DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–N–2381, FDA–2024–N–2019, FDA–2014–N–0987, FDA–2024–N–1382, and FDA–2022–N–1894]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Medical Device Recall Authority	0910–0432	3/31/2028
Guidance for Industry and FDA Staff; Class II Special Controls: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle	0910–0594	3/31/2028
Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications	0910–0796	3/31/2028
Electronic User Fee Payment Form Requests	0910–0805	3/31/2028
Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation B12 Pediatric Device Survey	0910–0912	3/31/2028

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12414 Filed 7–2–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–P–0333]

Determination That SYNDROS (Dronabinol) Solution, 5 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that SYNDROS (dronabinol) solution, 5 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for SYNDROS (dronabinol) solution, 5 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, *Awo.Archampong-Gray@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not 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 (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

SYNDROS (dronabinol) solution, 5 mg/mL, is the subject of NDA 205525, held by Chartwell Scheduled, LLC, and initially approved on July 1, 2016. SYNDROS is indicated in adults for the treatment of anorexia associated with weight loss in patients with acquired immune deficiency syndrome; and of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

SYNDROS (dronabinol) solution, 5 mg/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc. submitted a citizen petition dated January 20, 2025 (Docket No. FDA–2025–P–0333), under 21 CFR 10.30, requesting that the Agency determine whether SYNDROS (dronabinol) solution, 5 mg/mL, 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 SYNDROS (dronabinol) solution, 5 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that SYNDROS (dronabinol) solution, 5 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SYNDROS (dronabinol) solution, 5 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SYNDROS (dronabinol) solution, 5 mg/mL, 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 SYNDROS (dronabinol) solution, 5 mg/mL, 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: June 30, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12444 Filed 7–2–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0894]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; The Real Cost Monthly Implementation Assessment

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 August 4, 2025.

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 title of this information collection is ''The Real Cost Monthly Implementation Assessment.'' Also include the FDA docket number found in brackets in the heading of this document.

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

The Real Cost Monthly Implementation Assessment

OMB Control Number 0910—NEW

This information collection supports the development and implementation of FDA public education campaigns related to tobacco use. To reduce the public health burden of tobacco use in the United States and educate the public—especially young people—about the dangers of tobacco use, the FDA Center for Tobacco Products (CTP) is developing and implementing multiple public education campaigns.

FDA launched ''The Real Cost'' in February 2014, seeking to reduce tobacco use among at-risk teens ages 12–17 in the United States who are open to using tobacco products, or who have already experimented with tobacco products. Complementary evaluation studies, including the ''Evaluation of FDA's Public Education Campaign on Teen Tobacco (ExPECTT),'' were implemented to measure awareness of ''The Real Cost'' paid media campaign among teens ages 12–17 in the United States, and to understand how awareness is related to change in key outcomes.

Although outcome evaluation studies of ''The Real Cost'' have and continue to assess the impact of awareness on outcomes, no studies have sought to assess the implementation of ''The Real Cost.'' As FDA continues to increase the presence of ''The Real Cost'' on digital channels (*e.g.,* Hulu, YouTube, Instagram), the need for an implementation evaluation has become clear as these messages are received by the target audience on digital channels differently compared to how the messages are received on broadcast channels. Before the migration of campaign ads to digital channels, ads from ''The Real Cost'' were primarily aired on broadcast TV. In the broadcast space, for people to avoid receiving the message, they needed to be proactive (*e.g.,* finding the remote to change the channel or leaving the room). In the digital space, however, people need to be proactive to watch the full message, like stopping scrolling on social media or watching the full ad on YouTube. Assessment of this information is integral to understanding self-reported ad awareness levels, as well as how our audience experiences and processes the ads as they are airing in a digital setting.

Therefore, we propose to establish an umbrella generic ICR to help us understand, in a digital setting, how teens experience the messages, how they engage with messages, the extent to which teens report being exposed to messages, and how teens process the messages. Data gathered from this assessment will also provide the necessary and timely information to optimize campaign messages, the digital media buy (*i.e.,* where, how, and when ads are shown), and creative rotations (*i.e.,* which ads are shown).

''The Real Cost'' Monthly Implementation Assessment (MIA) umbrella generic is a mixed methods generic information collection (gen IC) mechanism that will be conducted using virtual discussion groups or interviews, as well as web-based surveys that are self-administered on personal computers or web enabled mobile devices to collect rapid data on ''The Real Cost'' stimuli. Survey data from up to 2,000 teens in the United States will be collected each month for up to 24 months. To be eligible, participants must be between the ages of 12–20 and have not taken the MIA survey within the past 3 months. Mixed methods data from up to 400 participants ages 12–20 years in the United States will be collected on a quarterly basis (*i.e.,* collected an average of four times a year). Participants will only be eligible to participate in an MIA mixed methods study if they have not already participated within the past year. We will use an Ipsos Knowledge Panel to