

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 DAURISMO (glasdegib). DAURISMO is indicated, in combination with low-dose cytarabine, for the treatment of newly diagnosed acute myeloid leukemia in adult patients who are 75 years old and older, or who have comorbidities that preclude use of intensive induction chemotherapy. Subsequent to this approval, the USPTO received a patent term restoration application for DAURISMO (U.S. Patent Nos. 8,148,401; 8,431,597) from Pfizer, Inc. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated December 26, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of DAURISMO 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 DAURISMO is 3,388 days. Of this time, 3,179 days occurred during the testing phase of the regulatory review period, while 209 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:* August 14, 2009. The applicant claims August 15, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 14, 2009, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* April 27, 2018. FDA

has verified the applicant's claim that the new drug application (NDA) for DAURISMO (NDA 210656) was initially submitted on April 27, 2018.

3. *The date the application was approved:* November 21, 2018. FDA has verified the applicant's claim that NDA 210656 was approved on November 21, 2018.

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 661 days or 1,121 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: March 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05305 Filed 3–12–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Infant and Maternal Mortality

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Infant and Maternal Mortality (ACIMM or Committee) has scheduled a public meeting. Information about ACIMM and the agenda for this meeting can be found on the ACIMM website at <https://www.hrsa.gov/advisory-committees/infant-mortality/index.html>.

DATES:

- April 2, 2024, 9 a.m. to 4 p.m. Central Time (CT);
- April 3, 2024, 12 p.m. to 6 p.m. CT; and
- April 4, 2024, 9 a.m. to 12 p.m. CT.

ADDRESSES: This meeting will be held in-person at Delmar Divine, 5501 Delmar Boulevard, St. Louis, Missouri 63112 and virtually via webinar. The webinar link and log-in information will be available at the ACIMM website before the meeting: <https://www.hrsa.gov/advisory-committees/infant-mortality/index.html>.

FOR FURTHER INFORMATION CONTACT:

Vanessa Lee, MPH, Designated Federal Official, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–0543; or SACIM@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACIMM is authorized by section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed by provisions of the Federal Advisory Committee Act (5 U.S.C. Chapter 10), as amended.

ACIMM advises the Secretary of Health and Human Services (Secretary) on department activities, partnerships, policies, and programs directed at reducing infant mortality, maternal mortality and severe maternal morbidity, and improving the health status of infants and women before, during, and after pregnancy. The Committee provides advice on how to coordinate federal, state, local, tribal, and territorial governmental efforts designed to improve infant mortality, related adverse birth outcomes, maternal health, as well as influence

similar efforts in the private and voluntary sectors. The Committee provides guidance and recommendations on the policies, programs, and resources required to address the disparities and inequities in infant mortality, related adverse birth outcomes and maternal health outcomes, including maternal mortality and severe maternal morbidity. With its focus on underlying causes of the disparities and inequities seen in birth outcomes for women and infants, ACIMM advises the Secretary on the health, social, economic, and environmental factors contributing to the inequities and proposes structural, policy, and/or systems level changes.

The agenda for the April 2–4, 2024, meeting is being finalized and may include the following topics: updates on the federal Healthy Start program; Committee discussions on the workgroup topics of rural health care access, social drivers of health, and women's health before/between pregnancies; federal updates; and remarks from individuals with lived experience and community members, including those representing community-based organizations, on how to achieve optimal maternal health and overall birth outcomes for underserved populations, including Black/African-American families. Agenda items are subject to change as priorities dictate. Refer to the ACIMM website listed above for any updated information concerning the meeting.

Members of the public will have the opportunity to provide written or oral comments. Requests to submit a written statement or make oral comments to ACIMM should be sent to Vanessa Lee, using the email address above at least 3 business days prior to the meeting. Public participants may submit written statements in advance of the scheduled meeting by emailing SACIM@hrsa.gov. Oral comments will be honored in the order they are requested and may be limited as time allows.

Individuals who plan to attend and need special assistance or a reasonable accommodation should notify Vanessa Lee at the contact information listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–05300 Filed 3–12–24; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2024–0183]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0109

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0109, Drawbridge Operation Regulations; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before May 13, 2024.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2024–0183] to the Coast Guard using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the “Public participation and request for comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at <https://www.regulations.gov>. Additionally, copies are available from: Commandant (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.*, chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's

likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2024–0183], and must be received by May 13, 2024.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Information Collection Request

Title: Drawbridge Operation Regulations.

OMB Control Number: 1625–0109.