(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 biological 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 biologic product BEXSERO (Meningococcal Group B vaccine). BEXSERO is indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B and is approved for use in individuals 10 through 25 years of age. Subsequent to this approval, the USPTO received patent term restoration applications for BEXSERO (U.S. Patent Nos. 8,273,360 and 8,663,656) from GlaxoSmithKline Biologicals SA, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated April 20, 2016, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of BEXSERO 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 BEXSERO is 3,963 days. Of this time, 3,779 days occurred during the testing phase of the regulatory review period, while 184 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 (21 U.S.C. 355(i)) became effective:* March 20, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on March 20, 2004.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262*): July 24, 2014. FDA has verified the applicant's claim that the biologics license application (BLA) for BEXSERO (BLA 125546/0) was initially submitted on July 24, 2014.

3. *The date the application was approved:* January 23, 2015. FDA has verified the applicant's claim that BLA 125546/0 was approved on January 23, 2015.

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 518 days or 255 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 ask for a redetermination (see **DATES**). 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. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (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 Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29025 Filed 12–2–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2896]

Public Meeting on Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the public meeting on Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products that was announced in the **Federal Register** on October 6, 2016. In that **Federal Register** notice, FDA requested comments on the approach to testing FDA recommended in its draft guidance ''General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products'' and FDA's efforts to develop standardized in vitro testing methodologies for evaluating the abuse deterrence of opioid drug products. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the Public Meeting on Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products published October 6, 2016 (81 FR 69532). Submit either electronic or written comments by January 3, 2017.

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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–N–2896 for ''Public Meeting on Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products; Extension of Comment Period.'' 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 Division of Dockets Management 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 Division of Dockets Management. 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.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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michelle Eby, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6184, Silver Spring, MD 20993, 301–796–4714, *Michelle.Eby@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 6, 2016 (81 FR 69532), FDA published a notice announcing a public meeting and requesting comments on the approach to testing FDA recommended in its draft guidance ''General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products'' [1] and FDA's efforts to develop standardized in vitro testing methodologies for evaluating the abuse deterrence of opioid drug products. The comment period ends on December 1, 2016. Because the Agency has received requests for an extension to allow interested persons additional time to submit comments, FDA is extending the comment period until January 3, 2017.

Additional comments specific to the draft guidance ''General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products'' should be submitted to the docket for the draft guidance (FDA–2016–D–0785) in lieu of, or in addition to, the docket for the public meeting. 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 December 1, 2016. Other comments should be submitted to this docket by January 3, 2016. FDA has committed to taking steps to address the epidemic of opioid abuse transparently and in close cooperation with stakeholders and will provide other opportunities to comment, as appropriate. For example, FDA intends to issue a general guidance for public comment describing the Agency's recommendations for standardized in vitro testing to evaluate purported abuse-deterrent properties and considerations for a potential applicant as it develops an abuse-deterrent formulation of an opioid drug product.

Dated: November 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29097 Filed 12–2–16; 8:45 am]

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[1] *http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm492172.pdf.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1089]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recommended Glossary and Educational Outreach To Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on recommended glossary and educational outreach to support use of symbols on labels and in labeling of in vitro diagnostic devices intended for professional use.

DATES: Submit either electronic or written comments on the collection of information by February 3, 2017.

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