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of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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

LOTENSIN HCT (benazepril hydrochloride; hydrochlorothiazide) oral tablets, 5 mg and 6.25 mg, are the subject of NDA 020033, held by U.S. Pharmaceutical Holdings I, LLC, and initially approved on May 19, 1992. LOTENSIN HCT is indicated for the relief of symptoms of depression. LOTENSIN HCT (benazepril hydrochloride; hydrochlorothiazide) oral tablets, 5 mg and 6.25 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

EAS Consulting Group, LLC submitted a citizen petition dated August 9, 2017 (Docket No. FDA–2017–P–4852), under 21 CFR 10.30, requesting that the Agency determine whether LOTENSIN HCT (benazepril hydrochloride; hydrochlorothiazide) oral tablets, 5 mg and 6.25 mg, were withdrawn from sale for reasons of safety or effectiveness.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 LOTENSIN HCT (benazepril hydrochloride; hydrochlorothiazide) oral tablets, 5 mg and 6.25 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 LOTENSIN HCT (benazepril hydrochloride; hydrochlorothiazide) oral tablets, 5 mg and 6.25 mg, from sale. We have also independently evaluated relevant literature and data for possible post-marketing 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 LOTENSIN HCT (benazepril hydrochloride; hydrochlorothiazide) oral tablets, 5 mg and 6.25 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 LOTENSIN HCT (benazepril hydrochloride; hydrochlorothiazide) oral tablets, 5 mg and 6.25 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: February 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03188 Filed 2–15–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0035]

Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of amyotrophic lateral sclerosis (ALS). Specifically, it addresses FDA's current thinking regarding the clinical development program and clinical trial designs for drugs to support an indication for the treatment of ALS. This guidance addresses the clinical development of drugs intended to treat the main neuromuscular aspects of ALS (*i.e.,* muscle weakness and its direct consequences, including shortened survival).

DATES: Submit either electronic or written comments on the draft guidance by April 17, 2018 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–2013–N–0035 for ''Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment; Draft Guidance for Industry''. 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: Billy Dunn, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–2250.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment.'' ALS is a progressive neurodegenerative disease that primarily affects motor neurons in the cerebral motor cortex, brainstem, and spinal cord, leading to loss of voluntary movement and difficulty in swallowing, speaking, and breathing. The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of ALS. Specifically, it addresses FDA's current thinking regarding the clinical development program and clinical trial designs for drugs to support an indication for the treatment of ALS. This guidance addresses the clinical development of drugs intended to treat the main neuromuscular aspects of ALS (*i.e.,* muscle weakness and its direct consequences, including shortened survival).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on developing drugs for the treatment of ALS. 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014, the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001, and the collections of information referred to in the guidance for industry entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' (available at *https://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127073.pdf*) have been approved under OMB control number 0910–0581.

III. Electronic Access

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

Dated: February 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03222 Filed 2–15–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0468]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on May 10, 2018, from 8 a.m. to 5 p.m.

ADDRESSES: Tommy Douglas Conference Center, the Ballroom, 10000 New Hampshire Ave., Silver Spring, MD 20903. The conference center's telephone number is 240–645–4000. Answers to commonly asked questions about FDA Advisory Committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/*