phase of the regulatory review period, while 457 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: May 25, 2005. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on May 25, 2005. 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 28, 2014. FDA has verified the applicant’s claim that the biologics license application (BLA) for IMLYGIC (BLA 125518) was initially submitted on July 28, 2014. 3. The date the application was approved: October 27, 2015. FDA has verified the applicant’s claim that BLA 125518 was approved on October 27, 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 1,826 days, 1,764 days, or 1400 days, respectively, 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: December 21, 2016.

Leslie Kux,
Associate Commissioner for Policy.