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 § 10.20 (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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, 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 drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug 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 drug 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 drug product MOVANTIK (naloxegol oxalate). MOVANTIK is indicated for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain. Subsequent to this approval, the USPTO received patent term restoration applications for MOVANTIK (U.S. Patent Nos. 7,662,365 and 7,786,133) from Nektar Therapeutics, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated October 30, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of MOVANTIK 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 MOVANTIK is 2,493 days. Of this time, 2,127 days occurred during the testing phase of the regulatory review period, while 366 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 (the FD&C Act) (21 U.S.C. 355(i)) became effective:* November 21, 2007. The applicant claims October 22, 2007, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 21, 2007, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* September 16, 2013. FDA has verified the applicant's claim that the new drug application (NDA) for MOVANTIK (NDA 204760) was initially submitted on September 16, 2013.

3. *The date the application was approved:* September 16, 2014. FDA has verified the applicant's claim that NDA 204760 was approved on September 16, 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 1,020 days or 272 days 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: February 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03245 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–2018–D–0481]

Submission of Content Necessary for Bioresearch Monitoring Inspection Planning for the Center of Drug Evaluation and Research; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled ''Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions'' along with the Bioresearch Monitoring Technical Conformance Guide Containing Technical Specifications (BIMO Technical Conformance Guide). The draft guidance and BIMO Technical Conformance Guide describe and provide specifications for the electronic submission of certain data and information in standardized formats. This information is used by the Center for Drug Evaluation and Research (CDER) in the planning of, and by FDA's Office of Regulatory Affairs (ORA) in the conduct of, bioresearch monitoring (BIMO) inspections. The draft guidance addresses major (*i.e.,* pivotal) studies used to support safety and efficacy claims in new drug applications (NDAs) and biologics license applications (BLAs) regulated by CDER, as well as certain supplemental applications containing new clinical study reports. This draft guidance, when finalized, is intended to assist applicants in the submission of electronic data and information in standardized formats, and supersedes the previously issued draft guidance entitled ''Providing Submissions in Electronic Format—Summary Level Clinical Site Data for CDER's Inspection Planning'' (December 2012) (Summary Level Clinical Site Draft Guidance).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 17, 2018.

ADDRESSES: You may submit comments 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–2018–D–0481 for ''Standardized Format for Electronic Submission of New Drug Application and Certain Biologics License Application Content for the Planning of Bioresearch Monitoring Inspections for Submissions to the Center for Drug Evaluation and Research; Draft Guidance for Industry; Bioresearch Monitoring Technical Conformance Guide Containing Technical Specifications; Availability.'' 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 ''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.

Submit written requests for single copies of this 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: Jean Mulinde, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0768.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of: (1) A draft guidance for industry entitled ''Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring Inspections (BIMO) for CDER Submissions'' and (2) the BIMO Technical Conformance Guide. This draft guidance and the BIMO Technical Conformance Guide describe and provide specifications for the electronic submission of data and information in standardized formats, for submitting information used by CDER in the planning of, and by ORA in the conduct

of, BIMO inspections. The draft guidance and the technical conformance guide address major (*i.e.,* pivotal) studies used to support safety and efficacy claims in NDAs, BLAs, and NDA and BLA supplemental applications containing new clinical study reports that are regulated by CDER.

To meet its review performance goals in accordance with CDER good review management principles and practices for products covered by the Prescription Drug User Fee Act, CDER generally initiates inspection planning early in the application review process (*i.e.,* during the filing determination and review planning phase). CDER's inspection planning includes the selection of clinical investigator sites and other regulated entities for on-site inspections, and the preparation of assignment memos and background packages that CDER provides to FDA's ORA, which performs FDA's BIMO inspections. CDER uses the data and information described in this guidance to plan BIMO inspections, including: (1) To facilitate the timely identification of sites for inspection and (2) to ensure the availability of information needed to conduct BIMO inspections by ORA investigators.

This draft guidance and the associated technical conformance guide supersede the previously issued Summary Level Clinical Site Draft Guidance that published in the **Federal Register** on December 19, 2012 (77 FR 75174). FDA carefully considered all of the comments received to the docket for the Summary Level Clinical Site Draft Guidance in developing this guidance. This draft guidance includes clarifications, additional detail on some topics, revised nomenclature for some data variables, and descriptions of additional data and information in standardized formats that are submitted in NDAs and BLAs to CDER, to facilitate the planning of routine BIMO inspections.

In section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k–1(a)), Congress granted explicit authorization to FDA to specify, in guidance, the electronic format for submissions under section 505(b), (i), or (j) of the FD&C Act (21 U.S.C. 355(b), (i), or (j)) and submissions under section 351(a) or (k) of the Public Health Service Act (42 U.S.C. 262(a) or (k)). Accordingly, to the extent that this guidance, when finalized, provides such requirements, as indicated by the use of the words *must* or *required,* this guidance will not be subject to the usual restrictions in FDA's good guidance practice (GGP) regulations, such as the requirement that guidances not establish legally enforceable responsibilities (see 21 CFR 10.115(d); see also the guidance for industry ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act,'' available at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

To comply with GGP regulations and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidance documents should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. FDA is not including this standard language in this draft guidance document because it is not an accurate description of this guidance. Insofar as this guidance specifies the format for electronic submissions pursuant to section 745A(a) of the FD&C Act, when finalized, it will have binding effect.

The draft guidance and the BIMO Technical Conformance Guide, when finalized, will represent the current thinking of FDA on standardized format for electronic submission of NDA and BLA content for the planning of BIMO inspections for CDER Submissions.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance and the associated technical conformance guide, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The draft guidance and the Bioresearch Monitoring Technical Conformance Guide provide the electronic format and specifications for submission of data and information used by CDER in the planning of, and by ORA in the conduct of, BIMO inspections. Data and information described in the draft guidance comprises information required in parts 312, 314, or 601 (21 CFR parts 312, 314, or 601), including case histories (§ 312.62(b)), information regarding foreign clinical studies not conducted under an investigational new drug application (IND) (§ 312.120), and the clinical data section (§ 314.50(d)(5)) and case report forms and tabulations (§ 314.50(f)), or in part 601 (§ 601.2 Applications for biologics licenses; procedures for filing) in an NDA, BLA, or supplement. The draft guidance and the associated technical conformance guide describe the electronic format of clinical study-level information, subject-level data line listings by clinical site, and the summary-level clinical site dataset that are submitted from all major (*i.e.,* pivotal) studies used to support safety and efficacy claims in NDAs, BLAs, and NDA and BLA supplemental applications containing new clinical study reports. The variables described in the format are elements currently used in other submissions; some of the variable names described in the summary-level clinical site dataset are new. The financial disclosure information is currently reported in Module 1 (region specific information) of the electronic common technical document, but is new as a variable in the summary-level clinical site dataset. In addition, identifying that a study has been conducted under an IND is new as a request in a dataset. Initial preparation of some of the clinical study-level information, the subject-level data line listings by clinical site, and the summary-level clinical site dataset and the development of new standard operating procedures (SOPs) would require added time. Once SOPs have been established, generation of the clinical study-level information, subject-level data line listings by clinical site, and the summary-level clinical site dataset should not involve significant

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