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we have at this time, FDA has determined under § 314.161 that SYNDROS (dronabinol) solution, 5 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that SYNDROS (dronabinol) solution, 5 mg/mL, was withdrawn for reasons of safety or effectiveness.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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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]

BILLING CODE 4164–01–P

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

collect data on ''The Real Cost'' stimuli. This design offers flexibility to assess new stimuli messages, as they air across various digital platforms, examine their performance over time, as well as the ability to pivot and add new survey measures as necessary. Monthly data will also allow us to obtain timely information on stimuli awareness, perceived effectiveness, as well as on teen attention and processing of the stimuli.

The purpose of FDA's ''The Real Cost'' MIA generic information collection is to evaluate the following key components about ''The Real Cost'' stimuli:

- Awareness of ''The Real Cost'' brand and stimuli.
- Attention behaviors when seeing ''The Real Cost'' stimuli.
- Processing of ''The Real Cost'' stimuli, including:
  - Engagement with the stimuli.
  - Main message comprehension.
  - Acceptance and/or rejection of the stimuli.
- Perceived effectiveness of ''The Real Cost'' stimuli.
- Potential unintended consequences of viewing ''The Real Cost'' stimuli.

In addition to the above components, the gen IC study will ask participants to report on tobacco use and other psychographic and demographic items. The time frame that the survey items will ask about for stimuli awareness (*i.e.,* past 30 days or past week) will depend on several factors, including how long the stimuli was on air. Each gen IC survey will take an average of approximately 25 minutes to complete per participant. As the survey items are tested, any irrelevant items will be cut as necessary. Stimuli creative for cigarette products and emerging tobacco products (*e.g.,* electronic nicotine delivery systems or ENDS) will be assessed; therefore, two similar surveys (one on ENDS-focused or emerging tobacco product stimuli and one on cigarette-focused stimuli) will be fielded as appropriate, but not within the same month.

In support of the provisions of the Tobacco Control Act that require FDA to protect the public health and to reduce tobacco use by minors, FDA requests OMB approval to collect information to evaluate CTP's public education campaign ''The Real Cost'' through the MIA under an umbrella generic information collection.

In the **Federal Register** of April 27, 2023 (88 FR 25660), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent; activity	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
Parent Screener	2,457,310	1	2,457,310	0.05 (3 minutes)	122,866
Parent Permission	1,842,983	1	1,842,983	0.05 (3 minutes)	92,149
Each Invitation Emails (Respondents ages 18–20)	54,577	1	54,577	0.02 (1 minute)	1,092
Youth Assent	29,836	1	29,836	0.05 (3 minutes)	1,492
Young Adult Consent	21,364	1	21,364	0.05 (3 minutes)	1,068
Online Survey	48,000	1	48,000	0.42 (25 minutes)	20,160
Mixed Methods (Online Survey + Virtual Discussion Group or Interview)	3,200	1	3,200	1.5 (90 minutes)	4,800
Reminder Emails	51,200	1	51,200	0.20 (12 minutes)	10,240
Total					253,867

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

Data collection under the MIA umbrella generic will occur over the course of 2 years (24 months) and will consist of administering a monthly survey to approximately 2,000 participants aged 12 to 20 *and* a quarterly mixed methods data collection to approximately 400 participants aged 12 to 20. We expect the screening process (3 minutes per response) to yield an approximate 2.3 to one ratio of eligible participants. We will need to screen approximately 97,440 potential participants each month (resulting in 2,457,310 screeners) over the study period. Since the eligible age for data collection is 12 to 20 years old, we intend to screen parents of eligible youth and young adults. Parents of the youth participants determined to be eligible through the screener will provide parent permission (3 minutes per response). We estimate that 1,842,983 of the parents who complete the screener will provide their permission for their youth to complete the online survey (approximately 75 percent of the 2,457,310 screened). In addition to recruiting respondents through parents, we will send direct invitations to young adult panel members (18–20 years old). We anticipate that 50 percent of young adults will agree to participate. We will send 508 direct invitations a month to young adult panel members (18–20 years old). Eligible youth (1,753,920) will provide their assent (3 minutes per response) to participate in the online survey (25 minutes per response). Participants who are 18 to 20 (19 to 20 in Alabama and Nebraska in accordance with state law) will provide their consent (3 minutes per response) to participate in the online survey. We estimate that approximately 42 percent of the 48,000 completed surveys will come from young adults aged 18 to 20 (19 to 20 in Alabama and Nebraska).

Over the course of the 24-month study period, we intend to survey approximately 2,000 young people ages 12–20 per month and have approximately 400 young people participate in mixed methods data collections per quarter. From completed screeners, we estimate that we will obtain data from approximately 29,836 youth and 21,364 young adults. This will give us a total of 48,000 participants for the survey study and 3,200 participants for the mixed methods data collection. The survey will be repeated with a new cross-sectional sample approximately every month over a period of 24 months; however, some participants will complete more than one wave. These 51,200 respondents will receive an invitation email to take part of the MIA study (1 minute) and 6 reminder emails (1 minutes each) for a total of 25 minutes for respondents to read and respond to the emails.

Several changes have been made to this information collection request since the 60-day notice was published in the **Federal Register**. These changes include: (1) editing to clarify that the ad campaign is intended for ''teens'' not just ''youth'', (2) removing the focus on video ads since the campaign may use other forms of communication to deliver its message and replacing the term ''ad''

with ''stimuli'', (3) removing the youth screener from the burden table because parents determine the eligibility of their youth aged 12–17 (18 to 20 in Alabama and Nebraska in accordance with state law), (4) removing the young adult screener from the burden table, which will not be needed because young adult panel members (18–20 years old) will only receive an email invitation to complete the survey, (5) updating the burden table to reflect that we will send direct invitations to young adult panel members (18–20 years old), (6) updating the permission, assent, and consents because of updated information on the expected sample breakdown from the sample vendor for the distribution of the sample who are 12–17 and 18–20, (7) removing the thank you email since that will not be a part of the data collection procedures, (8) updating the focus of the stimuli and survey because FDA will assess cigarettes, e-cigarettes, and other emerging tobacco products and (9) updating the annualized cost burden estimates based on current data. In addition to the implementation evaluation described above, we will conduct formative evaluation to assess perceptions to proposed stimuli and potential unintended consequences in order to inform the development of future messaging.

In addition to those changes described above since the publication of the 60-day **Federal Register** notice, on our own initiative for efficiency of Agency operations, we are revising the information collection request from a ''stand-alone'' to an umbrella generic. This change will enable FDA to rotate and test different modules of the MIA study on a monthly basis and collect mixed methods data in a timely and efficient manner.

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12420 Filed 7–2–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0956]

Agency Information Collection Activities; Proposed Collection; Comment Request; Warning Plans for Certain Tobacco Products

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 collection 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 provisions associated with warning plans for certain tobacco products.

DATES: Either electronic or written comments on the collection of information must be submitted by September 2, 2025.

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 September 2, 2025. 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 No. FDA–2025–N–0956 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Warning Plans for Certain Tobacco Products.'' 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