requests for waivers or reductions of ADUFA user fees, we developed guidance for industry (GFI) #170 entitled ''Animal Drug User Fees and Fee Waivers and Reductions'' (April 2023), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-170-animal-drug-user-fees-and-fee-waivers-and-reductions.* This document discusses the types of fees FDA is authorized to collect under section 740 of the FD&C Act, and how to request waivers or reductions from these fees. Further, this guidance also describes what information FDA recommends be submitted in support of a request for a fee waiver or reduction, a request for reconsideration of denial of a fee waiver or reduction request, or an appeal of the denial decision in accordance with 21 CFR 10.75; how to submit such a request or appeal; and FDA's process for reviewing such requests or appeals.

Similarly, we developed guidance for industry (GFI) #199 entitled ''Animal Generic Drug User Fees and Fee Waivers and Reductions'' (May 2009), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-199-animal-generic-drug-user-fees-and-fee-waivers-and-reductions.* This document discusses the types of fees FDA is authorized to collect under section 741(a)(1) of the FD&C Act, and how to request waivers or reductions from these fees. Further, this guidance also describes what information FDA recommends be submitted in support of a request for a fee waiver or reduction, a request for reconsideration of denial of a fee waiver or reduction request, or an appeal of the denial decision in accordance with 21 CFR 10.75; how to submit such a request or appeal; and FDA's process for reviewing such requests or appeals.

We use the information submitted by respondents to determine whether requests for waiver or reduction of user fees, reconsideration requests, or appeals may be granted.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act section; activity	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
User fee cover sheets, by type						
740(a)(1); Animal Drug User Fee cover sheet.	FDA 3546	15	1	15	1	15
741(a)(1); Animal Generic Drug User Fee cover sheet.	FDA 3728	22	2	44	.08 (5 minutes)	3.5
Waiver and other requests, by type						
740(d)(1)(A); significant barrier to innovation.	N/A	65	1	65	2	130
740(d)(1)(B); fees exceed cost	N/A	8	3.75	30	0.5 (30 minutes)	15
740(d)(1)(C); free choice feeds	N/A	4	1	4	2	8
740(d)(1)(D); minor use or minor species.	N/A	73	1	73	2	146
740(d)(1)(E); small business	N/A	1	1	1	2	2
741(d)(1); minor use or minor species.	N/A	2	1	2	2	4
Request for reconsideration of a decision.	N/A	1	1	1	2	2
21 CFR 10.75; Appeal of a decision.	N/A	1	1	1	2	2
Total						327.5

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

Our estimated burden for the information collection reflects an overall increase. We attribute this adjustment to an increase in the number of submissions we have received since our last evaluation. The total number of annual responses is based on the average number of submissions received by FDA in fiscal years 2019 to 2021. The estimated time we attribute to the hours per response is based on our experience with the various submissions and reflects the average burden we attribute to all respondents.

Dated: April 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08946 Filed 4–26–23; 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; Proposed Collection; Comment Request; The Real Cost Monthly Implementation Assessment

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 a notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed information collection entitled ''The Real Cost Monthly Implementation Assessment.''

DATES: Either electronic or written comments on the collection of information must be submitted by June 26, 2023.

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 June 26, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2023–N–0894 for ''The Real Cost Monthly Implementation Assessment.'' 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 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.

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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 youth ages 12 to 17 in the United States who are open

to smoking cigarettes and/or using electronic nicotine delivery systems (ENDS) products, or who have already experimented with cigarettes and/or ENDS 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 youth ages 12 to 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 skipping the 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, real-world setting.

Therefore, we propose a study to help us understand, in a digital setting, how youth experience the messages, how they engage with messages, the extent to which youth report being exposed to messages, and how youth process the messages. Studying exposure to ad messages as it naturally occurs in the real world can help us understand the points of connection—or disconnection—between the results of copy testing studies (which assess responses to the ads with forced exposure to them) and outcome evaluation findings (which are based on natural exposure to ads in the real world). 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 is a repeated cross-sectional survey that will be conducted using web-based surveys that are self-administered on personal computers or web enabled mobile devices to collect rapid data on ''The Real Cost'' ads. Data from up to 2,000 youth in the United States will be collected each month for up to 24 months. To be eligible, youth and young adults must be between the ages of 12 to 20 and have not taken ''The Real Cost'' Monthly Implementation Assessment survey within the past 3 months. We will use an Ipsos Knowledge Networks Panel to collect data on ''The Real Cost'' ads. This design offers flexibility to assess new ad 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 ad awareness, perceived effectiveness, as well as on youth attention and processing of the ads.

The purpose of FDA's ''The Real Cost'' Monthly Implementation Assessment is to evaluate the following key components about ''The Real Cost'' ads:

- Awareness of ''The Real Cost'' ads.
- Attention behaviors when seeing ''The Real Cost'' ads.
- Processing of ''The Real Cost'' ads, including:
  - Engagement with the ads.
  - Main message comprehension.
  - Acceptance and/or rejection of the ads.
- Perceived effectiveness of ''The Real Cost'' ads.
- Belief and knowledge tracking of ''The Real Cost'' ads.

In addition to the above components, the survey 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 ad awareness (*i.e.,* past 30 days or past week) will depend on several factors, including how long the ad was on air. The 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. Ad creative for both vaping and cigarette products will be assessed; therefore, two similar surveys (one on ENDS-focused ads and one on cigarette-focused ads) 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 Monthly Implementation Assessment.

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/Young Adult Screener	2,688,000	1	2,688,000	0.05 (3 minutes)	134,400
Parent Permission	2,016,000	1	2,016,000	0.05 (3 minutes)	100,800
Youth Screener	2,016,000	1	2,016,000	0.05 (3 minutes)	100,800
Youth Assent	36,000	1	36,000	0.05 (3 minutes)	1,800
Young Adult Consent	12,000	1	12,000	0.05 (3 minutes)	600
Online Survey	48,000	1	48,000	0.42 (25 minutes)	20,160
Invitation Email/Reminder Emails/Thank you Email	48,000	1	48,000	0.42 (25 minutes)	20,160
Total					378,720

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

Data collection for the Monthly Implementation Assessment will consist of administering a monthly survey to participants aged 12 to 20 over the course of 2 years (24 months). 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 112,000 potential parents and young adults each month (resulting in 2,688,000 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, as well as 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 2,016,000 of the parents who complete the screener will provide their permission for their youth to complete the online survey (approximately 75 percent of the 2,688,000 screened). Eligible youth (2,016,000) will provide their assent (3 minutes per response) to participate in the online survey (25 minutes per response). Participants that are 18 to 20 (19 to 20 in Alabama and Nebraska in accordance with state law) will complete the screener for themselves and provide their consent (3 minutes per response) to participate in the online survey. We estimate that approximately 25 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 study period, we intend to survey approximately 2,000 youth and young adults ages 12 to 20 per month for 24 months. From these completed screeners, we estimate that we will obtain data from 36,000 youth and 12,000 young adults. This will give us a total of 48,000 participants for the study. 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 48,000 respondents will receive an invitation email with a link to take the survey (4 minutes), six reminder emails (3 minutes each), and a thank you email (3 minutes) upon completion of the study for a total of 25 minutes for respondents to read and respond to the emails.

Dated: April 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08945 Filed 4–26–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1466]

Good Manufacturing Practices for Cosmetic Products Listening Session; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a virtual listening session entitled ''Good Manufacturing Practices for Cosmetic Products Listening Session.'' The purpose of the listening session is to consult cosmetics manufacturers, including smaller businesses, consumer organizations, and other experts, to inform Agency efforts to develop regulations to establish good manufacturing practices for facilities that manufacture or process cosmetic products distributed in the United States.

DATES: The virtual listening session will be held on June 1, 2023, from 10 a.m. to 1 p.m. Eastern Daylight Time (EDT) or until after the last public commenter has spoken, whichever occurs first. Submit requests to make oral presentations at the listening session by 6 p.m. EDT, May 18, 2023. Either electronic or written comments on this listening session must be submitted to the docket by July 3, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Additional details, such as registration information, are available at *https://www.fda.gov/cosmetics/cosmetics-news-events/public-meeting-good-manufacturing-practices-cosmetic-products-06012023.*

FDA is establishing a public docket for this listening session. 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. EDT at the end of July 3, 2023. 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–2023–N–1466 for ''Good Manufacturing Practices for Cosmetic Products Listening Session.'' 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