(2) For airplanes with agricultural configuration installed (SOO Mod 2/984), within the next 400 hours TIS after the effective date of this AD, inspect the exterior store support arm bracket at wing station (WS) 101.24 following the Accomplishment Instructions of SB V2/0009, Revision A.

(3) If any discrepancies are found during the inspections required in paragraphs (f)(1) and (2) of this AD, before further flight, repair or replace using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada; or Viking Air Limited's Transport Canada Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(4) Within 30 days after completing the inspections required in paragraphs (f)(1) and (2) of this AD, using the Operator Reply Form on page 7 of SB V2/0009, Revision A, report the inspection results to Viking Air Limited at the address specified in paragraph (h) of this AD.

(5) As of the effective date of this AD, do not install a wing on any airplane affected by this AD unless it has been inspected as specified in paragraph (f)(1) of this AD and paragraph (f)(2) of this AD, as applicable, and is found free of any discrepancies.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Aziz Ahmed, Aerospace Engineer, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 228–7329; fax: (516) 794–5531; email: *aziz.ahmed@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada; or Viking Air Limited's Transport Canada Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Reporting Requirements:* For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(h) Related Information

Refer to MCAI Transport Canada AD Number CF–2017–17, dated May 18, 2017, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0867. For service information related to this AD, contact Viking Air Limited Technical Support, 1959 De Havilland Way, Sidney, British Columbia, Canada, V8L 5V5; telephone: (North America) (800) 663–8444; fax: (250) 656–0673; email: *technical.support@vikingair.com;* Internet: *http://www.vikingair.com/support/service-bulletins.* You may review this referenced service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on August 29, 2017.

Melvin Johnson,

Deputy Director, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2017–18900 Filed 9–7–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA–2017–N–5092]

Review of Existing Center for Biologics Evaluation and Research Regulatory and Information Collection Requirements

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 the products regulated by the Center for Biologics Evaluation and Research (CBER).

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–5092 for ''Review of Existing Center for Biologics Evaluation and Research 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/2015-23389.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: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

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 CBER regulates a wide range of biological products and related products including: Allergenics, blood and blood products, certain medical devices for blood and tissues, gene therapies, human cells, tissues, and cellular and tissue-based products, vaccines, and xenotransplantation products. This document is seeking comments and information solely on regulations and approved information collections related to these product areas.

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

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. 2017–19032 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–5105]

Review of Existing Center for Devices and Radiological Health Regulatory and Information Collection Requirements

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 the products regulated by the Center for Devices and Radiological Health (CDRH).

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