Dated: November 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26306 Filed 11–29–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2459]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Product Jurisdiction and Combination Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 2, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0523. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Product Jurisdiction and Combination Products—21 CFR Parts 3 and 4

OMB Control Number 0910–0523—Extension

This information collection helps support implementation of statutory requirements that govern product jurisdiction and combination products. Congress expressly directed FDA to assign combination products to the appropriate Agency component for regulation as set forth in section 503(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353(g)). Congress also expressly directed FDA to determine the classification of a product as a drug, biological product, device, or combination product, or the component of the Agency that will regulate the product, as applicable, in response to a request submitted under section 563 of the FD&C Act (21 U.S.C. 360bbb–2).

Regulations in 21 CFR part 3 provide for product classification determinations and FDA designation on which Agency component will have primary jurisdiction for any drug, device, biological, or combination product, where such jurisdiction is unclear or in dispute. These determinations are made by our Office of Combination Products (OCP) upon receiving Requests for Designation (RFDs). We maintain a web page that includes contact and resource information pertaining to the RFDs process at *https://www.fda.gov/combination-products/jurisdictional-information.* As communicated on our web page, FDA welcomes comments from interested stakeholders on issues pertaining to OCP and encourages medical product developers to contact us if they are uncertain about the classification or assignment of their products and with questions regarding premarket or postmarket considerations for combination products. A dedicated mailbox is established at *combination@fda.hhs.gov.*

Similar to the RFD process, we have established the Pre-RFD process for sponsors to obtain preliminary, nonbinding feedback regarding medical product classification and assignment. Although Forms FDA 5003, 5004, and 5005 (pre-request and request for designation forms) were previously developed to facilitate information collection for Pre-RFDs and RFDs, we have more recently issued the following Agency guidance documents to provide instruction and recommendations to respondents regarding the submission of RFDs and Pre-RFDs.

- The guidance document entitled, ''How to Write a Request for Designation'' (April 2011), provides instruction regarding the information that needs to be submitted to OCP in an RFD as described in 21 CFR 3.7. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-write-request-designation-rfd.*
- The guidance document entitled ''How to Prepare a Pre-Request for Designation,'' (February 2018) was developed to assist sponsors in obtaining a preliminary, non-binding assessment regarding the classification and assignment of products from OCP through the Pre-RFD process. The guidance explains the Pre-RFD process and helps a sponsor understand the type of information to provide in a Pre-RFD submission. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-prepare-pre-request-designation-pre-rfd.*
- This information collection also includes burden associated with Combination Product Agreement Meetings (CPAM) requests. The guidance document entitled, ''Requesting FDA Feedback on Combination Products,'' (December 2020) was developed to discuss ways in which combination product sponsors can obtain feedback from FDA on scientific and regulatory questions and to describe best practices for FDA and sponsors when interacting on these topics. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requesting-fda-feedback-combination-products.*

The guidance documents were issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

The information collection also includes regulations in 21 CFR part 4 that govern current good manufacturing practice requirements and postmarketing safety requirements for combination products. We expect, however, that burden attendant to the associated recordkeeping, reporting, and/or disclosure activities is already accounted for in approved information collections that apply to drug, device, and/or biologic products specifically and respectively. Therefore, we do not ascribe separate burden in this information collection request for the activities generated by these requirements.

Respondents to the information collection are sponsors of medical products, including combination products. Based on submissions received by OCP during fiscal years 2020, 2021, and 2022, we account for 135 respondents annually.

In the **Federal Register** of July 31, 2023 (88 FR 49467), we published a 60-day notice soliciting comment on the proposed collection of information. One comment was received expressing interest in combination product

submissions, but was not responsive to the four information collection topics solicited in our notice and therefore we do not discuss the comment here.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3.7; request for designation (RFD)	55	1	55	24	1,320
Pre-RFD submissions	77	1	77	24	1,848
CPAM requests	3	1	3	25	75
Total					3,243

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

Our estimated burden reflects a decrease in the number of respondents (four respondents) and a corresponding decrease in total hours (96 hours). Based on a recent evaluation of CPAM requests received from each product center in fiscal years 2020, 2021, and 2022, our estimated annual burden for CPAM requests remains unchanged.

Dated: November 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26262 Filed 11–29–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–E–2198; FDA–2022–E–2202; FDA–2022–E–2203; and FDA–2022–E–2204]

Determination of Regulatory Review Period for Purposes of Patent Extension; Ukoniq

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 Ukoniq and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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 **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by January 29, 2024. 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 May 28, 2024. 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 January 29, 2024. 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 Nos. FDA–2022–E–2198; FDA–2022–E–2202; FDA–2022–E–2203; and FDA–2022–E–2204 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; UKONIQ.'' 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