for PDUFA Products'' have been approved under OMB control number 0910–0429.

### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: November 23, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021–26006 Filed 11–29–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–3233]**

### Request for Nominations for Voting Members on a Public Advisory Committee; Technical Electronic Product Radiation Safety Standards Committee

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) in the Center for Devices and Radiological Health. Nominations will be accepted for current and upcoming vacancies effective January 1, 2022, with this notice. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

**DATES:** Nominations received on or before January 31, 2022, will be given first consideration for membership on TEPRSSC. Nominations received after January 31, 2022, will be considered for nomination to the committee as later vacancies occur.

**ADDRESSES:** All nominations for membership should be sent electronically by accessing FDA's Advisory Committee Membership Nomination Portal at *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

**FOR FURTHER INFORMATION CONTACT:** Akinola Awojope, Office of Management Services, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993–0002, 301–636–0512, email: *Akinola.Awojope@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations for voting members on TEPRSSC that include five general public representatives and five government representatives.

### I. General Description of the Committee's Duties

The committee provides advice and consultation to the Commissioner of Food and Drugs (Commissioner) on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products, and may recommend electronic product radiation safety standards to the Commissioner for consideration.

### II. Criteria for Voting Members

The committee consists of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of science or engineering, applicable to electronic product radiation safety. Members will be invited to serve for overlapping terms of up to 4 years. Terms of more than 2 years are contingent upon the renewal of the committee by appropriate action prior to its expiration.

### III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: November 22, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021–26002 Filed 11–29–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2005–N–0101]**

### Agency Information Collection Activities; Proposed Collections; Comment Request; Prescription Drug User Fee Program

**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 collections 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 information collection associated with FDA's Prescription Drug User Fee program.

**DATES:** Submit either electronic or written comments on the collection of information by January 31, 2022.

**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 January 31, 2022. The *https://www.regulations.gov* electronic filing system will accept

comments until 11:59 p.m. Eastern Time at the end of January 31, 2022. 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–2005–N–0101 for ''Agency Information Collection Activities; Proposed Collections; Comment Request; Prescription Drug User Fee Program.'' 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:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

**Prescription Drug User Fee Program**

*OMB Control Number 0910–0297—Revision*

This information collection supports implementation of the Food and Drug Administration Prescription Drug User Fee (PDUFA) program. PDUFA was enacted in 1992 and authorizes FDA to collect fees from companies that produce certain human drug and biological products. Under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (sections 735 and 736 (21 U.S.C. 379g and 379h)), we have the authority to assess and collect user fees for certain new drug applications (NDAs) and new biologics license applications (BLAs). Under this authority, pharmaceutical companies pay a fee for certain new NDAs and BLAs submitted to FDA for review. We have established a PDUFA page on our website at *https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/* that includes resources and information regarding PDUFA topics at FDA.

Because the submission of user fees concurrently with applications is required, review of an application by FDA cannot begin until the fee is submitted. To assist respondents in this regard, we developed Form FDA 3397 entitled, ''Prescription Drug User Fee

Cover Sheet.'' Associated instructions may be found on our website at *https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119184.htm.* The cover sheet (Form FDA 3397) need not be submitted for certain FDA-regulated products, *e.g.,* generic drugs, and Whole Blood and Blood components for transfusion. The list of exempted products is included under the instructions to Form FDA 3397. Relatedly, sections 735 and 736 of the FD&C Act also provide for waiver, reduction, refund, and reconsideration requests. We developed the guidance document entitled ''Guidance for Industry—User Fee Waivers, Reductions, and Refunds for Drug and Biological Products,'' and Form FDA 3971 (Small Business Waivers and Refund Requests), which can be found on our website at *https://www.fda.gov/media/131797/download.*

We are revising the collection to include our current commitment goals, as set forth in the document ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022,'' also found on our website at *https://www.fda.gov/media/99140/download.* PDUFA is currently authorized through September 30, 2022, with reauthorization activities currently underway. The commitment goals represent the product of FDA's discussions with the regulated industry and public stakeholders, as mandated by Congress. FDA is committed to meeting these goals and to continuous operational improvements associated with PDUFA implementation. The commitment goals provide for the development and issuance of topic-specific guidance. We maintain a searchable guidance database on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-document.* In publishing the respective notices of availability for each guidance document, we include an analysis under the PRA and invite public comment on the associated information collection recommendations. In addition, all Agency guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Prescription drug user fee activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Sections 735 and 736 of the FD&C Act (PDUFA waivers, not including small business waivers) | 112 | 1.68 | 189 | 17 | 3,213 |
| Section 736(d)(1)(C) of the FD&C Act and Form FDA 3971 (small business waivers) | 37 | 1 | 37 | 2 | 74 |
| Reconsideration Requests | 6 | 1.67 | 10 | 24 | 240 |
| Appeal Requests | 1 | 1 | 1 | 12 | 12 |
| User Fee Cover Sheet Form FDA 3397 | 174 | 1 | 174 | 0.5 (30 minutes) | 87 |
| Total | | | 411 | | 3,626 |

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

Based on a review of Agency records, we estimate that the number of initial waiver requests submitted annually (excluding small business waiver requests under section 736(d)(1)(C)) of the FD&C Act) will be 189, submitted by 112 different applicants; and that 37 respondents annually will each submit a small business waiver request. We have included in the burden estimate the time for preparation and submission of application fee waivers for small businesses, including completion of Form FDA 3971. Small businesses requesting a waiver must submit documentation to FDA, including the number of their employees, as well as information that the application is the first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval.

We estimate receiving 10 requests for reconsideration annually (including small business waiver reconsiderations), and assume the average burden for preparing and submitting each request is 24 hours. In addition, we estimate receiving 1 request annually for appeal of user fee waiver determination, and assume the time needed to prepare an appeal is 12 hours. We have included in this estimate both the time needed to prepare the request for appeal to the Chief Scientist and User Fee Appeals Officer within the Office of the Commissioner, and the time needed to create and send a copy of the request for an appeal to the Director Division of User Fee Management within the Office of Management at FDA's Center for Drug Evaluation and Research.

We assume 87 hours of burden for completing and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet) for submission of a new drug application or biologics license application.

The information collection reflects an overall increase since our last request for OMB review and approval. We attribute this to expected fluctuations in submissions to the Agency.

Dated: November 19, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021–26079 Filed 11–29–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2020–E–2224]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; ZEPZELCA

**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 ZEPZELCA 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 drug product.

**DATES:** Anyone with knowledge that any of the dates as published (see