Federal Register / Vol. 82, No. 173 / Friday, September 8, 2017 / Proposed Rules 42501

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.

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. 2017–19033 Filed 9–7–17; 8:45 am]

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–5095 for “Existing Center for Tobacco Products Regulatory and Information Collection Requirements.”

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/2015-23369.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:** Gerie Voss, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 1–877–CTP–1373, gerie.voss@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.

FDA’s CTP regulates the manufacture, marketing, and distribution of tobacco products. This document is seeking comments and information solely on regulations and approved information collections related to this product area.

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.
II. Analysis

A. Identification of regulation

- Is the regulation still current, or is it outdated or unnecessary in some way?
- Have there been advancements 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?

B. Identification of the overlapping regulation(s) and responsible Federal Agency, or other Federal Agency regulations?

- 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 not, 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 guidelines 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?

C. Cost estimate

- Available data on cost or economic impact

D. Proposed solution

- Brief description of concern
- Proposed solution

TABLE 1—FORMAT FOR SUBMITTING COMMENTS

<table>
<thead>
<tr>
<th>Name of regulation</th>
<th>(For example, what innovation makes the regulation outdated? Why?)</th>
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</thead>
<tbody>
<tr>
<td>Type of product or FDA Center regulating the product.</td>
<td>(Quantified costs and/or cost savings. Qualitative description, if needed.)</td>
</tr>
<tr>
<td>Citation to Code of Federal Regulations and statutory citation (as applicable).</td>
<td>(Include your solution. For example, how would you modify the regulation? Provide specific text if you are recommending a modification.)</td>
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<tr>
<td>Approved information collection and OMB Control Number (as applicable).</td>
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<tr>
<td>Brief description of concern</td>
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<tr>
<td>Available data on cost or economic impact</td>
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<tr>
<td>Proposed solution</td>
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Dated: August 30, 2017.

Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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