additional work. The applicant would likely perform more quality assurance, which may add time to preparation and review of the submission.

Based on CDER's data on the number of NDAs, BLAs, and NDA and BLA supplemental applications containing new clinical study reports that would be covered by the draft guidance, we estimate that each year approximately 75 applicants will submit for 125 original NDA or BLA applications and 152 supplemental applications containing new clinical study reports. We estimate that the submission of the clinical study-level information, subject-level data line listings by clinical site, and the summary-level clinical site dataset for each application would take approximately 40 hours to prepare. Initial preparation of the clinical study-level information, subject-level data line listings by clinical site, and the summary-level clinical site dataset could involve the development of new SOPs for some applicants. We estimate that 75 applicants would take approximately 20 hours to develop and subsequently 2 hours annually to maintain and update the SOP(s). The clinical study-level information, subject-level data line listings by clinical site, and the summary-level clinical site dataset submitted with each application would likely involve additional quality assurance procedures, which would add approximately 2 hours for each submission.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in part 312 have been approved under OMB control number 0910–0014; the collections of information in part 314 have been approved under OMB control number 0910–0001; the collections of information in part 601 have been approved under OMB control number 0910–0338.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED REPORTING BURDEN [1]

Activity	Number of respondents (*i.e.,* applicants)	Number of responses per respondent (*i.e.,* applications)	Total responses	Hours per response	Total hours
Submissions (clinical study-level information, subject-level data line listings by clinical site, and the summary-level clinical site dataset)	75	3.7	277	40	11,080
Quality Assurance	75	3.7	277	2	554
Total					11,634

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total records	Hours per recordkeeper	Total hours
Develop Initial SOP(s)	75	1	75	20	1,500
Maintain and Update SOP(s)	75	1	75	2	150
Total					1,650

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

II. 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 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03236 Filed 2–15–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–P–4852]

Determination That LOTENSIN HCT (Benazepril Hydrochloride; Hydrochlorothiazide) Oral Tablets, 5 Milligrams and 6.25 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 LOTENSIN HCT (benazepril hydrochloride; hydrochlorothiazide) oral tablets, 5 milligrams (mg) and 6.25 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 benazepril hydrochloride; hydrochlorothiazide oral tablets, 5 mg and 6.25 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.

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]

BILLING CODE 4164–01–P

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.