while minimizing the risk that safety concerns would be raised by FDA during application review. They have also cited a perceived risk aversion on the part of drug developers, such that novel excipients may be avoided in drug development programs, even when the excipients have potential public health benefits.

With this information in mind, FDA's Center for Drug Evaluation and Research is considering developing a pilot program for the toxicological and quality evaluation of novel excipients. The Agency seeks information and comment on several aspects of such a program before deciding whether to develop it.

II. Possible Approach To Reviewing Novel Excipients

FDA is considering establishing a pilot program that would review a limited number of submissions per year. Any program developed by the Agency would be voluntary. FDA recognition of a novel excipient would not be necessary for the novel excipient to be included in a finished drug product described in an IND, an NDA, or a BLA.

Generally, FDA anticipates that a submission to a potential novel excipient review program would include toxicological studies supporting the safety of the novel excipient at anticipated levels and duration of exposure, by anticipated routes of administration. Additionally, FDA anticipates that submitters would provide identification and control information, including compositional and purity specifications for the novel excipient (see Excipients guidance).

FDA recognition of a novel excipient would mean that, based on a review of safety, manufacturing, and compositional information, FDA has determined that the proposed context of use (*e.g.,* acute or chronic exposure by specified route(s) of administration up to specified amounts) is expected to be safe. This determination would obviate the need for FDA review of the excipient in the context of an IND if its use in the investigational product is consistent with the recognized context of use. In the case of an NDA or a BLA seeking marketing approval or licensure of a finished drug or biological product containing a recognized excipient, FDA would review all information in the application relating to safety of the finished product. FDA expects that excipients reviewed under this program, after they are used in approved formulations, would be listed in the Inactive Ingredient Database.

III. Requested Information and Comments

Interested persons are invited to provide detailed comment on all aspects of this issue. Please read the information above regarding the submission of comments and confidential information. FDA is particularly interested in responses to the following questions:

1. What drug development challenges do drug sponsors encounter that could be addressed by using novel excipients?

2. Can stakeholders identify examples (specific or general) of novel excipients that have potential public health benefits?

3. FDA anticipates that a novel excipient recognition program would be limited to excipients that do not have a well-established history of safe use in food and that have potential public health benefits. We would be interested in stakeholder comment on these criteria.

4. Would FDA recognition of a novel excipient be sufficient to overcome any reluctance on the part of drug developers to use the novel excipient in a drug development program? Do drug development sponsors also look for a history of safe use in marketed drug products?

5. FDA envisions that an individual excipient manufacturer participating in a novel excipient recognition program would submit a complete package of safety data and certain chemistry, manufacturing, and controls information to support FDA's recognition of a novel excipient. This data and information would be based upon nonclinical studies of sufficient quality and quantity to allow for a safety evaluation, consistent with the Excipients guidance. We would be interested in stakeholder comment on this approach.

6. Are there adequate incentives for excipient manufacturers to engage in this process, particularly in situations in which multiple manufacturers may be undertaking to develop closely related novel excipients? If not, what incentives would encourage excipient manufacturers to engage in this process?

7. What information, if any, should FDA affirmatively disclose about a novel excipient evaluated under an eventual program in order to ensure the success of the program? For example, should FDA's evaluation be posted and explained publicly? Please note that FDA would handle disclosure of information submitted under the program in accordance with applicable law.

Dated: December 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–26266 Filed 12–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–E–1059; FDA–2019–E–1060; and FDA–2019–E–1061]

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

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 ANDEXXA 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 patents which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 3, 2020. 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 June 2, 2020. 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 February 3, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 3, 2020. 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–2019–E–1059; FDA–2019–E–1060; and FDA–2019–E–1061 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ANDEXXA.'' 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.

• 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.gpo.gov/fdsys/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.

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 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 ANDEXXA (coagulation factor Xa (recombinant) inactivated-zhzo). ANDEXXA is indicated for patients treated with rivaroxaban or apixaban, when reversal of anticoagulation is needed, due to life-threatening or uncontrolled bleeding. This indication is approved under accelerated approval based on the change from baseline in anti-human Factor Xa activity in healthy volunteers. An improvement in hemostasis has not been established. Continued approval for this indication may be contingent upon the results of studies to demonstrate an improvement in hemostasis in patients.

Subsequent to this approval, the USPTO received a patent term restoration application for ANDEXXA (U.S. Patent Nos. 8,153,590; 8,889,129; and 9,388,401) from Portola Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated May 13, 2019, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of ANDEXXA 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 ANDEXXA is 2,171 days. Of this time, 1,302 days occurred during the testing phase of the regulatory review period, while 869 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:* May 25, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 25, 2012.

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):* December 17, 2015. FDA has verified the applicant's claim that the biologics license application (BLA) for ANDEXXA (BLA 125586) was initially submitted on December 17, 2015.

3. *The date the application was approved:* May 3, 2018. FDA has verified the applicant's claim that BLA 125586 was approved on May 3, 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 applications for patent extension, this applicant seeks 661 days, 693 days, or 1,066 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 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–26251 Filed 12–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0731]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Eligibility Determination for Donors; and Current Good Tissue Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements for FDA regulations related to human cells, tissues, and cellular and tissue-based products (HCT/Ps) involving establishment registration and listing; eligibility determination for donors; and current good tissue practice (CGTP).

DATES: Submit either electronic or written comments on the collection of information by February 3, 2020.

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 February 3, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 3, 2020. 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–2013–N–0731 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Eligibility Determination for Donors; and Current Good Tissue Practice.'' 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.

- Confidential Submissions—To submit a comment with confidential