Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product OBIZUR (rpFVIII). OBIZUR is indicated for the treatment of bleeding episodes in adults with acquired hemophilia A. Subsequent to this approval, the USPTO received patent term restoration applications for OBIZUR (U.S. Patent Nos. 6,180,371; 6,458,563; and 7,560,107) from Emory University and (U.S. Patent No. 7,576,181) from Emory University, Baxter International, Inc., and Baxter Healthcare SA; and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In letters dated October 19, 2015, and January 11, 2016, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of OBIZUR represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for OBIZUR is 4,216 days. Of this time, 3,883 days occurred during the testing phase of the regulatory review period, while 333 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* April 10, 2003. The applicant claims May 27, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 10, 2003.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* November 25, 2013. The applicant claims October 10, 2013, as the date the biologics license application (BLA) for OBIZUR (BLA 125512/0) was initially submitted. However, FDA records indicate that BLA 125512/0 was submitted on November 25, 2013.

3. *The date the application was approved:* October 23, 2014. FDA has verified the applicant's claim that BLA 125512/0 was approved on October 23, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: October 17, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–22898 Filed 10–20–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–P–3581]

Determination That ELAVIL (Amitriptyline Hydrochloride) Oral Tablets, 10, 25, 50, 75, 100, and 150 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 or Agency) has determined that ELAVIL (amitriptyline hydrochloride) oral tablets, 10 milligrams (mg), 25 mg, 50 mg, 75 mg, 100 mg, and 150 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 amitriptyline hydrochloride oral tablets, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *stacy.kane@fda.hhs.gov.*

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.

ELAVIL (amitriptyline hydrochloride) oral tablets, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg, are the subject of NDA 012703, held by AstraZeneca, and initially approved on April 7, 1961. ELAVIL is indicated for the relief of symptoms of depression. ELAVIL (amitriptyline hydrochloride) oral tablets, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. In the **Federal Register** of June 16, 2006 (71 FR 34940), FDA announced that it was withdrawing approval of NDA 012703, effective June 16, 2006.

Alembic Pharmaceuticals Limited submitted a citizen petition dated June 5, 2017 (Docket No. FDA–2017–P–3581), under 21 CFR 10.30, requesting that the Agency determine whether ELAVIL (amitriptyline hydrochloride) oral tablets, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg, were 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 ELAVIL (amitriptyline hydrochloride) oral tablets, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ELAVIL (amitriptyline hydrochloride) oral tablets, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg, 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 drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ELAVIL (amitriptyline hydrochloride) oral tablets, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 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 ELAVIL (amitriptyline hydrochloride) oral tablets, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 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: October 17, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–22892 Filed 10–20–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidance for Methylphenidate Hydrochloride; New Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a new draft guidance for industry on generic methylphenidate hydrochloride oral extended-release tablets entitled ''Draft Guidance on Methylphenidate Hydrochloride.'' The new draft guidance, when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for methylphenidate hydrochloride oral extended-release tablets.

DATES: Submit either electronic or written comments on the draft guidance by December 22, 2017 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and