regulations enable a common understanding of the regulatory process by describing requirements to be followed by drug manufacturers, applicants, and FDA. Under part 211 (21 CFR part 211; see 21 CFR 211.94(e)(1)), specific requirements for medical gas containers and closures are also found in the regulations. Finally, the information collection also supports regulations codified under parts 610 and 680 (21 CFR parts 610 and 680), which reference certain CGMP regulations in part 211 (see §§ 610.12(g), 610.13(a)(2), 610.18(d), 680.2(f), and 680.3(f)).

These regulations set forth information collection requirements that allow FDA to meet its public health protection responsibilities. Products that fail to comply with CGMP requirements may be rendered adulterated under section 501(a)(2)(B) of the FD&C Act. To demonstrate that their products comply with the requirements of section 501(a)(2)(B), API manufacturers must maintain CGMP records; therefore, we have counted them among respondents who incur burden for the information collection. In the table below, we have included an additional 1,260 respondents to reflect API manufacturers not included in our previous submission for renewal.

To assist respondents with the information collection requirements for medical gases, we developed a draft guidance for industry entitled ''Current Good Manufacturing Practice for Medical Gases.'' This guidance, when finalized will discuss our recommendations regarding compliance with applicable requirements found in the regulations as they apply to these products. The guidance is available for download from our internet site at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/current-good-manufacturing-practice-medical-gases.* We believe the recommendations, if followed, will help respondents focus their information collection activities most efficiently with regard to demonstrating regulatory compliance.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN—APIS, FINISHED PHARMACEUTICALS, AND MEDICAL GASES [1] [2]

Section 501(a)(2)(B) of the FD&C Act; parts 210 and 211	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
CGMP API Manufacturers	1,260	256	322,560	0.82 (49.2 minutes)	264,499
CGMP Finished Pharmaceuticals Manufacturers (excludes medical gases).	3,270	299	977,730	0.64 (38 minutes)	625,747
CGMP Medical Gases Manufacturers.	2,284	280	639,520	0.62 (37 minutes)	396,502
Total			1,939,810		1,286,748

[1] There are no capital or operating and maintenance costs associated with the information collection.
[2] Records and burden per activity have been averaged and rounded.

Our estimated burden for the information collection reflects an overall decrease of 29,073 hours and 1,762 records annually for CGMP for finished pharmaceutical manufacturers, excluding those manufacturers of medical gases. Our estimated burden for the information collection also reflects an overall decrease of 486 hours and 1,574 records annually for medical gas manufacturers. Our inclusion of API manufacturers in this collection represents an addition of 264,499 hours and 322,560 records prepared.

Dated: February 25, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–04380 Filed 3–2–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0132]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration's Study of How Consumers Use Flavors To Make Inferences About Electronic Nicotine Delivery System Product Qualities and Intentions To Use (Phase 2)

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's investigation of how consumers use flavors to make inferences about Electronic Nicotine Delivery System (ENDS) product qualities and intentions to use.

DATES: Submit either electronic or written comments on the collection of information by May 3, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 3, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 3, 2021. 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–2021–N–0132 for ''Food and Drug Administration's Investigation of How Consumers Use Flavors to Make Inferences About Electronic Nicotine Delivery System (ENDS) Product Qualities and Intentions to Use (Phase 2).'' 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.

Food and Drug Administration's Study of How Consumers Use Flavors To Make Inferences About Electronic Nicotine Delivery System (ENDS) Product Qualities and Intentions To Use (Phase 2)

OMB Control Number 0910–NEW

ENDS, also called electronic cigarettes, e-cigarettes, and vaporizers, are deemed tobacco products and fall under FDA's regulatory scope. FDA has the authority under the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31, H.R. 1256) to regulate and restrict the marketing of tobacco products. However, given the recency of ENDS products to the market, limited research exists to inform the regulation of certain aspects of their marketing. Research to understand ''marketing influences on youth experimentation, initiation, use and cessation of tobacco products'' is a regulatory priority for the FDA Center for Tobacco Products (CTP).[1]

Flavors are a unique and important aspect of ENDS. ENDS use a liquid (''e-liquid'' or ''e-juice'') that can span a diverse range of flavors, from tobacco flavor, menthol, mint, fruit flavors, non-fruit sweet flavors (*e.g.,* crème brulee, gummi bears), spices (*e.g.,* cinnamon, vanilla), alcohol (*e.g.,* strawberry daiquiri, bourbon, Irish cream), and ''concept'' flavors (*e.g.,* ''Heliomilk'', ''Sungrazer''). Flavors are a regulatory area of interest, and FDA has issued an advance notice of proposed rulemaking (Docket No. FDA–2017–N–6565) ''to obtain information related to the role that flavors play in tobacco products,'' with a specific interest in how flavors may spur youth product initiation.

This study of ''How Consumers Make Inferences about ENDS'' is voluntary research. The primary goal of the study is to understand whether flavor-related imagery, descriptors, and flavor name modifiers affect product appeal, curiosity about the product, interest in

[1] *https://www.fda.gov/tobacco-products/research/research-priorities.*

using the product, and product perceptions among youth and young adults. The project will examine three features identified in the research team's prior work: the use of flavor-related imagery, the use of flavor descriptors (*e.g.,* ''cool'', ''fresh''), and the use of flavor name modifiers (*e.g.,* Cherry Crush).

The study will collect data from two groups of consumers: 2,500 youth (aged 13 to 17 years old) and 2,500 young adults (aged 18 to 24 years old). The sample will be stratified by ENDS and cigarette use, so that 625 participants in each age group will be (a) non-cigarette and non-ENDS users (N=625), (b) cigarette users only (N=625), (c) ENDS users only (N=625), and (d) dual ENDS and cigarette users (N=625). Participants will participate in a repeated measure experiment in which they will be asked to view five ads and report their liking of the ad, curiosity about using the product (an important precursor to use), and interest in using the product. Participants will also report additional perceptions of product qualities. Findings from this study will inform FDA rulemaking regarding the marketing and presence of flavor features in ENDS and be used to guide other public health agencies' policies and messaging regarding the role of flavors in ENDS.

Study Overview: In this study, youth non-cigarette and non-ENDS users, current cigarette smokers, ENDS only users, and dual users of ENDS and cigarettes, as well as young adult non-cigarette and non-ENDS users, current cigarette smokers, ENDS only users, and dual users of ENDS and cigarettes will be recruited from two existing internet online panels and screened for inclusion into the study. All recruited participants must complete a double opt-in procedure, and parents of youth participants must consent for their child to be on the panel. Youth will provide assent and young adults will provide consent to participate in the surveys. Per institutional review board approval, parental consent has been waived and will not be required for youth to participate in this study. The survey platform can detect and prevent duplicate responses by scanning for duplicate cookies and internet protocol (IP) addresses. Participants will receive a small incentive as a token of appreciation in exchange for their survey participation.

Participants who meet the inclusion criteria will be randomized to view five ads across five conditions to report their liking of the ad, curiosity about using the product (an important precursor to use), and interest in using the product. The order of ad presentation will be randomized. These procedures will minimize order effects as well as the likelihood of a demand characteristic in which a participant guesses the purpose of the experiment and intentionally or unintentionally alters their response.

Study outcomes include comparisons to assess the extent to which presence or absence of a flavor-representing image, name modifier, or descriptor will be associated with increased or decreased (a) product appeal, (b) curiosity about the product, (c) interest in using the product, and (d) increased positive product perceptions compared to a control condition ad (without or with flavor features).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Participant subgroup	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Number to read the survey invitation					
Youth (aged 13–17)	125,000	1	125,000	0.016 (1 minute)	2,084
Young adults (aged 18–24)	125,000	1	125,000	0.016 (1 minute)	2,084
Total	250,000				4,168
Number to complete the consent and screener					
Youth (aged 13–17)	3,750	1	3,750	0.116 (7 minutes)	438
Young adults (aged 18–24)	3,750	1	3,750	0.116 (7 minutes)	438
Total	7,500				876
Number to complete main study					
Youth (aged 13–17)	2,500	1	2,500	0.333 (20 minutes)	834
Young adults (aged 18–24)	2,500	1	2,500	0.333 (20 minutes)	834
Total	5,000				1,668
Total					6,712

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

FDA's burden estimate is based on prior experience with research that is similar to this proposed study (OMB control number 0910–0848). Applying assumptions from previous experience in conducting similar studies, approximately 250,000 respondents from an internet panel will be recruited via an email invitation, which is estimated to take 1 minute to read and respond. An estimated 7,500 (3,750 youth and 3,750 young adults) respondents will provide assent and consent and be screened to yield the desired sample size of 5,000 total (2,500 youth and 2,500 young adults) participants. The consent/screening process is estimated to take an average of 7 minutes per respondent. Participants that qualify for the study will be automatically directed to begin the online survey, which is estimated to take an average of 20 minutes per respondent.

The total estimated burden for the data collection is 6,712 hours.

Dated: February 25, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–04372 Filed 3–2–21; 8:45 am]

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