■ 2. Add § 870.1420 to subpart B to read as follows:

§ 870.1420 Coronary artery disease risk indicator using acoustic heart signals.

(a) *Identification.* A coronary artery disease risk indicator using acoustic heart signals is a device that records heart sounds including murmurs and vibrations to calculate a patient-specific risk of presence of coronary artery disease, as an aid in cardiac analysis and diagnosis.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must fulfill the following:

(i) Testing must include a discussion of the patient population and any statistical techniques used for analyzing the data; and

(ii) Testing must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified.

(2) Acoustic performance testing must evaluate microphone sensitivity, sound acquisition bandwidth, and amplitude accuracy. The acoustic sensor specifications and mechanism used to capture heart sounds must be described.

(3) A scientific justification for the validity of the algorithm(s) must be provided. This justification must fulfill the following:

(i) All inputs and outputs of the algorithm must be fully described;

(ii) The procedure for segmenting, characterizing, and classifying the acoustic signal must be fully described; and

(iii) This justification must include verification of the algorithm calculations and validation using an independent data set.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Human factors/usability testing must demonstrate that the user can correctly use the device, including device placement, based solely on reading the directions for use.

(7) Performance data must demonstrate the electromagnetic compatibility and electrical safety of the device.

(8) Labeling must include the following:

(i) A description of what the device measures and outputs to the user;

(ii) Instructions for proper placement of the device;

(iii) Instructions on care and cleaning of the device;

(iv) Warnings identifying sensor acquisition factors that may impact measurement results and instructions for mitigating these factors; and

(v) The expected performance of the device for all intended use populations and environments.

Dated: May 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–11699 Filed 5–31–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA–2019–N–3065]

RIN 0910–AI39

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Delayed Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: As required by an order issued by the U.S. District Court for the Eastern District of Texas, this action delays the effective date of the final rule (''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements''), which published on March 18, 2020. The new effective date is July 8, 2023.

DATES: The effective date of the rule amending 21 CFR part 1141 published at 85 FR 15638, March 18, 2020, and delayed at 85 FR 32293, May 29, 2020; 86 FR 3793, January 15, 2021; 86 FR 36509, July 12, 2021; 86 FR 50855, September 13, 2021; 86 FR 70052, December 9, 2021; and 87 FR 11295, March 1, 2022, is further delayed until July 8, 2023.

FOR FURTHER INFORMATION CONTACT: Courtney Smith, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1371, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 18, 2020, the Food and Drug Administration (FDA or Agency) issued a final rule establishing new cigarette health warnings for cigarette packages and advertisements. The final rule implements a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning label statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act of 1965 (Pub. L. 89–92) to require each cigarette package and advertisement to bear one of the new required warnings. The final rule specifies the 11 new textual warning label statements and accompanying color graphics. Pursuant to section 201(b) of the Tobacco Control Act, the rule was published with an effective date of June 18, 2021, 15 months after the date of publication of the final rule.

On April 3, 2020, the final rule was challenged in the U.S. District Court for the Eastern District of Texas.[1] On May 8, 2020, the court granted a joint motion to govern proceedings in that case and postpone the effective date of the final rule by 120 days.[2] On December 2, 2020, the court granted a new motion by the plaintiffs to postpone the effective date of the final rule by an additional 90 days.[3] On March 2, 2021, the court granted another motion by the plaintiffs to postpone the effective date of the final rule by an additional 90 days.[4] On May 21, 2021, the court granted another motion by the plaintiffs to postpone the effective date of the final rule by an additional 90 days.[5] On August 18, 2021, the court issued an order to postpone the effective date of the final rule by an additional 90 days.[6] On November 12, 2021, the court issued another order to postpone the effective date of the final rule by an additional 90 days.[7] On February 10, 2022, the court issued another order to postpone the effective date of the final rule by an

[1] *R.J. Reynolds Tobacco Co. et al.* v. *United States Food and Drug Administration et al.,* No. 6:20–cv–00176 (E.D. Tex. filed April 3, 2020).

[2] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. May 8, 2020) (order granting joint motion and establishing schedule), Doc. No. 33.

[3] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. December 2, 2020) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 80.

[4] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. March 2, 2021) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 89.

[5] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. May 21, 2021) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 91.

[6] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. August 18, 2021) (order postponing effective date), Doc. No. 92.

[7] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. November 12, 2021) (order postponing effective date), Doc. No. 93.

additional 90 days.[8] On May 10, 2022, the court issued another order to postpone the effective date of the final rule by an additional 90 days.[9] The court ordered that the new effective date of the final rule is July 8, 2023. Pursuant to the court order, any obligation to comply with a deadline tied to the effective date is similarly postponed, and those obligations and deadlines are now tied to the postponed effective date.

To the extent that 5 U.S.C. 553 applies to this action, the Agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exception in 5 U.S.C. 553(b)(B). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The 90-day postponement of the effective date, until July 8, 2023, is required by court order in accordance with the court's authority to postpone a rule's effective date pending judicial review (5 U.S.C. 705). Seeking prior public comment on this postponement would have been impracticable, as well as contrary to the public interest in the orderly issuance and implementation of regulations.

Dated: May 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–11568 Filed 5–31–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–990]

Schedules of Controlled Substances: Placement of Ganaxolone in Schedule V

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule; request for comments.

SUMMARY: On March 18, 2022, the United States Food and Drug Administration approved a new drug application for ZTALMY, an oral suspension of ganaxolone, for the treatment of seizures associated with cyclin-dependent kinase-like 5 deficiency disorder in patients two years of age and older. The Department of Health and Human Services provided the Drug Enforcement Administration with a scheduling recommendation to place ganaxolone and its salts in schedule V of the Controlled Substances Act. In accordance with the Controlled Substances Act, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, Drug Enforcement Administration is hereby issuing an interim final rule placing ganaxolone, including its salts in schedule V of the Controlled Substances Act.

DATES: This rule is effective June 1, 2022. Comments must be submitted electronically or postmarked on or before July 1, 2022. Interested persons may file written comments on this rulemaking in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.43(g). Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons may file a request for a hearing or waiver of a hearing in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.44. Requests for a hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before July 1, 2022.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–990'' on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.
- *Paper comments:* Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, VA 22152.
- *Hearing requests:* All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be sent to: Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note, all comments received in response to this docket are considered part of the public record. The Drug Enforcement Administration (DEA) will make comments available, unless reasonable cause is given, for public inspection online at *http://www.regulations.gov*. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want DEA to make it publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want DEA to make it publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

DEA will generally make available in publicly redacted form comments

[8] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. February 10, 2022) (order postponing effective date), Doc. No. 94.

[9] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. May 10, 2022) (order postponing effective date), Doc. No. 96.