the **FOR FURTHER INFORMATION CONTACT** section.

List of Subjects in 7 CFR Part 900

Administrative practice and procedure, Freedom of information, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth above, 7 CFR part 900 is amended as follows:

PART 900—GENERAL REGULATIONS

■ 1. The authority citation for part 900 continues to read as follows:

Authority: 7 U.S.C. 601–674 and 7 U.S.C. 7401.

■ 2. Add § 900.83 to subpart E read as follows:

§ 900.83 Conducting Meetings via Electronic Communication or Otherwise.

Notwithstanding any other provisions of a marketing order in this part, administrative bodies of fruit, vegetable, and specialty crop marketing orders, and their committees/subcommittees may, upon due notice to all members and the public:

(a) Conduct meetings by any means of communication available, electronic or otherwise, that effectively assembles members and the public, and facilitates open communication.

(b) Vote by any means of communication available, electronic or otherwise; Provided, That votes cast are verifiable and that quorum and other procedural requirements of each respective marketing order are met.

(c) With the approval of the Secretary, each administrative body may prescribe any additional procedures necessary to carry out the objectives of paragraphs (a) and (b) of this section.

Dated: May 11, 2018.

Bruce Summers,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2018–10487 Filed 5–16–18; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 101 and 116

[Docket No. APHIS–2014–0063]

RIN 0579–AE11

VSTA Records and Reports Specific to International Standards for Pharmacovigilance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the Virus-Serum-Toxin Act regulations concerning records and reports. This change requires veterinary biologics licensees and permittees to record and submit reports concerning adverse events associated with the use of biological products they produce or distribute. The information that must be included in the adverse event reports submitted to the Animal and Plant Health Inspection Service (APHIS) will be provided in separate guidance documents. These records and reports will help ensure that APHIS can provide complete and accurate information to consumers regarding adverse reactions or other problems associated with the use of licensed biological products.

DATES: Effective June 18, 2018.

FOR FURTHER INFORMATION CONTACT: Dr. Donna L. Malloy, Section Leader, Operational Support, Center for Veterinary Biologics Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 851–3426.

SUPPLEMENTARY INFORMATION:

Background

The Virus-Serum-Toxin Act regulations in 9 CFR part 116 (referred to below as the regulations) contain requirements for maintaining detailed records of information necessary to give a complete accounting of all the activities within a veterinary biologics establishment. These records include records and reports for unfavorable or unintended events that occur in animals after the use of a biological product.

On September 4, 2015, we published in the **Federal Register** (80 FR 53475–53478, Docket No. APHIS–2014–0063) a proposal [1] to amend the regulations by establishing definitions for the terms *adverse event* and *adverse event report* and by providing requirements for adverse event records and reports. The changes we proposed are consistent with guidelines set out by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). VICH is a unique project conducted under the World Organization for Animal Health that brings together the regulatory authorities of the European Union, Japan, and the United States and representatives from the animal health industry in the three regions. Regulatory authorities and industry experts from Australia, Canada, and New Zealand participate as observers.

The purpose of VICH is to harmonize technical requirements for veterinary medicinal products (both pharmaceuticals and biologics). As a VICH member, the Animal and Plant Health Inspection Service (APHIS) provides expertise on veterinary biological products and participates in efforts to enhance harmonization. Both APHIS and the animal health industry are committed to seek scientifically based harmonized technical requirements for the development and use of veterinary biological products. VICH Guideline GL42: Pharmacovigilance: Data Elements for Submission of Adverse Events Reports specifically addresses the information that should be included when submitting adverse event reports.[2]

We solicited comments concerning our proposal for 60 days ending November 3, 2015. We received four comments by that date. They were from industry associations, a manufacturer of veterinary biologics, and a private citizen. The commenters were generally supportive of the proposed rule but asked some questions and raised some concerns about the provisions. These comments are discussed below by topic.

General Comments

One commenter stated that the current system for detecting safety issues with products has historically worked well. The commenter did not believe there have been significant safety issues that have not been detected in a timely fashion.

APHIS agrees with the commenter that the existing system has worked well. However, we believe that this rule will significantly improve the existing system by enhancing our ability to monitor the observed performance of veterinary biologics. For example, currently each veterinary biologics manufacturer makes an independent determination concerning whether an adverse event report raises questions regarding purity, safety, potency, efficacy, preparation, testing, or distribution, and when and in what manner such a report of the adverse event will be provided to APHIS. Thus, without explicit reporting requirements concerning adverse events, reports that may signal problems concerning the use of veterinary biological products may not all be submitted to APHIS or may not be submitted in a timely manner.

[1] To view the proposed rule, supporting document, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0063.*

[2] The VICH pharmacovigilance guidelines can be accessed at *http://www.vichsec.org/guidelines/pharmacovigilance.html.*

Another objective of this rule is to implement VICH guidelines pertaining to international standards specific for pharmacovigilance, which may enhance the ability of the biologics industry to export their products.

One commenter noted that the only VICH guideline specifically referenced in the proposed rule is VICH GL42. The commenter stated that where the final rule, guidance documents, or APHIS practice touches upon the subject matter in the VICH guidelines, APHIS should look to all the VICH guidelines to harmonize definitions and practices to the furthest extent possible. The commenter specifically mentioned VICH GL24, Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports as one which APHIS should consider when establishing future regulations or guidelines.

APHIS agrees that consistency with all relevant VICH guidelines is important. In the proposed rule, we referenced GL42 because we were proposing to add definitions to 9 CFR part 101 which are consistent with definitions found in this guideline. In future actions, however, we will reference all VICH guidelines regarding pharmacovigilance. We will also review all VICH guidelines associated with pharmacovigilance and consider them when developing future guidance documents, and will provide an opportunity for the industry to review and comment on any such documents.

One commenter stated that this rule should not be implemented until APHIS has the capability to receive submissions electronically. The commenter further stated that in establishing this capability APHIS should utilize the VICH Guidelines for the Electronic Standards for Transfer of Data, and Data Elements for Submission of Adverse Event Reports (VICH GL42, 30, and 35).

APHIS agrees on the importance of electronic submission and we will prioritize the development of an electronic submission portal. However we do not agree that this rule should not be implemented until we have the capacity to receive electronic submissions. As noted above by another commenter, the current system for detecting safety signals with products has historically worked well. APHIS has, and will continue to have, the capability to receive adverse event information by phone, fax, email, etc. It is important to implement this rule in order to clarify specific reporting requirements and to harmonize with international standards. Since we already receive adverse event reports, we do not believe it is necessary to wait for the development of an electronic submission portal.

One commenter stated that the same adverse event may be reported separately by two or more parties, such as the veterinarian and animal owner. The commenter stated that APHIS should ensure that it has the capability to detect any duplicate reports.

We agree with the commenter and will work to develop internal systems to detect duplicate reports.

One commenter recommended that APHIS engage the industry in substantial discussion relative to the method and process it will use for signal detection and trend analysis and signal assessment and management. The commenter stated that government and industry have the same goal of marketing pure, potent, safe, and effective products and industry is open to maintaining a partnership in signal detection, trend analysis, and risk management.

APHIS agrees with the commenter and will continue to engage with industry as future guidance is developed.

One commenter asked for clarification of APHIS expectations on the maintenance of pharmacovigilance data and practices when a facility is inspected.

Proposed § 116.9(a) provides that records must be maintained for 3 years after the date that the adverse event report is received.

One commenter asked for clarification on the aspects of the adverse event data that will be subject to the Freedom of Information Act (FOIA) and/or routinely made available on the APHIS website. The commenter stated that they expected that FOIA requests for this data will be received and that this data has tremendous potential for misuse. The commenter strongly suggested that if the data is made available on the APHIS website, information should also be provided about the limitations on interpreting the data.

In general, if APHIS receives a FOIA request for publicly available information, we do not need to supply the information to the requester. Instead, we provide guidance on where the information is available and how often it is updated. If the FOIA request is for specific data that is not available publicly, then we are mandated to supply the information in its entirety without redaction. If it is information owned by a biologics manufacturer, then APHIS will send the FOIA request and responsive records to the manufacturer for review and redaction, if the responsive records contain confidential business information or trade secrets.

Because the adverse event reports we receive are voluntary, APHIS has not yet made summary reports available to the public. We are aware that the number of adverse event reports received are a very small percentage of what is occurring in the field. After mandatory adverse event reporting is implemented, APHIS will make summary reports publicly available on the APHIS website. APHIS is working to determine the specifics on how often those reports are published and what explanatory information is included.

Though we have not finalized a process to manage this data publicly, we do agree with the commenter about the limitations on interpreting the data when made public. For example, comparing products by the prevalence of adverse event cases reported can be misleading if one does not consider the number of animals exposed for each respective product. Prior to implementing the process for public disclosure of the data, we will explore the method that best serves all veterinary biologics stakeholders. Included in this will be the review and consideration of how the Food and Drug Administration handles their pharmacovigilance data.

One commenter recommended that APHIS remove the adverse event reporting restrictions on the licenses for conditionally licensed products. The commenter also recommended that APHIS engage with State veterinarians and inform them that adverse events will be made public and that the industry should not be required by the State to provide additional reports.

APHIS intends to engage with State veterinarians and other public groups to advise them of the availability of adverse event reports on the APHIS website. However, we will not remove adverse reporting restrictions on licenses because there may be specific issues associated with a product that require clarification on the license.

One commenter noted that the definition of an *adverse event* for diagnostic products includes ''failure in product performance.'' The commenter stated that most customer reports of problems can either be traced to technical errors, or cannot be replicated with the product itself. The commenter further stated that unverified reports should not be the basis of adverse event reports to APHIS. The commenter stated that it is fairly straightforward to verify a problem with kit performance, and it seems appropriate that this be part of the determination that an adverse event has occurred.

The commenter is correct that for diagnostic kits a ''failure in product performance'' refers to a verified failure of the product itself, and would not include reports associated with equipment failure or technical errors. We will clarify this in guidance documents.

In the proposed rule, we estimated that each report would require 0.33 hours to generate and submit. One commenter stated that this estimate is too low. The commenter stated that any formal communication with a regulatory agency requires fact-checking and review, which add to the time required to generate the report. The commenter stated that they believe that a minimum of two full-time equivalent hours would be required for a simple report, with 4 to 6 hours being a likely average for all reports.

APHIS recognizes the variability in the time that it will take to gather, review, assess, and report adverse event cases to the agency. For example, the type of product (vaccine, diagnostic test kits, etc.) can have a significant influence in the respective time required to process a case. The reporting time would also vary depending on whether a licensee/permittee submits cases individually or batches multiple ones in a single submission. Therefore, considering the variability of processing adverse event reports for licensees/permittees, we would agree that a more accurate estimate of burden would be a range of 1 to 3 hours.

Definitions

One commenter stated that the proposed definition of *adverse event* should align with the definition in VICH GL24.

VICH GL24, which refers to all veterinary medicinal products (VMP), defines an adverse event as ''any observation in animals, whether or not considered to be product-related, that is unfavorable and unintended and that occurs after any use of VMP (off-label and on-label uses). Included are events related to a suspected lack of expected efficacy according to approved labeling or noxious reactions in humans after being exposed to VMP(s).''

We proposed to define an *adverse event* as any observation in animals, whether or not the cause of the event is known, that is unfavorable and unintended, and that occurs after any use (as indicated on the label or any off-label use) of a biological product, including events related to a suspected lack of expected efficacy. For products intended to diagnose disease, adverse events refer to a failure in product performance that hinders an expected discovery of the correct diagnosis. APHIS believes that the two definitions are generally consistent and that the APHIS definition is appropriate for the regulation of veterinary biological products as compared to the regulation of all other veterinary medicinal products.

One commenter stated that the definition of *adverse event report* in VICH GL24 requires a ''direct communication'' while the proposed APHIS definition referred to ''any communication.'' The commenter stated APHIS should use the words ''direct communication'' because this language would trigger reporting based upon reliable information; and specifically would not trigger reporting simply because the licensee became aware of, for example, an unsubstantiated blog post or anti-product activity on the internet.

APHIS agrees with the commenter. We have amended the definition of *adverse event report* to read ''direct communication'' instead of ''any communication''.

One commenter noted that an *adverse event report* is defined as a communication received by a firm regarding an adverse event and which includes several pieces of information, including an ''identifiable animal.'' The commenter stated that test kits for diseases of livestock and poultry are most often used in laboratories, not at the location of the animals. The commenter further stated that laboratories would only rarely have access to individual animal identification devices in the normal course of their work. The commenter stated that if the intent of the rule is that all information listed must be available before a report to APHIS is required, that could greatly limit the number of reports. The commenter asked for clarification of the intent of the rule in this regard.

APHIS agrees that this could be clearer. In cases where specific information regarding an animal identity is not readily available, we consider the species for which the product was used to be the minimum information for an ''identifiable animal.''

Frequency of Reporting

One commenter noted that the terms *serious adverse event* and *unexpected adverse event,* which appear in VICH GL24, were not defined in the proposed rule. The commenter stated that those terms should not be considered factors that determine frequency of reporting.

APHIS intends to define these terms in guidance documents that will be made available for review and comment by the industry and public before they are finalized. APHIS will work with the industry to develop guidance on these topics as the need arises.

One commenter asked for clarification that APHIS is seeking spontaneous reports of adverse events, and not the results that could occur in clinical trials or other studies that would already be reported to APHIS in a study report, or adverse events that may be reported in the literature.

The commenter is correct. Adverse event reports should address events that occur in field use of the product, not the results of clinical trials.

One commenter stated that, in § 116.9(b)(1), ''immediate'' should be interpreted to mean ''within 3 business days'' to be consistent with Veterinary Services Memorandum 800.57 ''Market Suspensions.'' The commenter stated that this would allow time for preliminary investigation. The commenter also stated that APHIS should replace the term ''immediate'' with ''3 business days'' in this section, as well as in § 116.5(b).

APHIS agrees that it is practical to interpret ''immediately'' as ''within 3 business days'' and will clarify this in guidance documents, which will be needed to establish a consistent application to the interpretation of a serious event. The requirement in § 116.9(b)(1) is consistent with the established requirement in § 116.5(b), so we are making no changes to either paragraph.

One commenter recommended that APHIS eliminate the 15 business day reporting requirement and any use of the concepts of ''product-related'', ''serious'', and ''expected'' for case management timelines. The commenter stated that even if these are eliminated, APHIS would still receive those adverse event reports that impact the purity, potency, safety, or efficacy of the product on a 3 business day basis, and its ability to react very quickly to the most urgent situations would not be compromised. The commenter suggested that all other reports be submitted on the 90 calendar day requirement, which would provide sufficient time for a thorough investigation. A second commenter stated that a 90 day reporting period is too brief a period of time to submit reports; many of which will have nothing to report. The commenter suggested changes in the length of the reporting period over time

APHIS agrees with the first commenter that serious and unexpected adverse events will be reported immediately within 3 business days and

as such the requirement of 15 business days is not necessary. We have amended § 116.9(b)(2) to remove the 15 day reporting requirement. Adverse event reports will continue to be received immediately or within 90 calendar days. We have also amended § 116.9(b) to require that adverse event reports determined to be product-related, serious, and unexpected will be reported immediately and that other reports will be received within 90 days. We will also clarify that ''immediately'' means ''within 3 business days'' in guidance documents. We do not agree with the second commenter regarding the need for the 90 day reporting period, with changes in the length of the reporting period changing over time. Since we have removed the 15 day reporting period, the 90 day period will need to remain as a standard time. However, as pharmacovigilance data is accumulated APHIS will consider exemptions and will clarify in future guidance documents.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Orders 12866 and 13771 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is summarized below, regarding the economic effects of this rule on small entities. Copies of the full analysis are available on the *Regulations.gov* website (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

We are amending the Virus-Serum-Toxin Act regulations concerning records and reports. This change would require veterinary biologics licensees and permittees to record and submit reports concerning adverse events associated with the use of biological products they produce or distribute. The type of information that must be included in the adverse event reports submitted to APHIS would be provided in separate guidance documents.

We are taking this action in order to limit the harm to animals due to adverse events related to a product's purity, safety, potency, efficacy, preparation, testing, or distribution. Current regulations may hinder APHIS from taking expeditious action in cases where veterinary biologics are unsatisfactory.

For animal owners, the monetary benefits of the proposal are difficult to estimate because they would depend on unknowable factors—the significance or gravity of the harm that would be avoided with the rule in effect, and the number and value of animals thereby protected. Manufacturer costs to comply with the proposed rule are expected be minimal; most establishments that would be affected already maintain recordkeeping systems for adverse event reports that capture most if not all of the information that would be required. Most of the establishments that would be affected by the proposed rule are small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies where they are necessary to address local disease conditions or eradication programs. However, where safety, efficacy, purity, and potency of biological products are concerned, it is the Agency's intent to occupy the field. This includes, but is not limited to, the regulation of labeling. Under the Act, Congress clearly intended that there be national uniformity in the regulation of these products. There are no administrative proceedings which must be exhausted prior to a judicial challenge to the regulations under this rule.

Executive Order 13175

This rule does not significantly or uniquely affect the communities of Indian Tribal governments. The rule does not impose any mandate on Tribal governments or impose any duties on these entities. Thus, no further action is required under Executive Order 13175.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this final rule, which were filed under 0579–0209, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the **Federal Register** providing notice of what action we plan to take.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

Lists of Subjects

9 CFR Part 101

Animal biologics.

9 CFR Part 116

Animal biologics, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR parts 101 and 116 as follows:

PART 101—DEFINITIONS

■ 1. The authority citation for part 101 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 101.2 is amended by adding definitions for *Adverse event* and *Adverse event report* in alphabetical order to read as follows:

§ 101.2 Administrative terminology.

* * * * *

Adverse event. Any observation in animals, whether or not the cause of the event is known, that is unfavorable and unintended, and that occurs after any use (as indicated on the label or any off-label use) of a biological product, including events related to a suspected lack of expected efficacy. For products intended to diagnose disease, adverse events refer to a failure in product performance that hinders an expected discovery of the correct diagnosis.

Adverse event report. Direct communication concerning the occurrence of an adverse event from an identifiable first-hand reporter which includes the following information:

(1) An identifiable reporter;

(2) An identifiable animal;

(3) An identifiable biologic product; and

(4) One or more adverse events.

* * * * *

PART 116—RECORDS AND REPORTS

■ 3. The authority citation for part 116 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

■ 4. In § 116.1, paragraph (a)(3) is revised to read as follows:

§ 116.1 Applicability and general considerations.

(a) * * *

(3) Records (other than disposition records and adverse event records) required by this part must be completed by the licensee, permittee, or foreign manufacturer, as the case may be, before any portion of a serial of any product may be marketed in the United States or exported.

* * * * *

■ 5. Section 116.8 is revised to read as follows:

§ 116.8 Completion and retention of records.

All records (other than disposition records and adverse event records) required by this part must be completed by the licensee, permittee, or foreign manufacturer before any portion of a serial of any product may be marketed in the United States or exported. All records must be retained at the licensed or foreign establishment or permittee's place of business for a period of 2 years after the expiration date of a product or longer as may be required by the Administrator.

(Approved by the Office of Management and Budget under control number 0579–0013)

■ 6. Section 116.9 is added to read as follows:

§ 116.9 Recording and reporting adverse events.

(a) Licensees and permittees must maintain a detailed record for every adverse event report the licensee or permittee receives for any biological product it produces or distributes. These records shall be maintained for a period of 3 years after the date the adverse event report is received. The adverse event report form and guidance on how to complete it, including guidance specific to the various information blocks on the form, is available on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics* or by writing to APHIS Center for Veterinary Biologics, 1920 Dayton Avenue, P.O. Box 844, Ames, Iowa 50010.

(b) A report of all adverse events reports received by a licensee or permittee must be compiled and submitted to the Animal and Plant Health Inspection Service. The frequency of report submission is as follows:

(1) Immediate notification is required if at any time there are indications that raise questions regarding the purity, safety, potency, or efficacy of a product, or if it appears that there may be a problem regarding the preparation, testing, or distribution of a product.

(2) Adverse event reports determined by the licensee or permittee to be product-related, serious, and unexpected must also be reported immediately.

(3) All other adverse event reports must be reported within 90 calendar days of the date the report was first received.

(Approved by the Office of Management and Budget under control number 0579–0209)

Done in Washington, DC, this 11th day of May 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2018–10540 Filed 5–16–18; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0443; Product Identifier 2018–NE–14–AD; Amendment 39–19286; AD 2018–10–11]

RIN 2120–AA64

Airworthiness Directives; CFM International S.A. Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are superseding Airworthiness Directive (AD) 2018–09–10 for all CFM International S.A. (CFM) Model CFM56–7B engines. AD 2018–09–10 required initial and repetitive inspections of the concave and convex sides of the fan blade dovetail to detect cracking and replacement of any blades found cracked. This AD requires the same initial and repetitive inspections but revises the compliance time for the initial inspections of certain higher-risk fan blades. This AD was prompted by a recent engine failure due to a fractured fan blade that resulted in the engine inlet cowl disintegrating and debris penetrating the fuselage, causing a loss of pressurization, and prompting an emergency descent. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 1, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 1, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of May 14, 2018 (83 FR 19176, May 2, 2018).

We must receive any comments on this AD by July 2, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, contact CFM International Inc., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45125; phone: 877–432–3272; fax: 877–432–3329; email: *aviation.fleetsupport@ge.com.* You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7759. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0443.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0443; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–