thyroid hormones, changes to the microbiome, and possibly decreased IQ. These safety findings are not conclusive, but they warrant continued research and discussion.

Toward that end, FDA is collaborating with the Reagan-Udall Foundation for the FDA to convene a public meeting to seek input on the clinical use and safety concerns associated with orally ingestible unapproved prescription drug products containing fluoride for use in the pediatric population. The purpose of this meeting is to facilitate an exchange of perspectives from subject matter experts and patients on the benefits and risks of using these drug products in the pediatric population.

The Reagan-Udall Foundation for the FDA will facilitate the public meeting. The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) not-for-profit organization created by Congress to advance the mission of FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development; accelerate innovation; and enhance product safety.

II. Topics for Discussion at the Public Meeting

FDA seeks public input from clinical, patient, public health, and research communities on the clinical use of and safety concerns associated with orally ingestible unapproved prescription drug products containing fluoride for prevention of tooth decay in the pediatric population.[1] In particular, comments are sought on the following topics:

1. Please comment on the evidence supporting the current clinical uses of orally ingestible unapproved prescription drug products containing fluoride for tooth decay prevention in the pediatric population. What factors do clinicians consider when prescribing such drug products for the pediatric population?

2. Please comment on the safety concerns associated with these drug products, taking into account the amount of fluoride they provide when used as directed for prevention of tooth decay prevention in the pediatric population.

3. Based on the totality of the data available today, please comment on the continued use of these drug products for tooth decay prevention in the pediatric population considering the additional sources of fluoride available.

4. From the perspective of patients and clinicians, what are the potential impacts of removing these drug products from the market? Are there alternatives to use of these ingestible drug products to achieve these ends?

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://reaganudall.org/news-and-events/events/use-orally-ingestible-unapproved-prescription-drug-products-fluoride.* Please indicate either in-person or virtual attendance and provide complete contact information for each attendee.

Registration is free and based on space availability, with priority for in-person attendance given to early registrants. Persons interested in attending this public meeting in person must register online by July 22, 2025, at 5:00 p.m. Eastern Time. Early registration for in-person attendance is recommended because seating is limited; therefore, the number of participants from a single organization may be limited. While there is no deadline for persons interested in attending this public meeting virtually, they must register online to receive the link. Registrants will receive registration confirmation via email.

If you need special accommodations due to a disability, please contact Lea Ann Browning-McNee, Director of Communication and Stakeholder Engagement, Reagan-Udall Foundation for the FDA, 202–849–2075, *fluoride@reaganudall.org,* no later than July 16, 2025, at 5:00 p.m. Eastern Time.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. The deadline to request a public comment slot is 5:00 p.m. Eastern Time on July 9, 2025. Following the July 9 deadline, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin. Selected participants will be notified the week of July 14, 2025, and provided with instructions regarding submission of a single slide in PowerPoint format. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public workshop will also be available via webinar to virtual attendees who register at *https://reaganudall.org/news-and-events/events/use-orally-ingestible-unapproved-prescription-drug-products-fluoride.*

Notice of this meeting is given pursuant to 21 CFR 10.65.

Dated: June 11, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–10943 Filed 6–13–25; 8:45 am]

BILLING CODE 4164–01–P

[1] Although the Agency is aware that there are other fluoride-containing products on the market, including dietary supplements, this public meeting is focused only on orally ingestible unapproved prescription drug products containing fluoride.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–0134; FDA–2024–E–0135; FDA–2024–E–0157]

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

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 BEYFORTUS 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 human biological product.

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 August 15, 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 December 15, 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 August 15, 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–2024–E–0134; FDA–2024–E–0135; and FDA–2024–E–0157, for ''Determination of Regulatory Review Period for Purposes of Patent Extension; BEYFORTUS.'' 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: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

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 BEYFORTUS (nirsevimab-alip). BEYFORTUS is indicated for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in:

- Neonates and infants born during or entering their first RSV season.
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

Subsequent to this approval, the USPTO received patent term restoration applications for BEYFORTUS (U.S. Patent Nos. 10,689,437; 11,186,628; 11,661,449) from AstraZeneca AB, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated February 6, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of BEYFORTUS 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 BEYFORTUS is 3,387 days. Of this time, 3,092 days occurred during the testing phase of the regulatory review period, while 295 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: April 10, 2014. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 10, 2014.

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):* September 26, 2022. FDA has verified the applicant's claim that the biologics license application (BLA) for BEYFORTUS (BLA B761328) was initially submitted on September 26, 2022.

3. *The date the application was approved:* July 17, 2023. FDA has verified the applicant's claim that BLA B761328 was approved on July 17, 2023.

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 49 days, 445 days, or 708 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: June 11, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11043 Filed 6–13–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–E–3298; FDA–2023–E–3302; FDA–2023–E–3303; FDA–2023–E–3304; FDA–2023–E–3305; FDA–2023–E–3306; FDA–2023–E–3307; FDA–2023–E–3308;FDA–2023–E–3309]

Determination of Regulatory Review Period for Purposes of Patent Extension; [NAVITOR TRANSCATHETER AORTIC VALVE IMPLANT]

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 NAVITOR TRANSCATHETER AORTIC VALVE IMPLANT 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 may submit either electronic or written comments and ask for a redetermination by August 15, 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 December 15, 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 August 15, 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–3298; FDA–2023–E–3302; FDA–2023–E–3303; FDA–2023–E–3304; FDA–2023–E–3305; FDA–2023–E–3306; FDA–2023–E–3307; FDA–2023–E–3308; FDA–2023–E–3309 for Determination of Regulatory Review Period for Purposes of Patent Extension; NAVITOR TRANSCATHETER AORTIC VALVE IMPLANT. 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