Title III, Public Law 117–70, 1102 Stat. 4.

John M. Sweet, Jr.,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0573]

Changes to Third-Party Vendors for Risk Evaluation and Mitigation Strategies; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the establishment of a docket to solicit comments on factors that generally should be considered by the Secretary of Health and Human Services (Secretary) when reviewing modification requests from sponsors of drugs subject to risk evaluation and mitigation strategies (REMS) related to changes in third-party vendors engaged by sponsors to aid in implementation and management of the strategies.

DATES: Submit either electronic or written comments by July 21, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and 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 July 21, 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–2023–N–0573 for ''Proposed Changes to Third-Party Vendors Establishment of a Public Docket; Request for Comments.'' 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 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: Marcus Cato, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4475, 301–796–2380, *OSE.PMKTREGS@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 505–1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355–1), authorizes FDA to require a REMS if FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks. A REMS is a required risk management strategy that employs tools beyond prescribing information to ensure that the benefits of a drug outweigh its risks. A REMS may require a Medication Guide (or patient package insert) to provide risk information to patients, a communication plan to disseminate risk information to healthcare providers, and certain packaging and safe disposal systems for drugs that pose a serious risk of abuse or overdose. FDA may also require certain elements to assure safe use (ETASU) when such elements are necessary to mitigate a specific serious risk listed in the labeling of the drug. ETASU may include, for example, requirements that healthcare providers who prescribe the drug have particular training or experience, that patients using the drug be monitored, or that the drug be dispensed to patients with evidence or other documentation of safe-use conditions. Certain REMS with ETASU may also include an implementation system through which the applicant is able to monitor and evaluate implementation of the ETASU

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]

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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