drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts 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, Omegaven (fish oil triglycerides) indicated as a source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis. Subsequent to this approval, the USPTO received a patent term restoration application for Omegaven (U.S. Patent No. 9,566,260) from Children's Medical Center Corporation and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated November 29, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of Omegaven 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 Omegaven is 4,246 days. Of this time, 4,007 days occurred during the testing phase of the regulatory review period, while 239 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:* December 13, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 13, 2006.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 1, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for Omegaven (NDA 210589) was initially submitted on December 1, 2017.

3. *The date the application was approved:* July 27, 2018. FDA has verified the applicant's claim that NDA 210589 was approved on July 27, 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 application for patent extension, this applicant seeks 383 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: October 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–24124 Filed 10–31–23; 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; Correction

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

ACTION: Notice; correction.

SUMMARY: HRSA published a notice in the **Federal Register** of October 12, 2023, concerning a meeting of the Advisory Committee on Infant and Maternal Mortality. The document contained incorrect location information. The notice originally stated that the meeting would be held in person at HRSA Headquarters (5600 Fishers Lane, Room 5W07, Rockville, Maryland, 20857) and virtually via webinar. The meeting will now be fully virtual via webinar and not held in person. The webinar link and log-in information will be available at the Committee's 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, Room 18N84, Rockville, Maryland, 20857; 301–443–0543; or *SACIM@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of October 12, 2023, FR Doc. 2023–22509, page 70682, column 1, **ADDRESSES** section, paragraph 1, correct ''This meeting will be held in person at HRSA Headquarters (5600 Fishers Lane, Room 5W07, Rockville, Maryland, 20857) and virtually via webinar'' to read: ''This meeting will be held by webinar.''

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–24080 Filed 10–31–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as