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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

[Docket No. 2007P-0074]

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 18 and 19, 2007, from 8 a.m. to 5 p.m.

Addresses: Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select "2007P-0074—Final Monograph for Cough, Cold, Allergy, Brochodilator, Antiasthmatic Drug Products for Over-the-Counter Human Use" and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of business on August 28, 2007.

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Location: The National Labor College, Lane Kirkland Center, Solidarity Hall, 10000 New Hampshire Ave., Silver Spring, MD. The phone number is 301-431-6400.

Contact Person: Darrell Lyons, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: darrell.lyons@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 3014512541 and 8732310001. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committees will meet in joint session to discuss the safety and efficacy of over-the-counter (OTC) cough and cold products marketed for pediatric use. A citizen petition was submitted to FDA on March 1, 2007, that raised concerns about the safety and efficacy of cough and cold products in children under 6 years of age. The petition requested among other things that FDA amend the OTC drug monograph for Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (CCABADP) in 21 CFR Part 341 to require that labeling for OTC antitussive, expectorant, nasal decongestant, antihistamine, and combination cough and cold products state that these products have not been found to be safe or effective in children under 6 years of age for the treatment of cough and cold, and that these

products should not be used for the treatment of cough and cold in children under 6 years of age. In addition, the petitioner requested the agency to notify manufacturers of these products whose labeling either uses such terms as “infant” or “baby” or displays images of children under the age of 6, that such marketing is not supported by scientific evidence and that manufacturers will be subject to enforcement action at any time. The petition and additional information can be found at the following Web site: <http://www.fda.gov/ohrms/dockets/dockets/07p0074/07p0074.htm>.

The committee’s discussion will focus on several areas of interest which include: The extrapolation of efficacy data from adults to children of any age for cough and cold products; the safety profile of these products in children; the basis for dosing recommendations in the CCABADP monograph and the use of extrapolation of pharmacokinetic data to determine appropriate dosing in children; the basis of dosing recommendations for various age intervals of less than 2 years, 2 to 5 years of age, and 6 to 11 years of age; the use of the products in children less than 2 years of age; the potential for misuse, unintentional overdose, and excessive dosing; the ability of parents or caregivers to correctly dose and administer cough and cold products to their children; and the potential labeling changes recommended by the petitioner and the effects they will have on the use of these products in children and the recommendations of health providers.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web

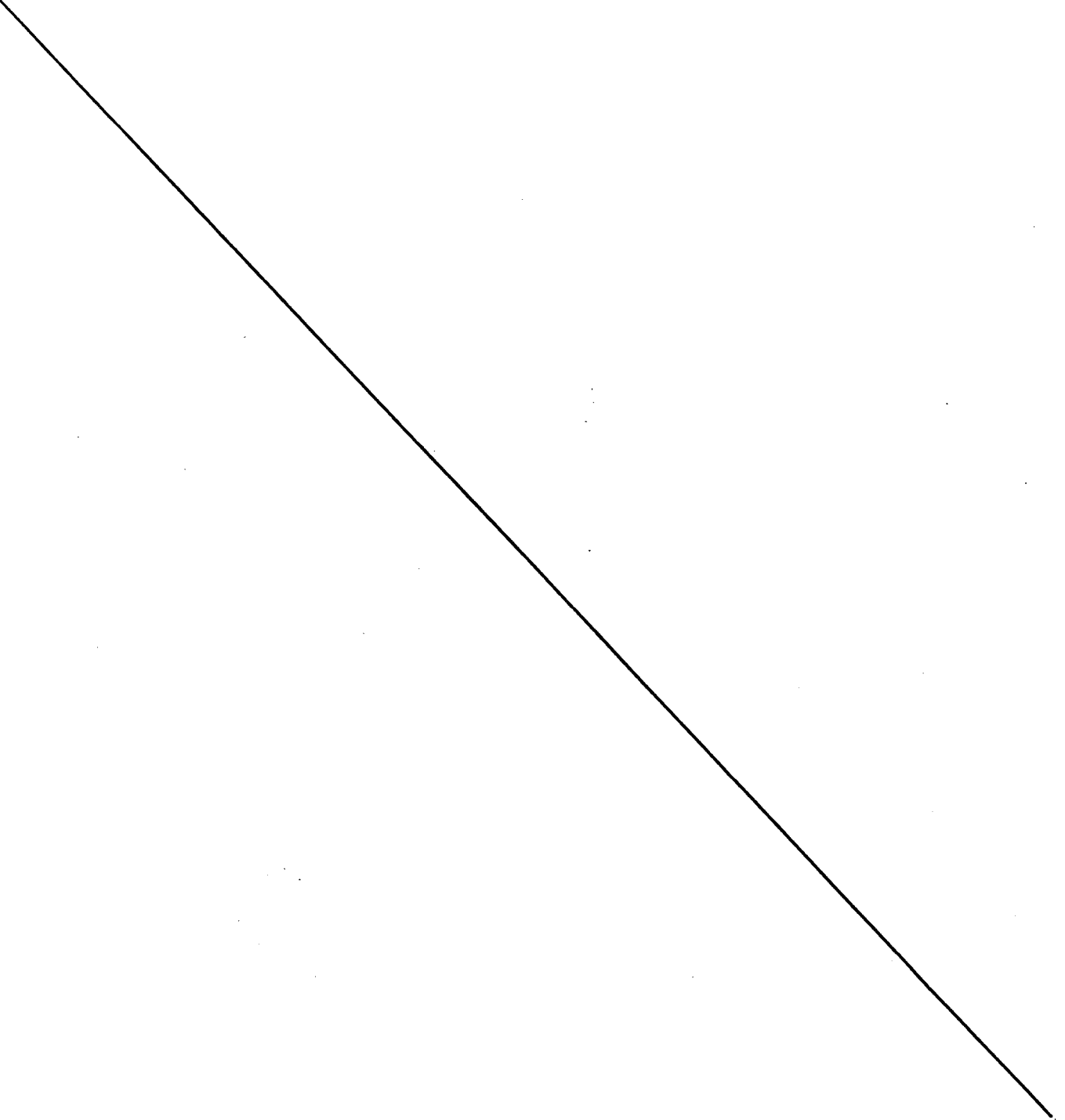
site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>; click on the year 2007 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 3, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 3 p.m. on October 18, 2007. Those desiring to make formal oral presentations 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 September 25, 2007. 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 by September 26, 2007.

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

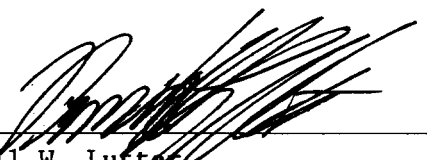
FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Darrell Lyons at least 7 days in advance of the meeting.

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. 2).

Dated: 8/9/07
August 9, 2007.



Randall W. Lutter
Deputy Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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