information for use throughout the global medicinal product development lifecycle. In 2013, FDA established an internal committee to determine the conformance of FDA standards to the ISO IDMP standards. Over several years, the committee analyzed the structure, format, and content of the Unique Ingredient Identifier, Structured Product Labeling Pharmaceutical Dosage Form Terminology, Unified Code for Units of Measure, and National Drug Code to assess their conformance to ISO 11238, ISO 11239, ISO 11240, and ISO 11615, respectively. FDA's internal committee determined that the Agency's standards conform to the ISO IDMP standards for regional use. Topics covered in this guidance include:

- Introduction and scope
- Introduction to the five ISO IDMP standards: ISO 11238 (substance), ISO 11239 (dose form), ISO 11240 (units of measure), ISO 11615 (medicinal product identification), and ISO 11616 (pharmaceutical product identification)
- Benefits of IDMP implementation and use, including drug safety and pharmacovigilance, medicinal product traceability for global supply chain integrity, and regulatory registration and exchange of medicinal product information
- FDA's approach to the IDMP standards
- Phased approach to the global implementation

The guidance represents the current thinking of FDA on ''Identification of Medicinal Products—Implementation and Use.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: March 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06587 Filed 3–29–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1393]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions

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: Submit written comments (including recommendations) on the collection of information by May 1, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0233. The title of this information collection is ''Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions—21 CFR Part 60

OMB Control Number 0910–0233—Extension

This information collection supports Agency regulations. FDA's patent extension activities are conducted under the authority of section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) and the Generic Animal Drug and Patent Term Restoration Act of 1988 (Pub. L. 100–670) (21 U.S.C. 301, *et seq.*). The regulations are codified in 21 CFR part 60, Patent Term Restoration. New human drug, animal drug, human biological, medical device, food additive, or color additive products regulated by FDA must undergo FDA safety, or safety and effectiveness review before marketing is permitted. If the product is covered by a patent, part of the patent's term may be consumed during this review, which diminishes the value of the patent.

In enacting section 505(j) of the FD&C Act and the Generic Animal Drug and Patent Term Restoration Act of 1988, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (USPTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years and is calculated by USPTO based on a statutory formula. When a patent holder submits an application for patent term extension to USPTO, USPTO requests information from FDA, including the length of the regulatory review period for the patented product. If USPTO concludes that the product is eligible for patent term extension, FDA publishes a notice that describes the length of the regulatory review period and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with ''due diligence.''

In 21 CFR 60.36(a) *due diligence* is defined as ''that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.'' As provided in § 60.30(c), a due diligence petition

''shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence.'' Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A due diligence petitioner not satisfied with FDA's decision regarding the petition may request, under § 60.40 (21 CFR 60.40), an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

In the **Federal Register** of August 10, 2022 (87 FR 48667), 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]

21 CFR part 60—patent term restoration	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Revision of regulatory review period determinations; § 60.24	4	1.25	5	100	500
Due diligence petitions; § 60.30	1	1	1	50	50
Due diligence hearings; § 60.40	1	1	1	10	10
Total					560

[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 decrease of 34 hours and 11 responses. Since publication of the 60-day notice, we have adjusted our burden estimate to reflect an annualized figure (reducing responses associated with § 60.24 by one-third), which results in a decrease to the currently approved burden. There is also a small adjustment decrease of one response associated with submissions received for revision of the regulatory review period determination under § 60.24 since our last review.

Dated: March 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06573 Filed 3–29–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0964]

GlaxoSmithKline Intellectual Property Development Ltd. England; Announcement of the Revocation of the Biologics License for BLENREP

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the revocation of the biologics license for BLENREP (belantamab mafodotin-blmf) powder for injection. GlaxoSmithKline Intellectual Property Development Ltd. England (GSK) requested withdrawal (revocation) of the biologics license and has waived its opportunity for a hearing.

DATES: The biologics license application (BLA) is revoked as of February 6, 2023.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On August 5, 2020, FDA approved the BLA for BLENREP (belantamab mafodotin-blmf) powder for injection held by GlaxoSmithKline Intellectual Property Development Ltd. England (GSK), c/o GlaxoSmithKline, 1250 South Collegeville Rd., Collegeville, PA 19426, indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent, under the Agency's accelerated approval regulations, 21 CFR part 601, subpart E. On November 2, 2022, FDA and GSK met to discuss the results of the confirmatory study required as a condition of BLENREP's accelerated approval, entitled ''Study of Single Agent Belantamab Mafodotin Versus Pomalidomide Plus Low-dose Dexamethasone (Pom/Dex) in Participants with Relapsed/Refractory Multiple Myeloma (DREAMM–3 trial)'' and considerations regarding withdrawal (revocation) of the biologics license for BLENREP because the confirmatory DREAMM–3 trial did not meet its primary endpoint to demonstrate superior progression-free survival. On November 18, 2022, GSK requested withdrawal (revocation), in writing, of the biologics license for BLENREP (belantamab mafodotin-blmf) powder for injection (BLA 761158) under § 601.5(a) (21 CFR 601.5(a)) and waived its opportunity for a hearing. On February 6, 2023, the Agency issued a letter to GSK revoking the biologics license for BLENREP (belantamab mafodotin-blmf) powder for injection (BLA 761158).

Therefore, under § 601.5(a), the Agency revoked the biologics license for BLENREP (belantamab mafodotin-blmf) powder for injection (BLA 761158), effective as of February 6, 2023, the date of FDA's letter revoking the biologics license for BLENREP.

Dated: March 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06576 Filed 3–29–23; 8:45 am]

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