TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section; activity	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
108.25(c)(2); Food process filing for acidified method.	2541e	726	11	7,986	0.333 (20 minutes)	2,659
108.35(c)(2); Food process filing for low-acid retorted method.	2541d	336	12	4,032	0.333 (20 minutes)	1,343
108.35(c)(2); Food process filing for water activity/formulation control method.	2541f	37	6	222	0.333 (20 minutes)	74
108.35(c)(2); Food process filing for low-acid aseptic systems.	2541g	42	22	924	0.75 (45 minutes)	693
108.25(d); 108.35(d) and (e); Report of any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce.	N/A	1	1	1	4	4
Total						4,883

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate of the number of respondents in table 1 on registrations, process filings, and reports received. The hours per response reporting estimates are based on our experience with similar programs and information received from industry.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
108, 113, and 114	10,392	1	10,392	250	2,598,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our regulations require that processors mark thermally processed low-acid foods in hermetically sealed containers (§ 113.60(c)) and acidified foods (§ 114.80(b)) with an identifying code to permit lots to be traced after distribution. No burden has been estimated for the third-party disclosure requirements in §§ 113.60(c) and 114.80(b) because the coding process is done as a usual and customary part of normal business activities. Coding is a business practice in foods for liability purposes, inventory control, and process control in the event of a problem. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: March 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05742 Filed 3–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–5280]

Determination of Regulatory Review Period for Purposes of Patent Extension; ESPEROCT

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ESPEROCT and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by May 22, 2023. 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 by September 21, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late,

untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 22, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–E–5280 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ESPEROCT.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product ESPEROCT (antihemophilic factor (recombinant), glycopegylated-exei). ESPEROCT is indicated for use in adults and children with hemophilia A for: (1) on-demand treatment and control of bleeding episodes, (2) perioperative management of bleeding, and (3) routine prophylaxis to reduce the frequency of bleeding episodes. Subsequent to this approval, the USPTO received a patent term restoration application for ESPEROCT (U.S. Patent No. 8,536,126) from Novo Nordisk A/S, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 20, 2020, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of ESPEROCT 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 ESPEROCT is 3,129 days. Of this time, 2,771 days occurred during the testing

phase of the regulatory review period, while 358 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:* July 29, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 29, 2010.

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):* February 27, 2018. FDA has verified the applicant's claim that the biologics license application (BLA) for ESPEROCT (BLA 125671) was initially submitted on February 27, 2018.

3. *The date the application was approved:* February 19, 2019. FDA has verified the applicant's claim that BLA 125671 was approved on February 19, 2019.

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 1,170 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 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05658 Filed 3–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Council on Graduate Medical Education

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

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates for consideration for appointment as members of the Council on Graduate Medical Education (COGME or Council). COGME provides advice and recommendations on policy, program development, and other matters of significance concerning the physician training and the physician workforce. Issues addressed by COGME include the supply and distribution of the physician workforce in the United States, including any projected shortages or excesses of physicians in medical and surgical specialties and subspecialities; international medical graduates; the nature and financing of undergraduate and graduate medical education; appropriation levels for certain programs under title VII of the PHS Act; and deficiencies in databases of the supply and distribution of the physician workforce and postgraduate programs for training physicians.

DATES: HRSA will accept nominations on a continuous basis.

ADDRESSES: Nomination packages may be mailed to Advisory Council Operations, Bureau of Health Workforce, HRSA, Room 15N–35, 5600 Fishers Lane, Rockville, Maryland 20857 or submitted electronically by email to: *BHWAdvisoryCouncilFRN@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Curi Kim, M.D., MPH, at 240–472–2313 or email at *ckim@hrsa.gov.* A copy of the current COGME charter, membership, and reports can be obtained by accessing the COGME website at *https://www.hrsa.gov/advisory-committees/graduate-medical-edu.*

SUPPLEMENTARY INFORMATION: Authorized in 1986, COGME submits advice and recommendations to the Secretary of HHS; the Senate Committee on Health, Education, Labor and Pensions; and the House of Representatives Committee on Energy and Commerce. Additionally, COGME encourages entities providing graduate medical education to voluntarily achieve the recommendations of the Council. Meetings take place at least twice per year.

Nominations: HRSA is requesting nominations for voting members to serve as Special Government Employees on COGME to include individuals who represent of practicing primary care physicians, national and specialty physician organizations, international medical graduates, medical student and house staff associations, schools of allopathic and osteopathic medicine, public and private teaching hospitals, and health insurers, business, and labor. The Secretary of HHS appoints COGME members to fulfill the duties of the Council. Interested applicants may self-nominate or be nominated by another individual or organization.

Individuals selected for appointment to COGME will be invited to serve for 4 years. Members appointed as SGEs receive a stipend and reimbursement for per diem and travel expenses incurred for attending COGME meetings and/or conducting other business on behalf of COGME, as authorized by section 5 U.S.C. 5703 for persons employed intermittently in government service and PHS Act section 762(g).

A nomination package should include the following information for each applicant: (1) if nominated by another individual or organization, a letter of recommendation from the nominator stating the basis for the nomination (*i.e.,* what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of COGME) and the nominee's field(s) of expertise as well as the nominator's name, affiliation, and contact information (address, daytime telephone number, and email address); (2) a letter of interest from the applicant stating the reasons the applicant would like to serve on COGME; and (3) a biographical sketch of the applicant, including the applicant's curriculum vitae and contact information (address, daytime telephone number, and email address). Nomination packages may be submitted directly by the applicant or by the person/organization nominating the candidate.

HHS endeavors to ensure that the membership of COGME is balanced fairly in terms of points of view represented and that individuals from a broad representation of geographic areas, gender, and ethnic and minority groups, as well as individuals with