III. References

The following references are on display in the Dockets Management Staff Office (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Executive Order 13771 (January 30, 2017); available at *https://www.federalregister.gov/documents/2017/02/03/2017-02451/reducing-regulation-and-controlling-regulatory-costs.*
2. Executive Order 13777 (February 24, 2017); available at *https://www.federalregister.gov/documents/2017/03/01/2017-04107/enforcing-the-regulatory-reform-agenda.*

Dated: August 30, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–19030 Filed 9–7–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA–2017–N–5093]

Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments and information.

SUMMARY: As part of the implementation of Executive Order 13771 entitled, ''Reducing Regulation and Controlling Regulatory Costs,'' and Executive Order 13777 entitled, ''Enforcing the Regulatory Reform Agenda,'' the Food and Drug Administration (FDA, Agency, or we) is seeking comments and information from interested parties to help FDA identify existing regulations and related paperwork requirements that could be modified, repealed, or replaced, consistent with the law, to achieve meaningful burden reduction while allowing us to achieve our public health mission and fulfill statutory obligations. This document relates to general regulatory and information collection requirements that affect multiple FDA Centers and/or Offices.

DATES: Submit either electronic or written comments on this document by December 7, 2017.

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 December 7, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of December 7, 2017. 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–2017–N–5093 for ''Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration.'' 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 Office between 9 a.m. and 4 p.m., Monday through Friday.

- 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.'' We will review this copy, including the claimed confidential information, in our 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.gpo.gov/fdsys/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 Office, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Megan Velez, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4830, *megan.velez@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. FDA's Regulatory Mission

FDA is responsible for protecting the public health by: (1) Ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; (2) ensuring the safety, security, and appropriate labeling of our nation's food supply, products that emit radiation, and cosmetics; and (3) regulating the manufacture, marketing, and distribution of tobacco products. Equally important, FDA promotes the public health by fostering and supporting innovative approaches and solutions for some of our nation's most compelling health and medical challenges.

This document is seeking comments and information solely on general regulations and approved information collections affecting multiple FDA Centers and/or Offices.

B. The Regulatory Reform Agenda: Executive Orders 13771 and 13777

On January 30, 2017, President Trump issued Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs'' (Ref. 1). This Executive Order states that the policy of the Executive Branch is to be prudent and financially responsible in the expenditure of funds, from both public and private sources, and that it is essential to manage the costs associated with complying with Federal regulations. On February 24, 2017, President Trump issued Executive Order 13777, entitled ''Enforcing the Regulatory Reform Agenda'' (Ref. 2). The purpose of this Executive Order is to alleviate unnecessary regulatory burdens placed on the American people. Executive Order 13777 directs each Agency to establish a Regulatory Reform Task Force (RRTF) to evaluate existing regulations and identify those that may merit repeal, replacement, or modification. Section 3(d) of the Executive Order provides that, at a minimum, each RRTF must attempt to identify regulations that:

- Eliminate jobs, or inhibit job creation;
- Are outdated, unnecessary, or ineffective;
- Impose costs that exceed benefits;
- Create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies;
- Are inconsistent with the requirements of the Information Quality Act, or the guidance issued pursuant to that Act, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; or
- Derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.

II. Request for Comments and Information

To assist with our implementation of Executive Orders 13771 and 13777 and support the work of the RRTF of the Department of Health and Human Services, FDA is issuing this Request for Information soliciting broad public comment on ways we can change our regulations to achieve meaningful burden reduction while continuing to achieve our public health mission and fulfill statutory obligations. We request comment, including supporting technical, scientific, economic, or other data, from all persons and entities significantly affected by FDA regulations, including consumers, patients and caregivers, researchers, healthcare institutions, the regulated industry, trade associations, public interest organizations, academia, and State, local, and tribal governments, as well as any other interested stakeholder. These comments and data will supplement and inform our own ongoing, systematic review of our regulations.

The following list of questions includes those that FDA is using to guide our initial review of our regulations. This list is intended to help the public in providing comments, not to restrict the issues that may be addressed.

- Is the regulation still current, or is it outdated or unnecessary in some way?
  - Have there been advancements and innovations in science, technology, or FDA or industry practice, or any other changes that suggest repeal of or modification to the regulation may be warranted or appropriate?
  - Has the regulation been superseded or made irrelevant or unenforceable by statute, another FDA regulation or guidance, a regulation by another Federal Agency, or controlling legal authority? If yes, identify the statute, regulation, guidance, or legal precedent and explain what FDA regulation is affected and in what way it is affected.
  - Is this regulation duplicative of requirements in other FDA regulations or other Federal Agency regulations? If yes, identify the overlapping regulation(s) and responsible Federal Agency and describe the way(s) in which the regulations overlap, as well as any suggestions with respect to how best to resolve the duplication.
- Have regulated entities had difficulties complying with the regulation? If yes, identify what entity or entities have had such difficulties and the nature of the difficulties.
- Does the regulation impose requirements that are also provided for in voluntary or consensus standards or guidance by third party organizations (*e.g.,* International Council for Harmonisation, International Organization for Standardization, Codex Alimentarius)? Do the entities covered by these standards or guidance take steps to meet the standards and to document that they meet the standards? If met, do the standards achieve the same level of public health protection as the FDA regulation? Are there entities who are not covered by these standards or guidances or who choose not to observe them?
- Does the regulation contain redundant, outdated, or unnecessary collections of information or retention of records, *e.g.,* reporting, recordkeeping, or labeling requirements? Explain in your response why the information is redundant, outdated, or unnecessary.
- Could the goal of the regulation be achieved by less costly means that would provide the same level of public health protection? If yes, provide examples of alternatives that may reduce costs to industry while retaining the same level of public health protection.
- What factors should FDA consider in selecting and prioritizing regulations and reporting requirements for reform?

The most current version of FDA regulations may be found at *https://www.ecfr.gov.* We request that comments be as specific as possible, include any supporting data or other information, such as cost information, provide a *Code of Federal Regulations* (CFR) citation when referencing a specific regulation, and provide specific suggestions regarding repeal, replacement, or modification. For comments relating to an information collection, cite to the approved information collection request and include the Office of Management and Budget (OMB) control number.

In addition, in order to enable us to more efficiently review and consider comments, we ask that the comments be submitted in the format shown in table 1 of this document.

TABLE 1—FORMAT FOR SUBMITTING COMMENTS

Name of regulation	
Type of product or FDA Center regulating the product.	
Citation to Code of Federal Regulations and statutory citation (as applicable).	
Approved information collection and OMB Control Number (as applicable).	
Brief description of concern	(For example, what innovation makes the regulation outdated? Why?)
Available data on cost or economic impact	(Quantified costs and/or cost savings. Qualitative description, if needed.)
Proposed solution	(Include your solution. For example, how would you modify the regulation? Provide specific text if you are recommending a modification.)

III. References

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2. Executive Order 13777 (February 24, 2017); available at *https://www.federalregister.gov/documents/2017/03/01/2017-04107/enforcing-the-regulatory-reform-agenda.*

Dated: August 30, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–19047 Filed 9–7–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 51

[EPA–HQ–OAR–2016–0456; FRL–9966–75–OAR]

RIN 2060–AS91

Method 202—Dry Impinger Method for Determining Condensable Particulate Emissions From Stationary Sources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In this action, the Environmental Protection Agency (EPA) proposes editorial and technical revisions to the EPA's Method 202—Dry Impinger Method for Determining Condensable Particulate Emissions from Stationary Sources to improve the consistency in results achieved across the testing community.

DATES:

Comments. Comments must be received on or before November 7, 2017.

Public Hearing. If a public hearing is requested by September 18, 2017, then we will hold a public hearing on October 10, 2017 at the location described in the **ADDRESSES** section. The last day to pre-register in advance to speak at the public hearing will be October 6, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2016–0456, to the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, Cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

Public Hearing. If a public hearing is requested, it will be held at EPA Headquarters, William Jefferson Clinton East Building, 1201 Constitution Avenue NW., Washington, DC 20004. If a public hearing is requested, then we will provide details about the public hearing on our Web site at: *https://www.epa.gov/emc/emc-proposed-test-methods.* The EPA does not intend to publish another document in the **Federal Register** announcing any updates on the request for a public hearing. Please contact Mr. Ned Shappley at (919) 541–7903 or by email at *shappley.ned@epa.gov* to request a public hearing, to register to speak at the public hearing, or to inquire as to whether a public hearing will be held.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the EPA Docket Center, EPA/DC, EPA WJC West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Mr. Ned Shappley, Office of Air Quality Planning and Standards, Air Quality Assessment Division, Measurement Technology Group (E143–02), Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541–5225; fax number: (919) 541–0516; email address: *shappley.ned@epa.gov.*

SUPPLEMENTARY INFORMATION: The following topics are discussed in this preamble.