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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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whether ELAVIL (amitriptyline hydrochloride) oral tablets, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg, were withdrawn from sale for reasons of safety or effectiveness.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

identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for ''Draft Guidance on Methylphenidate Hydrochloride.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Xiaoqiu Tang, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific guidances available to the public on FDA's Web site at *https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of a new draft guidance for generic methylphenidate hydrochloride oral extended-release tablets.

FDA initially approved new drug application 018029 for RITALIN–SR (methylphenidate hydrochloride oral extended-release tablets) in March 1982. We are now issuing a new draft guidance for industry on methylphenidate hydrochloride oral extended-release tablets (''Draft Guidance on Methylphenidate Hydrochloride'').

In May 2016, KVK-Tech, Inc. (KVK-Tech) submitted a citizen petition requesting, among other things, that FDA not accept for filing any new ANDAs or approve any already received ANDAs for methylphenidate hydrochloride oral extended-release tablets unless certain BE criteria are met. FDA will consider any comments on the draft guidance on BE recommendations for generic methylphenidate hydrochloride oral extended-release tablets before responding to KVK-Tech's citizen petition. (Docket No. FDA–2016–P–1247, available at *https://www.regulations.gov*).

The new draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The new draft guidance, when finalized, will represent the current thinking of FDA on the design of BE studies to support ANDAs for methylphenidate hydrochloride oral extended-release tablets. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: October 17, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Performance Review Board Members

Title 5, U.S.C. Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment of Performance Review Board Members be published in the **Federal Register**. The following persons may be named to serve on the Performance Review Boards or Panels, which oversee the evaluation of performance appraisals of Senior Executive Service members of the Department of Health and Human Services.

Employee Name

Barry, Daniel
Barlow, Amanda
Coughlin, Janis
Fantinato, Jessica
Gentile, John
Johnson, Jeffrey
Katz, Ruth
Kretschmaier, Michon
Lewis, Lisa
McDaniel, Eileen
Novy, Steve
Sample, Allen
Skeadas, Christos
Tobias, Constance
Weber, Mark