Approval Under OMB Delegated Authority of the Temporary Revision of the Following Information Collection

Report title: Reporting and Disclosure Requirements Associated with Emergency Lending Under Section 13(3).

Agency form number: FR A.

OMB control number: 7100–0373.

Frequency: Event-generated.

Respondents: Entities or persons borrowing under an emergency lending program or facility established pursuant to section 13(3) of the Federal Reserve Act.

Estimated number of respondents: FR A–1: 4,914; FR A–2: 3,073; FR A–3: 12,150; FR A–4: 5.

Estimated average hours per response: FR A–1: 8; FR A–2: 40; FR A–3, Lender per-loan certifications: 2; FR A–3, Borrower certifications: 8; FR A–4: 1.

Estimated annual burden hours: 257,305.

General description of report: The Board's Regulation A (12 CFR part 201) establishes policies and procedures with respect to emergency lending under section 13(3) of the Federal Reserve Act, as required by sections 1101 and 1103 of the Dodd-Frank Wall Street Reform and Consumer Protection Act. Regulation A requires that borrowers make two certifications in order to participate in any emergency lending authorized under section 13(3). These certifications, designated in this information collection as FR A–1, include that the borrowers are not insolvent and that they cannot obtain adequate credit accommodation.

In addition to these certifications, the Board may establish additional certification requirements for an individual emergency lending facility. The second part of the FR A information collection, the FR A–2, pertains to reporting requirements associated with individual facilities that are related to requirements of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The third part of FR A, designated as the FR A–3, pertains to reporting requirements specific to the Main Street Expanded Loan Facility, the Main Street New Loan Facility, the Main Street Priority Loan Facility, the Nonprofit Organization Expanded Loan Facility, and the Nonprofit Organization New Loan Facility (collectively, the ''Main Street Lending Program''). The fourth part of FR A, designated as the FR A–4, pertains to a disclosure requirement for Paycheck Protection Program (PPP) borrowers seeking to reduce the calculation of existing outstanding and undrawn available debt to participate in the Main Street Lending Program.

Legal authorization and confidentiality: The FR A is authorized pursuant to section 13(3) of the Federal Reserve Act, which sets out requirements for emergency lending. The obligation to respond is required to obtain a benefit.

The information collected under the FR A may be kept confidential under exemption 4 of the Freedom of Information Act, which protects commercial or financial information obtained from a person that is privileged or confidential.

Current actions: The Board is revising the FR A information collection to address information collection requirements related to borrowers under the Main Street Lending Program, who participate in the PPP. Participating borrowers seeking to reduce the calculation of ''existing outstanding and undrawn available debt'' for purposes of determining the maximum allowable loan amount under the Main Street Lending Program must provide its eligible lender either with the Small Business Administration form it has already completed and submitted to its PPP lender (which may be the same lender), or must complete and submit a Board form to its Main Street lender during the Main Street loan underwriting process, as applicable. The FR A respondent counts for all parts of the information collection are being revised to reflect updated estimates of lender participation in the Main Street Lending Program.

Detailed Discussion of Public Comments: On March 2, 2020, the Board published a notice in the **Federal Register** (85 FR 12295) requesting public comment for 60 days on the extension, without revision, of the FR A. One comment was received; it did not address aspects of the information collection as described in 5 CFR 1320.8(d). On May 15, 2020, following the temporary approval of a first set of revisions to the FR A, the Board published a **Federal Register** notice (85 FR 29447) requesting public comment for 60 days on those temporary revisions. On June 4, 2020, following the temporary approval of a second set of revisions to the FR A, the Board published a **Federal Register** notice (85 FR 34448) requesting public comment for 60 days on those temporary revisions. On August 21, 2020, following the temporary approval of a third set of revisions to the FR A, the Board published a **Federal Register** notice (85 FR 51715) requesting public comment for 60 days on those temporary revisions. Comments in response to all of those requests for comment are expected to be considered, along with any comments received in response to this request for comment.

Board of Governors of the Federal Reserve System, February 26, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–04362 Filed 3–2–21; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0362]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice for Manufacturing, Processing, Packing, and Holding of Finished Pharmaceuticals, Including Medical Gases, and Active Pharmaceutical Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 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 the information collection associated with current good manufacturing practice (CGMP) for drugs, finished pharmaceuticals, including medical gases, and active pharmaceutical ingredients (APIs).

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–2011–N–0362 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Manufacturing, Processing, Packing, and Holding of Finished Pharmaceuticals, Including Medical Gases, and Active Pharmaceutical Ingredients.'' 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: 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: 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, including each proposed extension of an existing 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.

Current Good Manufacturing Practice for Finished Pharmaceuticals, Including Medical Gases, and Active Pharmaceutical Ingredients—21 CFR parts 210 and 211 and 21 U.S.C 351(a)(2)(B).

OMB Control Number 0910–0139—Extension

This information collection supports FDA regulations that govern the manufacture, processing, packing, or holding of finished pharmaceuticals, including medical gases, and APIs. Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with CGMP regulations. FDA is responsible for enforcing the FD&C Act as well as related statutes, including the Public Health Service Act. Congress enacted these laws to ensure that covered products meet applicable requirements regarding the safety, identity and strength, and the quality and purity characteristics they purport or are represented to possess, and are labeled with adequate warnings and instructions for use.

The pharmaceutical or drug quality-related regulations appear in several parts of Title 21 Code of Federal Regulations (CFR) (Food and Drugs), including sections in parts 1 through 99, 200 through 299, 300 through 499, 600 through 799, and 800 through 1299. The

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:

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