and work to improve their implementation. Finally, REMS generally must have a timetable for submission of assessments of the strategy.

FDA can require a REMS before initial approval of a new drug application (NDA) or biologics license application (BLA) or after the drug has been approved if FDA becomes aware of new safety information about a drug and determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks. Under section 505–1(i)(1) of the FD&C Act, a drug that is approved under an abbreviated new drug application (ANDA) is only required to have certain elements of a REMS if these elements are required for the applicable listed drug: a Medication Guide or patient package insert, a packaging or disposal requirement, ETASU, and an implementation system.

When applicants develop REMS with ETASU, particularly those ETASU that require verification of certain conditions before the drug is dispensed, they often hire third-party vendors to design operational components to help implement and manage the program requirements. These third-party vendors, often referred to as REMS administrators, may perform a variety of functions for the REMS program, including building and operating a centralized database or repository for patient enrollment, prescriber and pharmacy certifications, and wholesaler enrollments. They often host a website or web portal that participants, such as patients, prescribers, pharmacies, and wholesalers, use to enroll in the program, and they provide the technological means for pharmacies and other dispensers to perform the necessary verifications at the point of dispensing. These operational components are often referred to collectively as the ''REMS system.'' In many cases, therefore, the REMS administrator performs critical functions in the daily operations of a REMS which directly impact patient access to the drug.

Applicants may submit modifications to their REMS at any time after approval which propose the addition, modification, or removal of any goal or element of the approved strategy. While FDA does not approve REMS administrators or changes in REMS administrators *per se,* an applicant's decision to change a REMS administrator may affect the REMS system, prompting an applicant to propose a REMS modification. Implementing such a change has the potential to cause significant disruptions in the operations of the program, including the ability for stakeholders to interact with the tools necessary to fulfill the various REMS requirements. These disruptions can impact patients' ability to access the drug.

The Consolidated Appropriations Act, 2023, signed into law on December 29, 2022, specified that ''[n]ot later than 90 days after the date of enactment of this Act, the Secretary shall open a single public docket to solicit comments on factors that generally should be considered by the Secretary when reviewing requests from sponsors of drugs subject to [REMS] to change third-party vendors engaged by sponsors to aid in implementation and management of the strategies. . . . Such factors include the potential effects of changes in third-party vendors on—(A) patient access; and (B) prescribing and administration of the drugs by healthcare providers.''

II. Request for Comments

FDA is soliciting comments from stakeholders regarding the factors that FDA should consider when it reviews a proposed REMS modification that is prompted by or related to a change in a REMS administrator for a REMS with ETASU. In addition to general factors, such as effect of the modification on patient access and prescribing and administration by healthcare providers, FDA is interested in comments on the following topics:

1. Comment on any stakeholder input that the applicant and/or REMS administrator should obtain prior to developing and implementing a new REMS system, including the extent and timing of stakeholder input.

2. Comment on whether the sponsor and/or REMS administrator should conduct testing of the changes to the operation of the REMS system prior to full implementation including:

- User acceptance testing with stakeholders and evaluation of any unexpected impact on stakeholder workflow
- An assessment of REMS data flows, including whether REMS data from the existing REMS system can be timely and successfully transferred to a new REMS system.

3. Comment on the amount of time needed to transition stakeholders from one REMS system to another REMS system (*e.g.,* enrollment or recertification), and the factors that go into that time frame.

4. Comment on whether the sponsor and/or the REMS administrator should conduct a failure modes and effects analysis to identify and plan for system failures. This includes providing for adequate support services in the event that the system fails to work as intended following full implementation of the new REMS system.

5. Comment on the metrics that the sponsor should capture to evaluate whether the REMS system was successfully and efficiently implemented.

Dated: March 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05962 Filed 3–22–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–E–2097]

Determination of Regulatory Review Period for Purposes of Patent Extension; CINTEC PLUS CYTOLOGY

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 CINTEC PLUS CYTOLOGY 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 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 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 19, 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–2020–E–2097 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; CINTEC PLUS CYTOLOGY.'' 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 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 CINTEC PLUS CYTOLOGY. CINTEC PLUS CYTOLOGY is a qualitative immunocytochemical assay intended for the simultaneous detection of the p16INK4a and Ki-67 proteins in cervical specimens collected by a clinician using an endocervical brush/spatula or broom collection device and placed in the ThinPrep Pap Test PreservCyt Solution. Subsequent to this approval, the USPTO received a patent term restoration application for CINTEC PLUS CYTOLOGY (U.S. Patent No. 8,367,353) from Ventana Medical Systems, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 9, 2020, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of CINTEC PLUS CYTOLOGY 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 CINTEC PLUS CYTOLOGY is 181 days. Of this time, 0 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 for this device, under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), became effective:* not applicable. The applicant claims that the investigational device

exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective on September 12, 2017. However, FDA records indicate that there was no IDE associated with the product, so the claimed date is not applicable.

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 12, 2019. The applicant claims September 11, 2019, as the date the premarket approval application (PMA) for CINTEC PLUS CYTOLOGY (PMA P190024) was initially submitted. However, FDA records indicate that PMA P190024 was submitted on September 12, 2019.

3. *The date the application was approved:* March 10, 2020. FDA has verified the applicant's claim that PMA P190024 was approved on March 10, 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 547 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 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05908 Filed 3–22–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–3014]

Determination of Regulatory Review Period for Purposes of Patent Extension; RECELL AUTOLOGOUS CELL HARVESTING DEVICE

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 RECELL AUTOLOGOUS CELL HARVESTING DEVICE 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 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 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 19, 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–3014 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; RECELL AUTOLOGOUS CELL HARVESTING DEVICE.'' 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