''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]

BILLING CODE 4164–01–P