alcohol during prescription use.[8] FDA was informed by the National Association of Boards of Pharmacy that, as of February 2008, no states had implemented regulations related to the request.

In December 2006, FDA issued proposed regulations for OTC labeling for acetaminophen containing products to require inclusion of new safety information and that the container and outer carton identify acetaminophen when it is an ingredient.[9] The final version of the regulation is currently under review.

In 2007, the Director of FDA's Center for Drug Evaluation and Research (CDER) convened a multidisciplinary working group in CDER to continue to evaluate the issues associated with acetaminophen-related liver injury and consider additional steps FDA could take to decrease the number of cases of acetaminophen-related liver injury. The working group considered detailed reviews of the issues from the Office of Nonprescription Products, the Office of Surveillance and Epidemiology and the Division of Anesthesia and Analgesic and Rheumatology Drug Products as part of its deliberations. The working group considered the full range of options proposed and made recommendations to the Center Director regarding which should be considered for implementation. Given the complex nature of the underlying problem of acetaminophen liver toxicity, the Center Director and the Working Group agreed that the options should be presented for public discussion prior to taking further action. The report of the Working Group will be available by or around May 22, 2009, at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2009 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons and Sponsors (representatives from industry) may present data, information, or views, orally or in writing, on issues pending before the committee.

All electronic and written submissions submitted to the Docket (see above section: *Addresses*) on or before June 8, 2009, will be provided to the committees.

Oral presentations from the public (excluding Sponsors) will be scheduled between approximately 1 p.m. to 2 p.m. on both days. Persons desiring to make formal oral presentations during this time should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 1, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak at the open public hearing session by June 3, 2009.

FDA will work with sponsors of acetaminophen products who wish to make presentations to ensure that adequate time, separate from the 1 p.m. to 2 p.m. time slots for the general Open Public Hearing, is provided. Sponsors interested in making formal presentations to the committees should notify the contact person on or before June 1, 2009. Sponsors with common interest are urged to coordinate their oral presentations.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Elaine Ferguson at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: April 16, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

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BILLING CODE 4160–01–S

[8] Letter from Steven Galson to State Boards of Pharmacy, *Acetaminophen Hepatotoxicity and Nonsteroidal Anti-Inflammatory Drug (NSAID)-Related Gastrointestinal and Renal Toxicity* (January 22, 2004), available on FDA's Web site at *http://www.fda.gov/cder/drug/analgesics/letter.htm*.)

[9] Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the Counter Human Use: Proposed Amendment of the Tentative Final Monograph: Required Warnings and Other Labeling, 71 FR 77314–52 (December 26, 2006) (Docket No.1977N–0094L) (amending 21 CFR 201.66, 201.322, 201.325, 343.50).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control, Initial Review Group, (NCIPC, IRG)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), CDC announces the following meeting of the aforementioned review group:

Times and Dates:

10 a.m.–10:10 a.m., May 18, 2009 (Open).

10:10 a.m.–4 p.m., May 18, 2009 (Closed).

Place: Teleconference, Toll Free: (877) 468–4185, Participant Passcode: 4475689.

Status: Portions of the meetings will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92–463.

Purpose: This group is charged with providing advice and guidance to the Secretary, Department of Health and Human Services, and the Director, CDC, concerning the scientific and technical merit of grant and cooperative agreement applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct specific research that focuses on prevention and control.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications submitted in response to Fiscal Year 2009 Requests for Applications related to the following individual research announcement: TS09001, Libbey Montana Amphibole Epidemiology Research Program (R01) and TS09002, Disease Progression in persons Exposed to Asbestos Contaminated Vermiculite Ore in Marysville, Ohio (R01).

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Lisa T. Garbarino, B.S., NCIPC, Division of Injury Response, CDC, 4770 Buford Highway, NE., M/S F62, Atlanta, Georgia 30341, Telephone (440) 723–1527. The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 16, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E9–9470 Filed 4–23–09; 8:45 am]

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