in that instance noted its intention to refrain from enforcement actions in the area.[2] But today's initiative marks the third time in as many months new agency leadership has issued expansive policy directives while related rulemakings proceed.[3] Publishing guidance during the pendency of a related rulemaking short-circuits the receipt of public input and conveys disdain for our stakeholders. I believe this practice does not constitute good government, so I dissent.

The FTC currently enforces several statutes that address negative option marketing,[4] including the Restore Online Shoppers' Confidence Act,[5] the Telemarketing Sales Rule,[6] the Use of Prenotification Negative Plans Rule,[7] the Postal Reorganization Act (also known as the Unordered Merchandise Rule),[8] and the Electronic Funds Transfer Act.[9] In addition, the FTC has brought numerous cases challenging negative option practices not covered by these statutes using Section 5 of the FTC Act.[10] Thus, there is a significant body of law in the form of FTC consents and litigated cases involving negative option practices.

In 2019, the Commission published a **Federal Register** Notice seeking comment on whether the Commission should expand its Prenotification Negative Option Rule to cover all types of negative option marketing, noting deceptive practices persist and the current regulatory patchwork does not provide a consistent framework for businesses.[11] We received 17 comments from business groups, consumer groups, and state attorneys general in response to that request for comment, representing a range of views and containing substantive and insightful information.

The Policy Statement acknowledges the ongoing rulemaking and states the Commission ''will continue to closely monitor compliance with the rules and laws applicable to negative option marketing, and is still considering various options in the rule review proceeding for the Negative Option Rule.'' A good government approach would be to publish this proposed guidance in the **Federal Register** with a discussion of how it comports with or differs from the comments we received in the rulemaking and seek comment on the proposed guidance.

Particularly given Chair Khan's stated goal of ''democratizing'' the FTC, one could be forgiven for viewing this as the best way in which to proceed. Alternatively, we could assimilate the feedback we received, close the rulemaking, and then publish this guidance. But the former approach is preferable—having determined as a unanimous Commission to embark on this rulemaking, rendering it moot at this early stage is akin to the elimination of opportunities for public input that the majority undertook in its changes to the Rules of Practice.[12]

There is no question the Commission has the authority to issue policy statements explaining its interpretation of the rules and laws it enforces. Moreover, this practice is a beneficial one: The FTC's business guidance facilitates transparency with respect to agency priorities and policy preferences, educates the business community, and drives compliance with the law. Our Division of Consumer and Business Education has received numerous awards for its publications, and I found FTC guidance documents helpful for client counseling purposes when I was in private practice.[13] Here, I agree this Policy Statement provides information that will be useful to businesses, and I largely support the guidance contained in the document. I believe, however, the Commission should either provide this guidance within the context of the open rulemaking or close the rulemaking and then issue the guidance.

For these reasons, I dissent.

[FR Doc. 2021–24094 Filed 11–3–21; 8:45 am]

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[2] *See* Enforcement Policy Statement Regarding Certain Imported Textile, Wool, and Fur Products (Jan. 3, 2013), *https://www.ftc.gov/news-events/press-releases/2013/01/ftc-announces-enforcement-policy-statementretailersdirectly; see also* 76 FR 68690 (Nov. 7, 2001); Press Release, FTC Seeks Public Input in Review of Textile Labeling Rules (Nov. 1, 2011), *https://wwwftc.gov/news-events/press-releases/2011/11/ftc-seeks-publicinputreview-textile-labeling-rules.*

[3] *See* Christine S. Wilson, FTC Comm'r, Dissenting Statement of Commissioner Christine S. Wilson Regarding the Policy Statement on Breaches by Health Apps and Other Connected Devices at 6 (Sept. 15, 2021), *https://www.ftc.gov/public-statements/2021/09/dissenting-statement-commissioner-christine-s-wilson-regardingpolicy* (describing issuance of Policy Statement on Breaches by Health Apps and Other Connected Devices during a related rulemaking; also describing rescission of agency guidance on treatment of debt in premerger notification context during a rulemaking covering precisely that issue).

[4] The Enforcement Policy Statement Regarding Negative Option Marketing explains that while negative options can take various forms, the central feature is ''each contains a term or condition under which the seller may interpret a consumer's silence or failure to take affirmative action to reject a good or service or to cancel the agreement as acceptance or continuing acceptance of the offer.''

[5] 15 U.S.C. 8401 through 8405.

[6] 16 CFR 310.

[7] 16 CFR 425.

[8] 39 U.S.C. 3009.

[9] 15 U.S.C. 1693 through 1693r.

[10] *See* 84 FR 52393, 52395–96 (Oct. 2, 2019) (ANPRM describing the cases the Commission has brought under Section 5 of the FTC Act).

[11] 84 FR 52393, 52394 (Oct. 2, 2019).

[12] 86 FR 38542 (July 22, 2021); *see also* Press Release, FTC Votes to Update Rulemaking Procedures, Sets Stage for Stronger Deterrence of Corporate Misconduct (July 1, 2021), *https://www.ftc.gov/news-events/pressreleases/2021/07/ftc-votes-update-rulemaking-procedures-sets-stage-stronger.*

[13] While in private practice, I also found informative the business guidance provided by expert FTC staff during speeches and panels. Unfortunately, our staff has been prohibited from delivering public remarks since Chair Khan's arrival in June.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–E–2124]

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

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for SEVENFACT 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 January 3, 2022. 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 3, 2022. 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. Electronic comments must be submitted on or before January 3, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 3, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service

acceptance receipt is 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–2020–E–2124 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; SEVENFACT.'' 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 SEVENFACT (coagulation factor VIIa (recombinant)-jncw (eptacog beta)). SEVENFACT is indicated for the treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with hemophilia A or B with inhibitors. Subsequent to this approval, the USPTO received a patent term restoration application for SEVENFACT (U.S. Patent No. 9,029,316) from Laboratoire Francais du Fractionnement et des Biotechnologies S.A. (LFB S.A.), and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 4, 2021, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of SEVENFACT 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 SEVENFACT is 2,785 days. Of this time, 1,518 days occurred during the testing phase of the regulatory review period, while 1,267 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: August 18, 2012. The applicant claims August 17, 2012, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 18, 2012, which was 30 days after FDA receipt of the IND.

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):* October 13, 2016. FDA has verified the applicant's claim that the biologics license application (BLA) for SEVENFACT (BLA 125641) was initially submitted on October 13, 2016.

3. *The date the application was approved:* April 1, 2020. FDA has verified the applicant's claim that BLA 125641 was approved on April 1, 2020.

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 482 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 28, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24065 Filed 11–3–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–1327 and FDA–2020–E–1333]

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

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 ADAKVEO 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 may submit either electronic or written comments and ask for a redetermination by January 3, 2022. 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 3, 2022. 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. Electronic comments must be submitted on or before January 3, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 3, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2020–E–1327 and FDA–2020–E–1333 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ADAKVEO.'' 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