Estimated Total Annual Burden Hours: 10,476.

Authority: 42 U.S.C. 603, 605, 607, 609, 611, and 613; Public Law 109–171. Public Law 118–5.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–26874 Filed 11–18–24; 8:45 am]

BILLING CODE 4184–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Establishment of the National Advisory Committee on the Trafficking of Children and Youth in the United States

AGENCY: Office on Trafficking in Persons, Administration for Children and Families, Department of Health and Human Services.

ACTION: Establishment of Federal advisory committee.

SUMMARY: The National Advisory Committee on the Trafficking of Children and Youth in the United States (Committee) was established on November 7, 2024, to build on the work of the previous National Advisory Committee on the Sex Trafficking of Children and Youth in the United States, authorized pursuant to section 121 of the Preventing Sex Trafficking and Strengthening Families Act. The Committee advises on practical and general policies concerning improvements in the Nation's response to the human trafficking of children and youth in the United States, including the cooperation of Federal, State, local, and Tribal governments; child welfare agencies; social service providers; physical health and mental health providers; victim service providers; Federal, State, and local police; juvenile detention centers; State or local courts with responsibility for conducting or supervising proceedings related to child welfare or social services for children and their families; runaway and homeless youth programs; schools; technology, gaming and entertainment industry; and businesses and organizations that provide services to youth. While addressing the response to the trafficking of children and youth, the Committee shall consider recommendations related to the intersection of sex trafficking and labor trafficking among children and youth in the United States. Note that this **Federal Register** Notice of the Charter filing should have been published 15 days in advance.

DATES: The Committee's charter was filed on November 7, 2024.

ADDRESSES: To learn more about the Committee, access the Committee's website: *https://www.acf.hhs.gov/otip/partnerships/national-advisory-committee.*

FOR FURTHER INFORMATION CONTACT: Katherine Chon (Designated Federal Officer) at (202) 205–5778 or *EndTrafficking@acf.hhs.gov* or 330 C Street SW, Washington, DC, 20201. Additional information is available at *https://www.acf.hhs.gov/otip/partnerships/the-national-advisory-committee.*

SUPPLEMENTARY INFORMATION: *Background of Committee:* Following the sunset of the statutorily authorized Committee in January 2022 (pursuant to section 121 of the Preventing Sex Trafficking and Strengthening Families Act (Pub. L. 113–183) and governed by the provisions of Public Law 92–463, as amended (5 U.S.C. app. 2), this Committee is established as a discretionary committee under the authorization of Secretary of the U.S. Department of Health and Human Services.

Membership: The Committee shall consist of no more than 25 members, whose diverse experience and background enable them to provide balanced points of view with regard to carrying out the duties of the Committee. The members shall be selected by the Secretary of HHS in consultation with DOJ. At least one Committee member shall be a survivor of child sex trafficking and one Committee member shall be a survivor of child labor trafficking. Two Committee members shall be a Governor of a State, one of whom shall be a member of the Democratic Party and one of whom shall be a member of the Republican Party. Governors may send a leadership-level designee representing a State agency to attend Committee meetings. The members will be selected from among advocacy and victim service organizations; survivors of child trafficking at least 18 years of age; child welfare representatives; State, Tribal and local government human services officials; health and mental health representatives; law enforcement and judiciary; juvenile and youth development specialists; educators; the technology, entertainment and gaming industries; and the business community. The Democratic and Republican Governors shall be selected in consultation with the National Governor's Association. The Committee shall convene at least twice a year. This is an unpaid position and Committee members will not be considered employees of the Federal Government other than reimbursement of travel expenses and a per diem allowance in accordance with Federal Government regulations.

Megan E. Steel,

Deputy Director, Office of the Executive Secretariat.

[FR Doc. 2024–26881 Filed 11–18–24; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–E–2610 and FDA–2023–E–2611]

Determination of Regulatory Review Period for Purposes of Patent Extension; AGILI–C

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 AGILI–C and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by January 21, 2025. 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 May 19, 2025. 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 January 21, 2025. 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 Nos. FDA–2023–E–2610 and FDA–2023–E–2611 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; AGILI–C.'' 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 biological 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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device AGILI–C. AGILI–C is indicated for the treatment of an International Cartilage Repair Society grade III or above knee-joint surface lesion(s), with a total treatable area of 1–7 cm^2, without severe osteoarthritis (Kellgren-Lawrence grade 0–3). Subsequent to this approval, the USPTO received patent term restoration applications for AGILI–C (U.S. Patent Nos. 8,808,725 and 11,116,873) from Cartiheal (2009) Ltd., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated January 18, 2024, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of AGILI–C 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 AGILI–C is 1,988 days. Of this time, 1,807 days occurred during the testing phase of the regulatory review period, while 181 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* October 20, 2016. FDA has verified the applicant's claim that the date the investigational device exemption for human tests to begin, as required under section 520(g) of the

FD&C Act, became effective October 20, 2016.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* September 30, 2021. FDA has verified the applicant's claim that the premarket approval application (PMA) for AGILI–C (PMA P210034) was initially submitted September 30, 2021.

3. *The date the application was approved:* March 29, 2022. FDA has verified the applicant's claim that PMA P210034 was approved on March 29, 2022.

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 189 days or 1,085 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: November 7, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26910 Filed 11–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4311]

Frequently Asked Questions—Developing Potential Cellular and Gene Therapy Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled ''Frequently asked Questions—Developing Potential Cellular and Gene Therapy Products.'' The draft guidance document provides industry with answers to frequently asked questions (FAQs) and commonly faced issues that arise during the development of cellular and gene therapy (CGT) products. The FAQs represent common questions directed to the Agency and span multiple disciplines, including regulatory review; chemistry, manufacturing, and controls (CMC); pharmacology/toxicology; clinical; and clinical pharmacology.

DATES: Submit either electronic or written comments on the draft guidance by February 18, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2024–D–4311 for ''Frequently asked Questions—Developing Potential Cellular and Gene Therapy Products.'' Received comments 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 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.*