site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On January 7, 2009, the committee will discuss new drug application (NDA) 20–427, vigabatrin, Ovation Pharmaceuticals, Inc., for the proposed indication of adjunctive therapy for the treatment of refractory complex partial seizures in adults. January 8, 2009, the committee will discuss NDA 22–006, vigabatrin, Ovation Pharmaceuticals, Inc., for the proposed indication of treatment of infantile spasms.

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 2009 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 December 23, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. 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 December 16, 2008. 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 December 17, 2008.

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 Diem-Kieu Ngo 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: October 16, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–25389 Filed 10–23–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Joint Meeting of the Pulmonary-Allergy Drugs Advisory Committee, Drug Safety and Risk Management 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: Pulmonary-Allergy Drugs Advisory Committee, Drug Safety and Risk Management 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 December 10 and 11, 2008, from 8:30 a.m. to 5 p.m.

Location: Hilton Washington DC/Rockville, Plaza Ballrooms, 1750 Rockville Pike, Rockville, MD. The hotel phone number is 301–468–1100.

Contact Person: Kristine T. Khuc, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5630 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, Fax: 301–827–6776, e-mail: *Kristine.Khuc@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), codes 301–451–2545, 301–451–2535, or 873–231–0001. 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 discuss the benefit risk assessment of long acting beta-2 adrenergic agonists for the treatment of asthma in adults and children.

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 2008 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 November 25, 2008. Oral presentations from the public will be scheduled between approximately 9 a.m. to 10 a.m. on December 11, 2008. 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 November 10, 2008. 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 November 17, 2008.

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 Kristine T. Khuc 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: October 16, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–25386 Filed 10–23–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0549]

Opportunity for Hearing on a Proposal to Withdraw Approval of Prescription Polyethylene Glycol 3350 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is proposing to withdraw approval of the following abbreviated new drug applications (ANDAs) for drug products containing polyethylene glycol 3350 (PEG 3350) labeled for prescription only use: ANDA 76–652 held by Schwarz Pharma, Inc.; ANDA 77–736 held by Kali Laboratories, Inc.; ANDA 77–706 held by Nexgen Pharma Inc. (formerly known as Anabolic Laboratories, Inc.); ANDA 77–893 held by Coastal Pharmaceuticals, Inc.; and ANDA 77–445 held by Teva Pharmaceutical Industries, Ltd. (collectively, the PEG 3350 ANDAs). The proposal is based on the switch of MiraLax from prescription only (''Rx only'') to over-the-counter (OTC) use. This switch was pursuant to the submission of a new drug application (NDA) for MiraLax (NDA 22–015), which was approved by the agency on October 6, 2006, establishing that PEG 3350 may be used safely and effectively without the supervision of a licensed healthcare professional. The Federal Food, Drug, and Cosmetic Act (the act) does not permit both Rx and OTC versions of the same drug product to be marketed at the same time. Under the act, a drug to which the prescription provisions of the act do not apply (i.e., an OTC drug) shall be deemed to be misbranded if at any time prior to dispensing the label of the product bears the ''Rx only'' symbol. Because the PEG 3350 generic drug products are labeled as Rx only, they are misbranded and may not be legally marketed. Thus, FDA is proposing to withdraw their approval.

DATES: Submit written or electronic requests for a hearing by November 24, 2008; submit data and information in support of the hearing request by December 23, 2008. Submit written or electronic comments by December 23, 2008.

ADDRESSES: Submit written requests for a hearing, any data and information justifying a hearing, and any other comments identified with Docket No. FDA–2008–N–0549 to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests for a hearing, any data and information justifying a hearing, and any other comments identified with Docket No. FDA–2008–N–0549 to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 10903 New Hampshire Ave., Bldg.51, rm. 6368, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION:

I. Background

A. Original Approval of MiraLax NDA and Subsequent ANDA Products

MiraLax is an osmotic laxative containing the active ingredient polyethylene glycol 3350. MiraLax was approved as a prescription drug on February 18, 1999, under Braintree Laboratories, Inc. (Braintree), NDA 20–698, for up to 14 days of use for the treatment of occasional constipation in adults. In patients with a history of constipation, MiraLax therapy increases the volume and frequency of bowel movements. The approved prescription dosing and administration regimen stated:

- ''The usual dose is 17 grams (about 1 heaping tablespoon) of powder per day (or as directed by physician) in 8 ounces of water. Each bottle of MiraLax is supplied with a measuring cap marked to contain 17 grams of laxative powder when filled to the indicated line.
- Two to 4 days (48 to 96 hours) may be required to produce a bowel movement.''

Five ANDAs for PEG 3350 powder for oral solution, 17 gram (g)/single-dose were subsequently submitted and approved based on this reference-listed drug MiraLax Powder for Oral Solution for Rx only use. These ANDAs were approved under the requirements of section 505(j) of the act (21 U.S.C. 355(j)) and §§ 314.92 and 314.94 (21 CFR 314.92 and 314.94). The approved labeling of these PEG 3350 ANDA products is the same as that of the reference-listed drug, NDA 20–698.

B. Switch of Innovator Product

On October 6, 2006, FDA approved a new NDA for MiraLax (NDA 22–015) submitted by Braintree, switching its use from Rx only to OTC. By approving this NDA, FDA determined that PEG 3350 may be used safely and effectively OTC for the treatment of occasional constipation and that the Rx only limitation on PEG 3350 for occasional constipation was no longer necessary or appropriate. The sponsor was granted 3 years of exclusivity based on the studies necessary to establish that PEG 3350 would be safe and effective when used OTC for the treatment of occasional constipation. According to FDA's Approved Drug Products With Therapeutic Equivalence Evaluations, NDA 22–015 is the subject of marketing exclusivity for the OTC use of MiraLax until October 6, 2009. Schering-Plough Corp. now holds NDA 22–015 and markets its PEG 3350 product for OTC use under the brand name MiraLax®.

C. The Durham-Humphrey Amendments

The distinction between prescription and OTC drugs was codified by the Durham-Humphrey Amendments, which were enacted in order to address the marketplace confusion that arose from the simultaneous marketing of identical or nearly identical drugs on a prescription and OTC basis for identical or equivalent uses (Public Law 82–215, 65 Stat. 648 (1951). See, e.g., H.R. Rep. No. 82–700, at 5 (1951); see also 70 FR 52050 at 52051, September 1, 2005). Prescription drugs are defined as those which because of their toxicity or other potentiality for harmful effect, or the method of use, or the collateral measures necessary to their use, are not safe for use except under the supervision of a practitioner licensed to administer such drugs, or those drugs which are limited by an approved application under section 505 of the act