have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (21 CFR 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

ACTIGALL (ursodiol) capsule, 150 mg, is the subject of NDA 019594, held by Teva Branded Pharmaceutical Products R&D, Inc., and initially approved on December 31, 1987. ACTIGALL is indicated for patients with radiolucent, noncalcified gallbladder stones less than 20 millimeters in greatest diameter in whom elective cholecystectomy would be undertaken except for the presence of increased surgical risk due to systemic disease, advanced age, or idiosyncratic reaction to general anesthesia or for those patients who refuse surgery, and for the prevention of gallstone formation in obese patients experiencing rapid weight loss.

ACTIGALL (ursodiol) capsule, 150 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Pharmobedient Consulting, LLC submitted a citizen petition dated January 14, 2025 (Docket No. FDA–2025–P–0184), under 21 CFR 10.30, requesting that the Agency determine whether ACTIGALL (ursodiol) capsule, 150 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ACTIGALL (ursodiol) capsule, 150 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ACTIGALL (ursodiol) capsule, 150 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ACTIGALL (ursodiol) capsule, 150 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to this drug product may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09779 Filed 5–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–0507]

Replacing Color Additives in Approved or Marketed Drug Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Replacing Color Additives in Approved or Marketed Drug Products.'' This draft guidance provides recommendations for replacing color additives in approved or marketed drug products. If a color additive is replaced in a drug product, information to support the change should be retained and available at the manufacturing facility. Additionally, this draft guidance recommends that new drug application (NDA) and abbreviated new drug application (ANDA) holders submit information to support color additive replacements in changes being effected in 30 days (CBE–30) supplements. Although a qualitative or quantitative change to an inactive ingredient is generally considered a major change, in many cases, replacing a color additive with one that is listed in the color additive regulations is unlikely to adversely affect the identity, strength, quality, purity, or potency of the drug product. Therefore, this draft guidance recommends a CBE–30 for such a change.

DATES: Submit either electronic or written comments on the draft guidance by July 29, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2025–D–0507 for ''Replacing Color Additives in Approved or Marketed Drug Products.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Ashley Boam, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4192, Silver Spring, MD 20993–0002, 301–796–6341, *cder-quality-policy@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Replacing Color Additives in Approved or Marketed Drug Products.'' This draft guidance provides recommendations for replacing color additives in approved or marketed drug products. If a color additive is used in a drug product, the color additive must conform to FDA's color additive regulations. If FDA deems the color additive unsafe and repeals the color additive regulation, the color additive must be removed or replaced. Color additives can also be replaced for other reasons (*e.g.,* as a business decision).

This draft guidance describes considerations for replacing a color additive, regardless of the reason for the change, including:

• Ensuring that the selected color additive conforms with the color additive requirements (see section 721(a)–(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379e(a)–(b)) and parts 70–71, 73–74, and 80–82 (21 CFR parts 70–71, 73–74, and 80–82))

• Updating information, including labeling, composition statements, master batch records, and drug product specifications (as applicable)

• Documenting information to support the change, including maintaining appropriate records at the manufacturing site (see 21 CFR 211.180)

• Submitting information to support the change in a supplement (for application products)

Although a qualitative or quantitative change in inactive ingredients is generally considered a major change, in many cases, replacing a color additive with one that is listed in the color additive regulations (parts 73, 74 and 82) is unlikely to adversely affect the identity, strength, quality, purity, or potency of the drug product. Therefore, replacing a color additive can generally be considered a moderate change that applicants can submit in a CBE–30.

The recommendations in this draft guidance apply to two groups: *applicants* and *manufacturers.* In this draft guidance, the term *applicants* refers to holders of approved NDAs or ANDAs for drug products that are regulated by CDER. In this draft guidance, the term *manufacturers* refers to manufacturers of:

• Drug products marketed under an NDA or ANDA (including contract manufacturers)

• Drug products that are not marketed under a drug application, including nonprescription drugs subject to section 505G of the FD&C Act (21 U.S.C. 355h) (*i.e.,* over-the-counter monograph drug products)

• Compounded drug products subject to section 503B of the FD&C Act (21 U.S.C. 353b)

• Other drug products that are subject to current good manufacturing practice (CGMP) requirements

Some entities may be both *applicants* and *manufacturers.* These entities should follow the appropriate recommendations for their roles in each specific situation.

The recommendations in this draft guidance do not apply to drug products in which a color additive is the active pharmaceutical ingredient (*e.g.,* methylene blue). The recommendations also do not apply to drugs approved under section 505(b)(2) of the FD&C Act (21 U.S.C. 355(b)(2)) for which replacing a color additive would create a *different drug* (see also 21 CFR 314.70(h)). Additionally, because biological products rarely include color additives, the recommendations in this draft guidance do not apply to products that have an approved biologics license application. However, if a color additive is used as an inactive ingredient in a biological product, the additive must be listed in the color additive regulations and its use must conform to the regulation (see section 721(a)–(b) of the FD&C Act and parts 70, 71, 73, 74, and 80 through 82).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Replacing Color Additives in Approved or Marketed Drug Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. As we develop any final guidance on this topic, FDA will consider comments on the applicability

of Executive Order 14192, per OMB guidance M–25–20, and in particular, on any costs or cost savings.

II. Paperwork Reduction Act of 1995

While this draft guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in §§ 70.25 and 71.1 relating to the submission of color additive petitions including labeling have been approved under OMB control number 0910–0016. The collections of information in 21 CFR 201.56 and 201.57 relating to the submission of labeling for prescription drug products and biological products have been approved under OMB control number 0910–0572. The collections of information in 21 CFR parts 210 and 211 relating to CGMP requirements, including manufacturing records, have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 314 relating to the submission of NDAs and ANDAs, as well as related post approval submissions (including annual reports) and drug master files, have been approved under OMB control number 0910–0001. The collections of information relating to labeling for certain over-the-counter products have been approved under OMB control number 0910–0340.

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/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: May 27, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09800 Filed 5–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7094–N–03; OMB Control No.: 2506–0171]

60-Day Notice of Proposed Information Collection: HOME Investment Partnerships Program

AGENCY: Office of Community Planning and Development. HUD.

ACTION: Notice of proposed information collection.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* July 29, 2025.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal.

Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to *www.regulations.gov.* Interested persons are also invited to submit comments regarding this proposal and comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Urnell Johnson, PRA Laision for Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW, Room 7232, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Danielle Frazier, Director, Financial & Information Services Division, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email *Danielle.Frazier@hud.gov,* telephone (202) 402–7354. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Frazier.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: HOME Investment Partnerships Program.

OMB Approval Number: 2506–0171.

Type of Request: Extension of Approved Collection.

Form Number: HUD 27055.

Description of the need for the information and proposed use: The information collected through HUD's Integrated Disbursement and Information System (IDIS) (24 CFR 92.502) is used by HUD Field Offices, HUD Headquarters, and HOME Program Participating Jurisdictions (PJs). The information on program funds committed and disbursed is used by HUD to track PJ performance and to determine compliance with HOME regulations. The project-specific property, tenant, owner, and financial data is used to compile annual reports to Congress required at Section 284(b) of the HOME Investment Partnerships Act, as well as to make program management decisions about how well program participants are achieving the statutory objectives of the HOME Program. Program management reports are generated by IDIS to provide data on the status of program participants' commitment and disbursement of HOME funds. These reports are provided to HUD staff as well as to HOME PJs.

Management reports required in conjunction with the Annual Performance Report (§ 92.509) are used by HUD Field Offices to assess the effectiveness of locally designed programs in meeting specific statutory requirements and by Headquarters in preparing the Annual Report to Congress. Specifically, these reports permit HUD to determine compliance with the requirement that PJs provide a 25 percent match for HOME funds expended during the Federal fiscal year (Section 220 of the Act) and that program income be used for HOME eligible activities (Section 219 of the Act), as well as the Women and Minority Business Enterprise requirements (§ 92.351(b)).

Financial, project, tenant and owner documentation is used to determine compliance with HOME Program cost limits (Section 212(e) of the Act), eligible activities (§ 92.205), and eligible costs (§ 92.206), as well as to determine whether program participants are achieving the income targeting and affordability requirements of the Act (Sections 214 and 215). Other information collected under Subpart H (Other Federal Requirements) is