ANNUAL BURDEN ESTIMATES—Continued

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Semi-structured interviews Head Start Health Managers	40	1	.75	30
Semi-structured interviews Head Start Teachers and Family Service Workers	60	1	.75	45

Estimated Total Annual Burden Hours: 4394.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 4, 2012.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2012–262 Filed 1–10–12; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–P–0743 and FDA–2011–P–0822]

Determination That AVALIDE (Hydrochlorothiazide and Irbesartan), Oral Tablets, 25 Milligrams/300 Milligrams and 12.5 Milligrams/75 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that AVALIDE (hydrochlorothiazide and irbesartan), oral tablets, 25 milligrams (mg)/300 mg and 12.5 mg/75 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for hydrochlorothiazide and irbesartan, oral tablets, 25 mg/300 mg and 12.5 mg/75 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Jane Inglese, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6210, Silver Spring, MD 20993–0002, (301) 796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

AVALIDE (hydrochlorothiazide and irbesartan), oral tablets, 25 mg/300 mg and 12.5 mg/75 mg, are the subject of NDA 20–758, held by Sanofi-Aventis, and initially approved on September 30, 1997. AVALIDE is indicated for treatment of hypertension in patients whose blood pressure is not adequately controlled on monotherapy. AVALIDE is also indicated for initial therapy for hypertension in patients who are likely to need multiple drugs to achieve their blood pressure goals.

AVALIDE (hydrochlorothiazide and irbesartan), oral tablets, 25 mg/300 mg and 12.5 mg/75 mg are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

EAS Consulting Group, LLC on behalf of Aurobindo Pharmaceuticals, Ltd. submitted a citizen petition dated October 11, 2011 (Docket No. FDA–2011–P–0743), under § 10.30 (21 CFR 10.30), 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. 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.

[FR Doc. 2012–312 Filed 1–10–12; 8:45 am]

BILLING CODE 4160–01–P

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