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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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10.30, requesting that the Agency determine whether REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, was withdrawn from sale for reasons of safety or effectiveness.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time, FDA has determined under § 314.161 that REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, was not withdrawn for reasons of safety or effectiveness.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no data or other information suggesting that REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, was withdrawn for reasons of safety or effectiveness.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 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.


Leslie Kux, Assistant Commissioner for Policy.

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The committee will discuss and make recommendations on the proposed regulatory classification for dental 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 buccolingual 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/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.