restoration. In a letter dated February 8, 2018, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of TYMLOS 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 TYMLOS is 4,130 days. Of this time, 3,735 days occurred during the testing phase of the regulatory review period, while 395 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* January 8, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was January 8, 2006.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* March 30, 2016. FDA has verified the applicant's claim that the new drug application (NDA) for TYMLOS (NDA 208743) was initially submitted on March 30, 2016.

3. *The date the application was approved:* April 28, 2017. FDA has verified the applicant's claim that NDA 208743 was approved on April 28, 2017.

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 724 days, 1,123 days, or 1,128 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: October 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22956 Filed 10–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2434]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 November 21, 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 0910–0429. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products

OMB Control Number 0910–0429—Extension

This information collection supports the above captioned Agency guidance document. The guidance document was issued to help individuals with procedures on formal meetings between FDA and sponsors or applicants regarding the development and review of Prescription Drug User Fee Act (PDUFA) products. The guidance describes procedures for requesting, scheduling, conducting, and documenting such formal meetings. The guidance provides information on how FDA interprets and applies section 119(a) of the Food and Drug Administration Modernization Act of 2007 (Pub. L. 105–115), specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 12.47 and 312.82 (21 CFR 312.47 and 312.82)). The collection of information described in the guidance reflects the current and past practice of sponsors and applicants to submit meeting requests and background information prior to a scheduled meeting. Agency regulations currently permit such requests and recommend the submission of an information package before an ''end-of-phase 2 meeting'' (§§ 312.47(b)(1)(ii) and (iv)) and a ''pre-NDA meeting'' (§ 312.47(b)(2)). While the information collection provisions of § 312.47 are currently approved under OMB control number 0910–0014, the guidance provides additional recommendations for submitting information to FDA in support of a meeting request. The guidance document is available on our website at: *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM590547.pdf.*

Request for a Meeting—Consistent with recommendations found in the guidance, a sponsor or applicant interested in meeting with the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) should submit a

meeting request to the appropriate FDA component as an amendment to the application for the underlying product in accordance with our regulations (§§ 312.23, 314.50, and 601.2 (21 CFR 312.23, 314.50, and 601.2)). Information provided to the Agency as part of an investigational new drug application (IND), new drug application (NDA), or biological license application (BLA) must be submitted with an appropriate cover form. Form FDA 1571 must accompany IND submissions, and Form FDA 356h must accompany NDA and BLA submissions. These Agency forms are approved under OMB control numbers 0910–0014 and 0910–0338, respectively.

We recommend that a request be submitted in this manner to ensure that each request is kept in the administrative file with the complete application, and to ensure that pertinent information about the request is entered into appropriate tracking databases. Using information from our tracking databases enables us to monitor progress on activities attendant to scheduling and holding a formal meeting and to ensure that appropriate steps will be taken in a timely manner.

The guidance recommends that meeting requests include the following information:

- Information identifying and describing the product
- the type of meeting being requested
- a brief statement of the purpose of the meeting
- a list of objectives and expected outcomes from the meeting
- a preliminary proposed agenda
- a draft list of questions to be raised at the meeting
- a list of individuals who will represent the sponsor or applicant at the meeting
- a list of Agency staff requested to be in attendance
- the approximate date that the information package will be sent to the Agency
- suggested dates and times for the meeting

We use the information to determine the purpose of the meeting, the necessary participants, the proposed agenda, and to schedule the meeting.

Information Package—The guidance also recommends that a sponsor or applicant submitting an information package provide summary information relevant to the product and supplementary information pertaining to any issue raised by the sponsor, applicant, or FDA. Information packages should generally include:

- Identifying information about the underlying product
- a brief statement of the purpose of the meeting
- a list of objectives and expected outcomes of the meeting
- a proposed agenda for the meeting
- a list of specific questions to be addressed at the meeting
- a summary of clinical data that will be discussed (as appropriate)
- a summary of preclinical data that will be discussed (as appropriate)
- chemistry, manufacturing, and controls information that may be discussed (as appropriate)

The information package enables Agency staff to prepare for the meeting and allows appropriate time for reviewing relevant product data. Although FDA reviews similar information in the meeting request, the information package should provide updated data reflecting the most current and accurate information available to the sponsor or applicant.

In the **Federal Register** of July 11, 2018 (83 FR 32130), 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]

Guidance recommendations	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Meeting Requests:					
CDER	1,319	2.31	3,058	10	30,580
CBER	301	1.21	363	10	3,630
Subtotal					34,210
Information Packages:					
CDER	1,149	2.19	2,522	18	45,396
CBER	187	1.12	210	18	3,780
Subtotal					49,176
Total					83,386

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

Our estimated burden for the information collection reflects an overall increase since the previous OMB approval. We attribute this adjustment to an increase in the number of meeting requests and information packages received over the last few years.

Based on Agency data, we estimate 1,319 sponsors and applicants (respondents) request 3,058 formal meetings with CDER annually, and 301 respondents request 363 formal meetings with CBER annually regarding the development and review of a PDUFA product. The hours per response, which is the estimated number of hours that a respondent spends preparing the information to be submitted with a meeting request in accordance with the guidance, is estimated to be 10 hours. We expect it takes this amount of time to gather and copy brief statements about the product as well as a description of the purpose and details of the meeting.

Also consistent with Agency data, we estimate 1,149 respondents submitted 2,522 information packages to CDER annually, and 187 respondents submitted 210 information packages to CBER annually, prior to a formal meeting regarding the development and review of a PDUFA product. We estimate 18 hours is needed to prepare

the information package in accordance with the guidance.

Dated: October 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22954 Filed 10–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 050

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 050'' (Recognition List Number: 050), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit electronic or written comments concerning this document at any time. These modifications to the list of recognized standards are effective October 22, 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–2004–N–0451 for ''Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 050.'' 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. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 050.

- 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 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.

An electronic copy of Recognition List Number: 050 is available on the internet at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section IV for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 050 modifications and other standards related information. Submit written requests for a single hard copy of the document entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 050'' to Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5514, Silver Spring, MD 20993, 301–796–6287. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8144.

FOR FURTHER INFORMATION CONTACT: Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5514, Silver Spring, MD 20993, 301–796–6287, *CDRHStandardsStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device