

determine whether AVALIDE (hydrochlorothiazide and irbesartan), oral tablets, 25 mg/300 mg, were withdrawn from sale for reasons of safety or effectiveness. In addition, Lupin Pharmaceuticals, Inc. submitted a citizen petition dated November 10, 2011 (Docket No. FDA-2011-P-0822), under § 10.30, also requesting that the Agency determine whether AVALIDE (hydrochlorothiazide and irbesartan), oral tablets, 25 mg/300 mg, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petitions did not address the 12.5 mg/75 mg strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

After considering the citizen petitions and reviewing Agency records, and based on the information we have at this time, FDA has determined under § 314.161 that AVALIDE (hydrochlorothiazide and irbesartan), oral tablets, 25 mg/300 mg and 12.5 mg/75 mg were not withdrawn for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that AVALIDE (hydrochlorothiazide and irbesartan), oral tablets, 25 mg/300 mg and 12.5 mg/75 mg were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of AVALIDE (hydrochlorothiazide and irbesartan), oral tablets, 25 mg/300 mg and 12.5 mg/75 mg from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that AVALIDE (hydrochlorothiazide and irbesartan), oral tablets, 25 mg/300 mg and 12.5 mg/75 mg were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list AVALIDE (hydrochlorothiazide and irbesartan), oral tablets, 25 mg/300 mg and 12.5 mg/75 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to AVALIDE (hydrochlorothiazide and irbesartan), oral tablets, 25 mg/300 mg and 12.5 mg/75 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the

Agency will advise ANDA applicants to submit such labeling.

Dated: January 5, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; 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 Committee: Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

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

Date and Time: The meeting will be held on March 14, 2012, from 7:30 a.m. to 3 p.m.

Location: Gaylord National Hotel and Convention Center, Maryland Ballroom C, 201 Waterfront St., National Harbor, MD 20745. The hotel's phone number is (301) 965-4000.

Contact Person: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, (301) 796-9001, FAX: (301) 847-8533, email: ACPS-CP@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-(800) 741-8138 ((301) 443-0572 in the Washington, DC area), and follow prompts to the desired center or product area. 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 committee will discuss the clinical pharmacology aspects of

pediatric clinical trial design and dosing to optimize pediatric drug development. FDA will seek input on how to strategically inform pediatric clinical trial design and dosing by utilizing existing knowledge, including available adult and nonclinical data. The discussion will include the role of modeling and simulation including physiologically-based pharmacokinetic modeling in pediatric drug development. Modeling and simulation is the application of mathematical approaches to predicting what will happen in a clinical trial with pediatric patients when a particular dose of a drug is used.

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/AdvisoryCommittees/Calendar/default.htm>. 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 February 29, 2012. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.m. Those individuals interested in making 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 February 21, 2012. 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 February 22, 2012.

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 Yvette Waples 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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.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: January 5, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-324 Filed 1-10-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Arthritis 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 Committee: Arthritis Advisory Committee.

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

Date and Time: The meeting will be held on March 12, 2012, from 8 a.m. to 5:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room, (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Philip A. Bautista, Center for Drug Evaluation and Research, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, (301) 796-9001, FAX: (301) 847-8533, email:

AAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-(800) 741-8138 ((301) 443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. 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 committee will discuss the anti-nerve growth factor (Anti-NGF) drug class that is currently under development and the safety issues possibly related to these drugs. These drugs are being developed for the treatment of a variety of chronic painful conditions including osteoarthritis, chronic lower back pain, diabetic peripheral neuropathy, post-herpetic neuralgia, chronic pancreatitis, endometriosis, interstitial cystitis, vertebral fracture, thermal injury, and cancer pain. The committee will be asked to determine whether reports of joint destruction represent a safety signal related to the Anti-NGF class of drugs, and whether the risk benefit balance for these drugs favors continued development of the drugs as analgesics.

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/AdvisoryCommittees/Calendar/default.htm>. 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 February 27, 2012. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those individuals interested in making 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 February 16, 2012. 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 February 17, 2012.

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 Philip A. Bautista 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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.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: January 5, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-326 Filed 1-10-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Agency Information Collection Activities: Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery: IHS Web Site Customer Service Satisfaction Survey

AGENCY: Indian Health Service, HHS.

ACTION: 30-Day notice of submission of information collection approval from the Office of Management and Budget (OMB) and request for comments.