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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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 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 is indicated for the treatment of amyotrophic lateral sclerosis (ALS). Specifically, it 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DATES: Submit either electronic or written comments on the draft guidance by April 17, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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.
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/GuidanceDocuments/default.htm or https://www.regulations.gov.