Board of Governors of the Federal Reserve System, January 8, 2018.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2018–00341 Filed 1–10–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0275]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Certification To Accompany Drug, Biological Product, and Device Applications or Submissions

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 February 12, 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 0910–0616. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Certification To Accompany Drug, Biological Product, and Device Applications or Submissions (Form FDA 3674)

OMB Control Number 0910–0616—Extension

The information required under section 402(j)(5)(B) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(5)(B)) is submitted in the form of a certification, Form FDA 3674, which accompanies applications and submissions currently submitted to FDA and already approved by OMB. The OMB control numbers and expiration dates for those applications and submissions are: 21 CFR parts 312 and 314 (human drugs), OMB control number 0910–0014, expiring February 28, 2019, and OMB control number 0910–0001, expiring December 31, 2017; 21 CFR parts 312 and 601 (biological products), OMB control number 0910–0014, expiring February 28, 2019, and OMB control number 0910–0338, expiring March 31, 2020; and 21 CFR parts 807 and 814 (devices), OMB control number 0910–0120, expiring June 30, 2020, and OMB control number 0910–0231, expiring March 31, 2020.

Title VIII of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) amended the PHS Act by adding section 402(j). The provisions broadened the scope of clinical trials subject to submitting information and required additional information to be submitted to the clinical trials databank (*https://clinicaltrials.gov*) (FDA has verified the website address, but FDA is not responsible for any subsequent changes to the website after this document publishes in the **Federal Register**) previously established by the National Institutes of Health (NIH)/National Library of Medicine. This includes expanded information on applicable clinical trials and summary information on the results of certain clinical trials. The provisions include responsibilities for FDA as well as several amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act).

One provision, section 402(j)(5)(B) of the PHS Act, requires that a certification accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification, Form FDA 3674, that all applicable requirements of section 402(j) of the PHS Act have been met. Where available, such certification must include the appropriate National Clinical Trial (NCT) numbers that are assigned upon submission of required information to the NIH databank at *https://clinicaltrials.gov.*

The proposed extension of the collection of information is necessary to satisfy the previously mentioned statutory requirement. The importance of obtaining these data relates to adherence to the legal requirements for submissions to the clinical trials registry and results databank, and ensuring that individuals and organizations submitting applications or reports to FDA under the listed provisions of the FD&C Act or the PHS Act adhere to the appropriate legal and regulatory requirements for certifying to having complied with those requirements. The failure to submit the certification required by section 402(j)(5)(B) of the PHS Act, and the knowing submission of a false certification, are both prohibited acts under section 301 of the FD&C Act (21 U.S.C. 331). Violations are subject to civil money penalties. The Form FDA 3674 provides a convenient mechanism for sponsors/applicants/submitters to satisfy the certification requirements of the statutory provision.

To assist sponsors/applicants/submitters in understanding the statutory requirements associated with Form FDA 3674, we have provided a guidance available at: *https://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm.* This guidance recommends the applications and submissions FDA considers should be accompanied by the certification form, Form FDA 3674. The applications and submissions identified in the guidance are reflected in the burden analysis. In 2017, we updated the guidance to include references to the NIH Final Rule implementing 402(j) of the PHS Act (42 U.S.C. 282(j)). The final rule, published on September 21, 2016 (81 FR 64982) (42 CFR part 11), clarifies the requirements for submission of clinical trial information to *https://clinicaltrials.gov.*

Investigational New Drug Applications. FDA's Center for Drug Evaluation and Research (CDER) received 1,669 investigational new drug applications (INDs) and 15,285 clinical protocol IND amendments in calendar year (CY) 2016. CDER anticipates that IND and clinical protocol amendment submission rates will remain at or near this level in the near future.

FDA's Center for Biologics Evaluation and Research (CBER) received 381 new

INDs and 456 clinical protocol IND amendments in CY 2016. CBER anticipates that IND and clinical protocol amendment submission rates will remain at or near this level in the near future. The estimated total number of submissions (new INDs and new protocol submissions) subject to mandatory certification requirements under section 402(j)(5)(B) of the PHS Act is 16,954 for CDER plus 837 for CBER, or 17,791 submissions per year. The minutes per response is the estimated number of minutes that a respondent would spend preparing the information to be submitted to FDA under section 402(j)(5)(B) of the PHS Act, including the time it takes to enter the necessary information on the form.

Based on its experience with current submissions, FDA estimates that approximately 15 minutes on average would be needed per response for certifications that accompany IND applications and clinical protocol amendment submissions. It is assumed that most submissions to investigational applications will reference only a few protocols for which the sponsor/applicant/submitter has obtained an NCT number from *https://clinicaltrials.gov* prior to making the submission to FDA. It is also assumed that the sponsor/applicant/submitter has electronic capabilities allowing them to retrieve the information necessary to complete the form in an efficient manner.

Marketing Applications/Submissions. In CY 2016, CDER and CBER received 252 new drug applications (NDA)/biologics license applications (BLA)/resubmissions and 1,067 NDA/BLA amendments for which certifications are needed. CDER and CBER received 253 efficacy supplements/resubmissions to previously approved NDAs/BLAs in CY 2016. CDER and CBER anticipate that new drug/biologic applications/resubmissions and efficacy supplement submission rates will remain at or near this level in the near future.

FDA's Center for Devices and Radiological Health (CDRH) received a total of 330 new applications for premarket approvals (PMA), 510(k) submissions containing clinical information, PMA supplements, applications for humanitarian device exemptions (HDE) and amendments in CY 2016. CDRH anticipates that application, amendment, supplement, and annual report submission rates will remain at or near this level in the near future.

FDA's Office of Generic Drugs (OGD) received 1,036 abbreviated new drug applications (ANDAs) in 2016. OGD received 698 bioequivalence amendments/supplements in 2016. OGD anticipates that application, amendment, and supplement submission rates will remain at or near this level in the near future.

Based on its experience reviewing NDAs, BLAs, PMAs, HDEs, 510(k)s, and ANDAs and experience with current submissions of Form FDA 3674, FDA estimates that approximately 45 minutes on average would be needed per response for certifications that accompany NDA, BLA, PMA, HDE, 510(k), and ANDA marketing applications and submissions. It is assumed that the sponsor/applicant/submitter has electronic capabilities allowing them to retrieve the information necessary to complete the form in an efficient manner.

In the **Federal Register** of September 22, 2017 (82 FR 44417), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Center/Activity	Number of respondents (investigational applications)	Number of respondents (marketing applications)	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER						
New Applications (IND)	1,669		1	1,669	0.25 (15 minutes)	417
Clinical Protocol Amendments (IND).	15,285		1	15,285	0.25 (15 minutes)	3,821
New Marketing Applications/ Resubmissions (NDA/BLA).		198	1	198	0.75 (45 minutes)	149
Clinical Amendments to Marketing Applications.		1,067	1	1,067	0.75 (45 minutes)	800
Efficacy Supplements/ Resubmissions.		219	1	219	0.75 (45 minutes)	164
CBER						
New Applications (IND)	381		1	381	0.25 (15 minutes)	95
Clinical Protocol Amendments (IND).	456		1	456	0.25 (15 minutes)	114
New Marketing Applications/ Resubmissions (NDA/BLA).		54	1	54	0.75 (45 minutes)	41
Clinical Amendments to Marketing Applications.		0	1	0	0.75 (45 minutes)	0
Efficacy Supplements/ Resubmissions (BLA only).		34	1	34	0.75 (45 minutes)	26
CDRH						
New Marketing Applications (includes PMAs, HDEs, Supplements and 510(k)s expected to contain clinical data).		330	1	330	0.75 (45 minutes)	247

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

FDA Center/Activity	Number of respondents (investigational applications)	Number of respondents (marketing applications)	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
OGD						
Original Applications		1,036	1		0.75 (45 minutes)	777
Bioequivalence Supplements/ Amendments.		698	1		0.75 (45 minutes)	524
Total						7,175

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

Dated: January 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00354 Filed 1–10–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2016–E–3310 and FDA–2016–E–3341]

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

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 ENTYCE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that animal 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 March 12, 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 July 10, 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 March 12, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of March 12, 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 Nos. FDA–2016–E–3310 and FDA–2016–E–3341 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ENTYCE.'' 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