Notice of Meeting; 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.'' FDA 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 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 the 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: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–2855, Fax: 301–847–8533, email: *CRDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss new drug application 213931, for tenapanor hydrochloride tablets, submitted by Ardelyx, Inc., for the control of serum phosphorus levels in adults with chronic kidney disease on dialysis. The committee will be asked to comment on whether the size of the treatment effect on serum phosphorus is clinically meaningful and whether tenapanor's benefits outweigh its risks.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before November 1, 2022, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 2:30 p.m. and 3:30 p.m. eastern time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 24, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 25, 2022.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact LaToya Bonner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 12, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20198 Filed 9–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3065]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Products; Required Warnings for Cigarette Packages and Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 collection of information entitled, ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements.''

DATES: Either electronic or written comments on the collection of information must be submitted by November 18, 2022.

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 November 18, 2022. 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–N–3065 for ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements.'' 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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements—21 CFR Part 1141

OMB Control Number 0910–0877—Extension

This information collection supports FDA regulations and guidance. Tobacco products are generally governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t).

On March 18, 2020, FDA issued a final rule establishing new cigarette health warnings for cigarette packages and advertisements entitled ''Tobacco

Products; Required Warnings for Cigarette Packages and Advertisements'' (85 FR 15638; *https://www.federalregister.gov/d/2020-05223*). 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 (FCLAA) (15 U.S.C. 1333) 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.

Section 1141.10(g) (21 CFR 1141.10(g) and section 4(c) of the FCLAA sets forth the specific marketing requirements relating to the random and equal display and distribution of required warnings on cigarette packaging and quarterly rotation of required warnings in alternating sequence in cigarette advertising and requires the submission of plans outlining how the cigarette packaging and advertising will comply with such requirements. FDA must review and approve cigarette plans in advance of any person displaying or distributing cigarette packages or advertisements for products that are required to carry the required warnings, and a record of the FDA-approved plan must be established and maintained by the tobacco product manufacturer.

To implement these statutory and regulatory requirements, cigarette plans will be reviewed by FDA upon submission by respondents. FDA published a guidance document on July 9, 2021, entitled ''Submission of Plans for Cigarette Packages and Cigarette Advertisements'' which describes cigarette plans information, format and submission (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-plans-cigarette-packages-and-cigarette-advertisements-revised*).

Pursuant to section 201(b) of the Tobacco Control Act, FDA finalized the ''Required Warnings for Cigarette Packages and Advertisements'' rule with an effective date of June 18, 2021, 15 months after the date of publication. On April 3, 2020, the final rule was challenged in the U.S. District Court for the Eastern District of Texas.[1] The effective date of the final rule has been delayed in accordance with orders issued by the U.S. District Court for the Eastern District of Texas. Visit FDA's website at *https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-labeling-and-health-warning-requirements* for updates regarding the effective date of the rule and related timelines, including the recommended date for submitting cigarette plans for FDA review.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Part 1141 and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Original Submission (Initial Plan)	59	1	59	150	8,850
Supplement	30	1	30	75	2,250
Total					11,100

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates are based on FDA's experience with information collections for other tobacco product plans (*i.e.,* smokeless, OMB control number 0910–0671 and cigars, OMB control number 0910–0768) and 2017 Treasury Alcohol and Tobacco Tax and Trade Bureau data.

FDA estimates 59 entities are affected. We estimate these 59 entities will submit initial plans, and it will take an average of 150 hours per respondent to prepare and submit a plan for packaging and advertising for a total of 8,850 hours. We estimate that about half of respondents will submit a supplement. If a supplement to an approved plan is submitted, FDA estimates it will take half the time per response. We estimate receiving 30 supplements at 75 hours per response for a total of 2,250 hours. FDA estimates that the total hours for submitting initial plans and supplements will be 11,100.

Section 1141.10(g)(4) establishes that each tobacco product manufacturer required to randomly and equally display and distribute warnings on cigarette packages or quarterly rotate warnings in cigarette advertisements in accordance with an FDA-approved plan under section 4 of the FCLAA and part 1141 must maintain a copy of the FDA-approved plan (approved under § 1141.10(g)(3)). This copy of such FDA-approved plan must be available for inspection and copying by officers or employees of FDA. This subsection requires that the FDA-approved plan must be retained while in effect and for a period of not less than 4 years from the date it was last in effect.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Part 1141 and activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Original Submission (Initial Plan) Records	59	1.5	89	3	267
Total					267

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[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).

FDA estimates that 59 recordkeepers will keep a total of about 89 records at 3 hours per record for a total of 267 hours. As stated previously, these estimates are based on FDA's experience with information collections for other tobacco product plans (*i.e.,* smokeless, OMB control number 0910–0671 and cigars, OMB control number 0910–0768). Based on our estimates for the submission of one-time, initial plans and supplements (*i.e.,* that all respondents will submit one-time, initial plans and about half of respondents will submit supplements to FDA-approved plans), we estimate that each recordkeeper will keep an average of 1.5 records.

FDA concludes that the required warnings for cigarette packages and cigarette advertisements in § 1141.10 are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501–3521). Rather, these labeling statements are a ''public disclosure'' of information originally supplied by the Federal Government to the recipient for the purpose of ''disclosure to the public'' (5 CFR 1320.3(c)(2)).

Since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: September 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20196 Filed 9–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Hypertension Summit

AGENCY: Office on Women's Health (OWH), Office of the Assistant Secretary for Health (OASH), Department of Health and Human Services (HHS).

ACTION: Notice of event.

SUMMARY: The U.S. Department of Health and Human Services' Office on Women's Health (OWH) is providing notice of a virtual Hypertension Summit focused on innovations and evidence to bridge practice gaps in the field of hypertension treatment and prevention. The purpose of the Hypertension Summit is to exchange information about this topic and seek input on an individual basis from: patients who have benefited from innovative approaches to treating hypertension; subject matter experts; Phase 1 awardees of the HHS Hypertension Innovator Award Competition; and members of OWH's Self-Measured Blood Pressure Program (SMBP). This Hypertension Summit will highlight research from the Women's Health Initiative that impacts heart health and women's health. This Hypertension Summit is open to the public. Individuals interested in attending this Hypertension Summit must register to attend as instructed below.

DATES: OWH will host the Hypertension Summit on October 19, 2022, during the 3rd annual observance of National Women's Blood Pressure Awareness Week (NWBPAW), October 16–22, 2022.

ADDRESSES: The Hypertension Summit will be held virtually.

FOR FURTHER INFORMATION CONTACT: Contact Jeff Ventura at *Womenshealth@hhs.gov* or 202–690–7650 or go to *https://www.womenshealth.gov/hypertensionsummit* for more information.

SUPPLEMENTARY INFORMATION:

Meeting Accessibility: The Hypertension Summit will be held virtually.

All attendees must register to receive the virtual conference information for the Hypertension Summit.

For more information on how to register to attend, please visit *https://www.zoomgov.com/webinar/register/WN_Z33WazyITyaeP29xVmyIKw.*

Background: The HHS Office on Women's Health (OWH) is charged with providing expert advice and consultation to the Secretary concerning scientific, legal, ethical, and policy issues related to women's health. OWH establishes short-range and long-range goals within the Department and coordinates on activities within the Department that relate to disease prevention, health promotion, service delivery, research, and public and health care professional education, for issues of particular concern to women throughout their lifespan. OWH monitors the Department's activities regarding women's health and identifies needs regarding the coordination of activities. OWH is also responsible for facilitating the exchange of information through the National Women's Health Information Center. Additionally, OWH coordinates efforts to promote women's health programs and policies with the private sector. National Women's Blood Pressure Awareness Week (NWBPAW) is an observance that focuses on evidence to address practice gaps and to improve women's health outcomes related to hypertension.

The Hypertension Summit will occur during NWBPAW and will emphasize the importance of blood pressure control. The Hypertension Summit will facilitate the exchange information and seek input on an individual basis from: patients, who have benefited from innovative approaches to treating hypertension; subject matter experts; Phase 1 awardees of the HHS Hypertension Innovator Award Competition; and members of OWH's Self-Measured Blood Pressure Program (SMBP).

Topics covered during the Hypertension Summit: The agenda will be made up of several panels and presentations focusing on the innovations and evidence to bridge practice gaps in the field of hypertension treatment and prevention. Topics may include, but are not limited to, innovations and evidence to bridge practice gaps in the field of hypertension, self-measured blood pressure, telehealth, technology, health equity, hypertension in pregnancy and/or postpartum, home-based care, and health team integration.

The Hypertension Summit is open to the public. Information regarding the start and end times and any updates to agenda topics will be available at *https://www.womenshealth.gov/hypertensionsummit* closer to the date of the Hypertension Summit.

Procedures for Attendance: https://www.zoomgov.com/webinar/register/WN_Z33WazyITyaeP29xVmyIKw.

Dated: September 12, 2022.

Dorothy Fink,

Deputy Assistant Secretary for Women's Health, Office of the Assistant Secretary for Health.

[FR Doc. 2022–20214 Filed 9–16–22; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which