I. Background

Menopause is often a time of tremendous transition and change for women. The effects of menopause on the PK and PD of drugs are largely unknown. Sex hormone changes during menopause may affect the metabolic pathways of drugs by affecting drug metabolizing enzymes. Hormone changes may also affect other pathways that play an important role for drug disposition and excretion. In addition, many women experience weight gain at menopause. Together, these changes associated with menopausal transition have the potential to affect the PK of medications used for indications not related to menopause. Furthermore, physiologic changes in menopause may result in altered sensitivity to drug response independent of changes in PK. This public workshop will provide insight into identifying the research and data gaps regarding the potential impact of menopause on PK/PD, highlighting areas with the greatest need for further research and exploration.

II. Topics for Discussion at the Public Workshop

This public workshop will include presentations and session discussions by experts in the fields of clinical pharmacology, obstetrics and gynecology, endocrinology, and clinical care. Each session will include a Q&A session to respond to questions from attendees.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://www.fda.gov/consumers/public-meetings-workshops-and-webinars/menopause-potential-impact-clinical-pharmacology-and-opportunities-future-research-10112023*. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Registrants will receive confirmation when they have been accepted. If you need special accommodations due to a disability, please contact Lisa Lineberger at *OWHmeetings@fda.hhs.gov* no later than October 10, 2023.

Dated: September 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20454 Filed 9–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0908]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Submission of Petitions: Food Additive, Color Additive (Including Labeling), Submission of Information to a Master File in Support of Petitions; and Electronic Submission Using Food and Drug Administration Form 3503

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 October 23, 2023.

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 0910–0016. Also include the FDA docket number found in brackets in the heading of this document.

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

Submission of Petitions: Food Additive, Color Additive (Including Labeling), Submission of Information to a Master File in Support of Petitions; and Electronic Submission Using Form FDA 3503–21 CFR 70.25, 71.1, and 171.1 and 21 CFR parts 172, 173, 179, and 180 OMB Control Number 0910–0016—Extension.

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe, unless: (1) the additive and its use, or intended use, are in conformity with a regulation issued under section 409 that describes the condition(s) under which the additive may be safely used; (2) the additive and its use, or intended use, conform to the terms of an exemption for investigational use; or (3) a food contact notification submitted under section 409(h) is effective. Food Additive Petitions (FAPs) are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 of FDA's regulations (21 CFR 171.1) specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the conditions under which the additive may be safely used. Parts 172, 173, 179, and 180 (21 CFR parts 172, 173, 179, and 180) contain labeling requirements for certain food additives to ensure their safe use.

Section 721(a) of the FD&C Act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f). Color Additive Petitions (CAPs) are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 of the Agency's regulations (21 CFR 71.1) specifies the information that a petitioner must submit to establish the safety of a color additive and to secure the issuance of a regulation permitting its use. FDA's color additive labeling requirements in § 70.25 (21 CFR 70.25) require that color additives that are to be used in food, drugs, cosmetics, or medical devices be labeled with sufficient information to ensure their safe use.

FDA scientific personnel review FAPs to ensure the safety of the intended use of the additive in or on food, or that may be present in food as a result of its use in articles that contact food. Likewise, FDA personnel review CAPs to ensure the safety of the color additive prior to its use in food, drugs, cosmetics, or medical devices.

Respondents may transmit FAP or CAP regulatory submissions in electronic format or paper format to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition (CFSAN) using Form FDA 3503. Form FDA 3503 helps the respondent organize their submission to focus on the information needed for FDA's safety review. Form FDA 3503 can also be used to organize information within a master file submitted in support of petitions according to the items listed on the form. Master files can be used as repositories for information that can be referenced in multiple submissions to the Agency, thus minimizing paperwork burden for food and color additive approvals.

We improved the information collection by using the CFSAN Online Submission Module (COSM). COSM provides a real-time user interface process that assists respondents in preparing and making submissions to CFSAN. COSM is a web-based tool that supports electronic submissions, thereby eliminating the need for printing and mailing of paper submissions. COSM is available 24 hours a day and 7 days a week. Further information about COSM, including user instruction, is available on the internet at: *https://www.fda.gov/food/registration-food-facilities-and-other-submissions/cfsan-online-submission-module-cosm.*

Description of respondents: Respondents are businesses engaged in the manufacture or sale of food, food ingredients, color additives, or substances used in materials that come into contact with food.

In the **Federal Register** of February 1, 2023 (88 FR 6757), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section; or FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Submission of Petitions: Color Additive Including Labeling—70.25 and 71.1	2	1	2	1,337	2,674	$5,600
Submission of Petitions: Food Additive Including Labeling—171.1	3	1	3	7,093	21,279	0
Form FDA 3503 [2]	5	1	5	1	5	0
Total	.....	.....	.....	.....	23,958	5,600

[1] There are no capital costs associated with this collection of information.
[2] Form FDA 3503 is used for both CAPs and FAPs.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden by 1 hour. Our estimate of burden attributable to FAPs or CAPs is based on our experience with the information collection, which has not changed since our last review, and reflects the average number of petitions we have received annually over a period of 10 years. The attendant burden we estimate also reflects an industry average, although burden associated with individual petitions may vary depending on the complexity of the petition, and the amount and type of data needed for scientific analysis.

CAPs are subject to fees. The listing fee for a CAP ranges from $1,600 to $3,000, depending on the intended use of the color additive and the scope of the requested amendment. A complete schedule of fees is set forth in 21 CFR 70.19. An average of one Category A and one Category B CAP is expected per year. The maximum CAP fee for a Category A petition is $2,600, and the maximum CAP fee for a Category B petition is $3,000. Because an average of two CAPs are expected per calendar year, the estimated total annual cost burden to petitioners for this startup cost would be less than or equal to $5,600 ((1 × $2,600) + (1 × $3,000) listing fees). There are no capital costs associated with CAPs.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the FD&C Act and other specific labeling Acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for §§ 70.25 and 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling requirements under parts 172, 173, 179, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Dated: September 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20451 Filed 9–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3742]

Scientific Challenges and Opportunities To Advance the Development of Individualized Cellular and Gene Therapies; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA or Agency), Center for Biologics Evaluation and Research (CBER) is requesting information from stakeholders regarding critical scientific