant, existing systems that could serve as a business model for a central PMI repository?

(3) *What approaches should be considered to ensure that FDA can rapidly move from the current system to a new PMI paradigm?*

- How might the existing framework be phased if a new framework is phased in?

- How should a new PMI system be applied to generic drugs?

(4) *What accommodations might be needed to ensure that PMI is accessible to special populations (e.g., elderly, children, those with low literacy, the visually impaired)?*

III. How to Register and/or Participate in the Public Hearing

FDA is seeking input from a broad group of stakeholders, including interested prescribers, pharmacists, other health care professionals, consumers, pharmacies, CMI developers, publishers, industry, and any other interested parties. FDA's Conference Center at the White Oak Campus is a Federal facility with security procedures and limited seating. Attendance is free and will be on a first-come, first-served basis. To register for

the public hearing, email your registration to PMIpublicmeeting@fda.hhs.gov. Registration information should include registrant name, company or organization, address, phone number, and email address. Because seating is limited, FDA may limit the numbers of participants from each organization. Registrants will receive confirmation once they have been accepted for participation in the workshop. Onsite registration on the day of the hearing will be based on space availability on the day of the event starting at 7:30 a.m. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the hearing at <http://www.fda.gov/Drugs/NewsEvents/ucm219716.htm>.

Individuals who wish to present at the public hearing must register on or before September 13, 2010, through the email PMIpublicmeeting@fda.hhs.gov, and state this intention on their notice of participation. An abstract of the presentation along with slides are due on September 17, 2010. You must provide complete contact information, including name, title, affiliation, address, email, and phone number. In section II of this document, FDA has included questions for comment. You should identify by number each question you wish to address in your presentation, so that FDA can consider that in organizing the presentations. FDA will do its best to accommodate requests to speak, and will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. An agenda will be available approximately 1 week before the hearing at <http://www.fda.gov/Drugs/NewsEvents/ucm219716.htm>.

If you need special accommodations because of disability, please contact Denise Hinton (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the hearing.

A live webcast of this hearing will be viewable at <https://collaboration.fda.gov/p15d109272010/> on September 27 and <https://collaboration.fda.gov/p15d209272010/> on September 28. If you have never attended an Adobe® Acrobat® Connect™ Pro meeting before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. For a quick overview, go to http://www.adobe.com/go/connectpro_overview.

IV. Notice of Hearing Under Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15

(21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by senior management from the Office of the Commissioner, the Center for Drug Evaluation and Research, and the Center for Biologics and Research.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see section VI of this document). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

V. Comments

Regardless of attendance at the public hearing, interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments. 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. To ensure consideration, submit comments by October 29, 2010. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and

Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

VII. References

1. “Useful Written Consumer Medication Information (CMI)” published in July 2006, available on the Internet at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080602.pdf>.

2. Kimberlin CL, Winterstein AG. “Expert and Consumer Evaluation of Consumer Medication Information—2008.” Final Report to FDA. November 2008 available on the Internet at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ReportsBudgets/UCM163783.pdf>.

3. FDA’s Risk Communication Advisory Committee meeting, held on February 26 and 27, 2009 (73 FR 74505, December 8, 2008), available on the Internet at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM152593.pdf>.

4. “Providing Effective Information to Consumers about Prescription Drug Risks and Benefits—The Issues Paper” from the 2009 public workshop available on the Internet at <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM182799.pdf>.

5. “Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Patient Information Prototypes,” available on the Internet at ² <http://edocket.access.gpo.gov/2010/pdf/2010-10359.pdf>

Dated: August 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–21326 Filed 8–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0002]

Withdrawal of Approval of New Animal Drug Applications; Dichlorophene and Toluene Capsules

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing

² FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.

approval of two new animal drug applications (NADAs) for use of dichlorophene and toluene deworming capsules for cats and dogs. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the regulations to remove portions reflecting approval of these NADAs.

DATES: Withdrawal of approval is effective September 7, 2010.

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9079; email: john.bartkowiak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514 has requested that FDA withdraw approval of NADA 101–497 for TINY TIGER (dichlorophene/toluene) Worming Capsules, NADA 101–498 for LK (dichlorophene/toluene) Worming Capsules because they are no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADAs 101–497 and 101–498, and all supplements and amendments thereto, is hereby withdrawn, effective September 7, 2010.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these NADAs.

Dated: August 23, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2010–21295 Filed 8–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2010–0071]

National Protection and Programs Directorate; Agency Information Collection Activities; Office of Infrastructure Protection; Chemical Security Awareness Training Program

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 60-Day notice and request for comments.

Extension of a Currently Approved Information Collection: 1670–0009.

SUMMARY: The Department of Homeland Security, National Protection and

Programs Directorate, Office of Infrastructure Protection, Sector-Specific Agency Executive Management Office (NPPD/SSA EMO), submits the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until October 26, 2010. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Written comments and questions about this Information Collection Request should be forwarded to the Department of Homeland Security, NPPD/SSA EMO, Chemical Sector-Specific Agency, 245 Murray Lane, SW., Mail Stop 0608, Washington, DC 20528–0608. E-mailed requests should go to Amy Graydon at chemicalsector@dhs.gov. Written comments should reach the contact person listed no later than October 26, 2010. Comments must be identified by DHS–2010–0071 and may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>.

- *E-mail:* chemicalsector@dhs.gov.

Include the docket number in the subject line of the message.

Instructions: All submissions received must include the words “Department of Homeland Security” and the docket number for this action. Comments received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided.

SUPPLEMENTARY INFORMATION: The Chemical Sector-Specific Agency, within the DHS NPPD/SSA EMO, provides an on-line voluntary training program to improve security in the chemical industry sector. Information is automatically collected in a computer database as a result of individuals engaging in the training. Explicit reporting or recordkeeping is not required. The training is designed for the general chemical facility employee. U.S. chemical industry direct employment is about 850,000 (2009 per the American Chemistry Council); approximately 400,000 employees are estimated as potential participants. Estimated duration in the first year to complete the registration, training, and survey is 60 minutes, and less if individuals take refresher training in succeeding years. Minimal participation data is collected as trainees complete the online exercises. Upon completion,