these estimates were made. We use this estimate consistently throughout the table and calculate the ''total annual responses'' by multiplying the number of responses per respondent by the number of respondents.

Dated: May 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11273 Filed 5–10–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–P–1000]

Determination That REV–EYES (Dapiprazole Hydrochloride Ophthalmic Solution), 0.5%, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Drug Administration (FDA) has determined that REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for dapiprazole hydrochloride ophthalmic solution, 0.5%, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: David E. Markert, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3602.

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 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, is the subject of NDA 19–849, held by Angelini Pharmaceuticals Inc., and initially approved on December 31, 1990. REV–EYES is indicated for the treatment of iatrogenically induced mydriasis produced by adrenergic (phenylephrine) or parasympatholytic (tropicamide) agents.

REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

CUSTOpharm, Inc., submitted a citizen petition dated September 11, 2012 (Docket No. FDA–2012–P–1000), under 21 CFR 10.30, requesting that the Agency determine whether REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of REV–EYES (dapiprazole hydrochloride ophthalmic solution). 0.5%. from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, 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 REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, 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: May 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11285 Filed 5–10–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0677]

Dental Products Panel of the Medical Devices 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: Dental Products Panel of the Medical Devices 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 July 18th, 2013, from 8 a.m. to 2:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B and C, 620 Perry Pkwy., Gaithersburg, MD,

20877. The hotel phone number is 301–977–8900.

Contact Person: Sara J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 66, Rm. 1611, Silver Spring, MD, *Sara.Anderson@fda.hhs.gov,* 301–796–7047, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On July 18, 2013, the committee will discuss and make recommendations on the proposed regulatory classification for dental devices known as Endosseous Dental Implants (Blade-form), one of the remaining preamendments Class III devices. The Class III blade-form endosseous dental implant is a device placed into the maxilla or mandible and composed of biocompatible material, such as commercially pure titanium, with sufficient strength to support a dental restoration, such as a crown, bridge, or denture, intended for the purpose of replacing tooth (or teeth) roots and extending a support post through the gingival tissue into the oral cavity to restore chewing function. The blade-form implant is generally a rectangular shape or rounded corner rectangle shape (in the mesio-distal plane) with a narrow tapered (narrow at the apical edge) edge (in the bucco-lingual plane) similar in shape to a razor blade. Other blade designs, such as square, V-shaped, and triangles have also been used. The blade-form implants are either one-piece or two-piece implants designed with one to three cylindrical abutment posts extending from the coronal aspect of the blade through the soft tissue and into the oral cavity.

On January 4, 2013 (FDA–2012–N–0677), FDA issued a proposed order which, if made final, would reclassify the blade-form endosseous dental implant into class II (special controls). The committee's discussion will involve making recommendations regarding regulatory classification to either reaffirm Class III or reclassify these devices into Class II and comment on whether the proposed Special Controls are adequate to reasonably ensure the safety and effectiveness of blade-form endosseous dental implants. The regulatory history of blade-form endosseous dental implant has been discussed as part of the proposed order (FDA–2012–N–0677).

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 meeting 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 July 9, 2013. On July 18, 2013, oral presentations will be scheduled between approximately 1 p.m. and 2 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 June 28, 2013. 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 July 1, 2013.

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 AnnMarie Williams, Conference Management Staff, at *Annmarie.Williams@fda.hhs.gov* or 301 796–5966 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: May 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11286 Filed 5–10–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.