was initially submitted on August 30, 2012.

3. *The date the application was approved:* August 13, 2014. FDA has verified the applicant's claim that NDA 204569 was approved on August 13, 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 application for patent extension, this applicant seeks zero 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 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–02763 Filed 2–9–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5624]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Content and Format of Labeling for Human Prescription Drugs and Biological Products; Requirements for Pregnancy and Lactation Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 14, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0624. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Content and Format of Labeling for Human Prescription Drugs and Biological Products; Requirements for Pregnancy and Lactation Labeling

OMB Control Number 0910–0624—Extension

This information collection supports Agency regulations regarding the content and format requirements for pregnancy and lactation labeling. In the **Federal Register** of December 4, 2014 (79 FR 72064), FDA published a final rule entitled ''Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling.'' The final rule amended FDA regulations concerning the content and format of the ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of the ''Use in Specific Populations'' section of the labeling for human prescription drugs. The regulations now require, among other things, a summary of the risks of using a drug during pregnancy and lactation and a discussion of the data supporting that summary. The labeling must also include relevant information to help health care providers make prescribing decisions and counsel women about the use of drugs during pregnancy and lactation. The final rule eliminated the pregnancy categories A, B, C, D, and X. In addition, FDA eliminated the ''Labor and delivery'' subsection because the ''Pregnancy'' subsection includes information on labor and delivery. The final rule also required that the labeling include relevant information about pregnancy testing, contraception, and infertility for health care providers prescribing for females and males of reproductive potential. In addition, the final rule provided for a 10-year implementation schedule for compliance with the relevant regulations. As the implementation schedule is realized, FDA plans to discontinue this separate information collection and incorporate the provisions into existing collections as appropriate.

The content and format requirements apply to:

- Applications submitted on or after June 30, 2015 (§§ 314.50 (21 CFR 314.50), 314.70(b) (21 CFR 314.70(b)), 601.2 (21 CFR 601.2), and 601.12(f)(1)) (21 CFR 601.12(f)(1));
- amendments to applications pending on June 30, 2015 (§§ 314.60 (21 CFR 314.60), 601.2, and 601.12(f)(1));
- supplements to applications approved from June 30, 2001, to June 30, 2015 (§§ 314.70(b) and 601.12(f)(1)); and
- annual reports for applications approved before June 30, 2001, that contain a pregnancy category, to report removal of the pregnancy category letter in their labeling (§§ 314.70(d) and 601.12(f)(3)).

Under § 201.57(c)(9)(i) and (ii) (21 CFR 201.57(c)(9)(i) and (ii)), holders of approved applications must provide new labeling content in a new format—that is, to rewrite the pregnancy and lactation portions of each drug's labeling. Section 201.57(c)(9)(iii) requires that labeling must include the

new subsection 8.3, ''Females and males of reproductive potential.'' Application holders are required to submit prior approval supplements to their approved applications before distribution of the new labeling, as required in § 314.70(b) or § 601.12(f)(1) (21 CFR 601.12(f)(1)).

Under 21 CFR 201.80(f)(6)(i), holders of approved applications are required to remove the pregnancy category designation (*e.g.,* ''Pregnancy Category C'') from the ''Pregnancy'' subsection of the ''Precautions'' section of the labeling. These application holders must report the labeling change in their annual reports, as required in § 314.70(d) or § 601.12(f)(3).

In the **Federal Register** of October 4, 2017 (82 FR 46248), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. Two comments were received in response to the notice, however both comments discussed specific requirements found in FDA regulations rather than the four information collection topics solicited in our notice under the PRA. We have therefore not made adjustments to our burden estimate for the information collection, which is as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of submission (21 CFR section)	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
New NDAs/ANDAs/BLAs/efficacy supplements submitted on or after June 30, 2015, including amendments to applications pending as of June 30, 2015 (§§ 314.50, 314.60, 314.70(b), 601.2, 601.12(f)(1)).	390	~10	4,000 (Submitted during 10-year period after June 30, 2015).	40	160,000

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of submission (21 CFR section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Supplements to applications approved June 30, 2001 to June 30, 2015 (§§ 314.70(b), 601.12(f)(1)).	390	26	10,150 (Submitted 3rd, 4th, and 5th years after June 30, 2015).	120	1,218,000
Annual report submission of revised labeling for applications that contain a pregnancy category, approved before June 30, 2001 (§§ 314.70(d), 601.12(f)(3)).	320	~17	5,500 (Submitted 3rd year after June 30, 2015).	40	220,000
Total	.....	.....	.....	.....	1,438,000

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

As indicated in tables 1 and 2, we estimate the burden associated with the information collection to be 1,598,000 hours. We estimate 4,000 applications containing the subject labeling will be submitted by approximately 390 applicants and repackagers and relabelers to FDA over the 10-year period beginning June 30, 2015. This figure (4,000 applications) includes labeling for approximately 800 applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 505(b)) or section 351 of the Public Health Service Act (42 U.S.C. 262), 1,200 applications submitted under section 505(j) of the FD&C Act, and 2,000 revised drug product labeling from repackagers and relabelers for approximately 2,000. This estimate also includes labeling amendments submitted to FDA for applications pending as of the effective date of the final rule. We estimate it will take applicants 40 hours to prepare and submit the subject labeling. This estimate applies only to the requirements found in the previous paragraphs and does not indicate the total hours required to prepare and submit complete labeling for these applications. The information collection burden to prepare and submit labeling in accordance with §§ 201.56 (21 CFR 201.56), 201.57, and 201.80 is approved by OMB under control numbers 0910–0572 and 0910–0001.

In addition, during the third, fourth, and fifth years after the effective date of the final rule, the Agency estimates that it will receive approximately 10,150 supplements to applications that were either approved from June 30, 2001, to the effective date or were pending as of the effective date. This estimate includes supplements for approximately 1,080 new drug application (NDAs), and biologics license applications (BLAs), and efficacy supplements; 1,320 abbreviated new drug application (ANDA) supplements; and 7,750 drug product labeling supplements from repackagers and relabelers. FDA estimates 390 application holders, repackagers, and relabelers will submit these supplements, and that it will take 120 hours to prepare and submit each supplement.

Finally, we estimate that application holders will submit 5,500 annual reports to FDA during the third year after the effective date for applications that contain a pregnancy category, approved before June 30, 2001. This estimate includes approximately 1,340 NDAs and BLAs and approximately 4,160 ANDAs containing labeling changes as a result of the final rule. FDA estimates that approximately 320 application holders will submit these annual reports, and that it will take approximately 40 hours for each submission. The burden for this information collection has not increased since the last collection.

Dated: February 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–02765 Filed 2–9–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–E–3877]

Determination of Regulatory Review Period for Purposes of Patent Extension; AKYNZEO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for AKYNZEO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 13, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 13, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 13, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 13, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2015–E–3877 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; AKYNZEO.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 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.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.

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