(d) Subject

Air Transport Association (ATA) of America Code 27, Flight control systems.

(e) Unsafe Condition

This AD was prompted by a report indicating that some inboard and outboard trailing edge flap rotary actuators may have been assembled with an incorrect no-back brake rotor-stator stack sequence during manufacturing. We are issuing this AD to detect and replace incorrectly assembled rotary actuators, which could cause accelerated unit wear that will eventually reduce braking performance. This degradation could lead to loss of no-back brake function and reduced controllability of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Retained Inspection and Other Actions

For The Boeing Company Model 787–8 and 787–9 airplanes identified in Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 001, dated November 3, 2015: Within 60 months after February 21, 2017 (the effective date of AD 2017–01–02), do an inspection of the inboard and outboard trailing edge flap rotary actuator for any discrepant rotary actuator, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 001, dated November 3, 2015; or Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 003, dated July 28, 2017. If any discrepant rotary actuator is found, within 60 months after February 21, 2017, do the actions specified in paragraph (g)(1) or (g)(2) of this AD, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 001, dated November 3, 2015; or Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 003, dated July 28, 2017. After the effective date of this AD only Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 003, dated July 28, 2017, may be used.

(1) Replace the discrepant rotary actuator.

(2) Check the maintenance records to determine the flight cycles of each discrepant rotary actuator and, within 60 months after February 21, 2017 (the effective date of AD 2017–01–02), do all applicable related investigative and corrective actions.

(h) New Requirements: Inspection, Related Investigative and Corrective Actions

For airplanes not identified in Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 001, dated November 3, 2015, which have an Original Certificate of Airworthiness or Export Certificate of Airworthiness with a date on or before the effective date of this AD: Within 60 months after the effective date of this AD, do an inspection of the inboard and outboard trailing edge flap rotary actuator for any discrepant rotary actuator, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 003, dated July 28, 2017. If any discrepant rotary actuator is found, within 60 months after the effective date of this AD, do the actions specified in paragraph (h)(1) or (h)(2) of this AD, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 003, dated July 28, 2017.

(1) Replace the discrepant rotary actuator.

(2) Check the maintenance records to determine the flight cycles of each discrepant rotary actuator and, within 60 months after the effective date of this AD, do all applicable related investigative and corrective actions.

(i) Parts Installation Limitation

As of the effective date of this AD, no person may install, on any airplane, a rotary actuator with a part number and serial number identified in Appendix A of Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 003, dated July 28, 2017, unless the actuator has been permanently marked in accordance with Task 2 of Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 003, dated July 28, 2017, with ''B787–81205–SB270032–00 INCORPORATED.''

(j) Credit for Previous Actions

(1) This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 002, dated November 3, 2016.

(2) This paragraph provides credit for the actions specified in paragraph (h) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 001, dated November 3, 2015, or Boeing Alert Service Bulletin B787–81205–SB270032–00, Issue 002, dated November 3, 2016.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (l)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs approved previously for AD 2017–01–02 are approved as AMOCs for the corresponding provisions of this AD.

(5) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (k)(5)(i) and (k)(5)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(l) Related Information

(1) For more information about this AD, contact Douglas Tsuji, Senior Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 1601 Lind Avenue SW, Renton, WA 98057–3356; phone: 425–917–6546; fax: 425–917–6590; email: *douglas.tsuji@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on January 30, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–03026 Filed 2–13–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA–2017–N–6381]

RIN 0910–AH51

Postmarketing Safety Reports for Approved New Animal Drugs; Electronic Submission Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing to amend its postmarketing safety reporting regulations for approved new animal drugs to require that certain adverse drug experience and product/manufacturing defect reports be submitted to FDA in an electronic format that we can process, review, and archive. This action is intended to improve our systems for collecting and analyzing postmarketing safety reports. The proposed change would help us to more rapidly review postmarketing safety reports, identify emerging safety problems, and disseminate safety information in support of our public health mission. In addition, the proposed amendments would facilitate international harmonization and exchange of safety information.

DATES: Submit either electronic or written comments on the proposed rule by April 30, 2018. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by March 16, 2018.

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 April 30, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 30, 2018. 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–6381 for ''Postmarketing Safety Reports for Approved New Animal Drugs; Electronic Submission 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 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.'' 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.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, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (PRA) to the Office of Management and Budget (OMB) in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with the title, ''Records and Reports Concerning Experience with Approved New Animal Drugs.''

FOR FURTHER INFORMATION CONTACT: *With regard to the proposed rule:* Linda Walter-Grimm, Center for Veterinary Medicine (HFV–240), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5762, *Linda.Walter-Grimm@fda.hhs.gov.*

With regard to the information collection: 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:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

FDA is issuing this proposed rule to amend our regulations under § 514.80 (21 CFR 514.80) to require electronic submission of certain postmarketing

safety reports for approved new animal drugs and to provide a procedure for requesting a temporary waiver of the requirement. This action is intended to improve our systems for collecting and analyzing postmarketing safety reports. The proposed change would help us to more rapidly review postmarketing safety reports, identify emerging safety problems, and disseminate safety information in support of our public health mission. In addition, the proposed amendments would facilitate international harmonization and exchange of safety information.

B. Summary of the Major Provisions of the Proposed Rule

We require applicants to submit to us postmarketing safety reports of adverse drug experiences and product/manufacturing defects for approved new animal drugs (see § 514.80). An applicant is defined as ''a person or entity who owns or holds on behalf of the owner the approval for an NADA [new animal drug application] or an ANADA [abbreviated new animal drug application], and is responsible for compliance with applicable provisions of the act and regulations.'' (§ 514.3 (21 CFR 514.3)) In addition, nonapplicants, defined in § 514.3 as ''any person other than the applicant whose name appears on the label and who is engaged in manufacturing, packing, distribution, or labeling of the product,'' may elect to submit adverse drug experience reports directly to us (§ 514.80(b)(3)).

We propose to require electronic submission for the following reports for approved new animal drugs: 3-day alert reports that applicants elect to submit directly to FDA's Center for Veterinary Medicine (CVM) in addition to the requirement they have to submit these reports on paper Form FDA 1932 to the appropriate FDA District Office or local FDA resident post; 15-day alert reports and followup reports; product/manufacturing defect and adverse drug experience reports submitted by nonapplicants who elect to report adverse drug experiences directly to CVM in addition to providing these reports to the applicant; product/manufacturing defect and adverse drug experience reports (including reports of previously not reported adverse drug experiences that occur in postapproval studies) required to be submitted as part of the periodic drug experience report. We propose to replace the current paper submission process with the electronic submission requirement and a procedure for requesting a temporary waiver of the electronic submission requirement. Finally, we propose to clarify where to submit reports not required to be submitted electronically. Under the proposed rule, we would continue to require 3-day alert reports to be submitted to the appropriate FDA District Office or local FDA resident post. However, as noted, if in addition to the report an applicant submits on paper Form FDA 1932 to the appropriate FDA District Office or local FDA resident post, an applicant elects to submit a 3-day field alert report directly to CVM, the applicant would be required to submit the report to CVM electronically.

C. Legal Authority

Our legal authority to require electronic submission of postmarketing safety reports for approved new animal drugs derives from sections 201, 301, 501, 502, 512, and 701 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321, 331, 351, 352, 360b, and 371).

D. Costs and Benefits

The purpose of this proposed rule is to require electronic submission of certain postmarketing safety reports for approved new animal drugs. The rule, if finalized, would also provide a procedure for requesting a temporary waiver of the electronic reporting requirement for ''good cause'' shown, such as a natural disaster. As currently proposed, this rule would not change the content of the postmarketing safety reports or the frequency of the reporting requirements. Currently, most submitters have chosen, voluntarily, to use electronic submission for the reports that would be affected by this proposed rule. As of 2016, approximately 99.7 percent of postmarketing safety reports eligible for electronic submission were electronically submitted. Thus, this proposed rule would affect a small proportion of these reports.

The major benefits of this proposed rule, if finalized, would be to animal health and the Agency in the form of quicker access to postmarketing safety information. The annual cost savings to the Agency is estimated at $7,535. The present value of these benefits over 10 years is $64,272 at a 3 percent discount rate, and $52,920 at a 7 percent discount rate.

Total one-time costs to industry would be $61,311 for changing standard operating procedures (SOPs) and training employees to electronically submit postmarketing safety reports in accordance with the new SOPs. Recurring costs to the Agency would be $153 per year, for processing the waivers to the electronic reporting requirement. Annualizing these costs over a 10-year period, we estimate total annualized costs to be $7,131 at a 3 percent discount rate, and $8,310 at a 7 percent discount rate. The present value of these costs over 10 years is $60,823 at a 3 percent discount rate, and $58,368 at a 7 percent discount rate.

II. Background

When a new animal drug is approved and enters the market, the product is introduced to a larger population in settings different from the controlled studies required by the approval process. New information generated during the postmarketing period offers further insight into the benefits and/or risks of the product, and evaluation of this information is important to ensure the safe and effective use of these products.

A. Need for the Regulation

CVM receives information regarding adverse drug experiences for approved new animal drugs from postmarketing safety reports. For over 25 years, we have received these safety reports on paper. However, the majority of submitters have chosen, voluntarily, to utilize electronic submission as electronic means became available. As of 2016, approximately 99.7 percent of postmarketing safety reports eligible for electronic submission were electronically submitted. The proposed rule would require electronic submission of the remaining 0.3 percent of postmarketing safety reports eligible for electronic submission.

Electronic submission improves our ability to process and archive postmarketing safety reports in a timely manner, and to make postmarketing reports more readily available for analysis. Information from electronic and paper reports is entered into our computerized database, which is designed to support our postmarketing safety surveillance program for animal drug products. Scientists at CVM use the database to make decisions about product safety, which may include regulatory action. Electronically submitted reports are available for analysis as soon as they have been processed, generally within 2 days of receipt. Safety reports submitted to us on paper must be physically received, reviewed, and then manually entered into our computerized database, a process that can take several weeks. Paper reports increase the time it takes us to review safety information, impede our ability to analyze the data comprehensively, and hinder our ability to quickly identify problems. Voluntary electronic submission of safety reports has been an important step in improving

our postmarketing surveillance capabilities.

The proposed rule, which would require electronic submission of certain postmarketing safety reports, would further improve our systems for collecting and analyzing these reports and would save FDA an expected $7,459 annually, primarily in the cost of processing paper submissions. The proposal would:

- Expedite our access to safety information and provide us data in a format that would support more efficient and comprehensive reviews;
- Enhance our ability to rapidly communicate information about suspected problems to animal owners, veterinarians, consumers, and industry within the United States and internationally in support of our public health mission; and
- Eliminate or reduce the time and costs to industry associated with submitting paper reports, and the time, costs, errors, and physical storage needs of the Agency associated with manually entering data from paper reports into the electronic system for review and analysis.

The proposed rule would allow us to be more responsive to rapidly occurring changes in the technological environment. Consistent with our current practice for voluntarily provided electronic submissions, the proposed rule would require that data in electronic submissions conform to the data elements in Form FDA 1932 and our technical documents on how to provide electronic submissions (*e.g.,* method of transmission and processing, media, file formats, preparation and organization of files). The proposed rule would allow us to issue updated technical documents, as necessary. The most current information on submitting postmarketing safety reports to us in electronic format can be found on our web page at *http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm212682.htm* (see, *e.g.,* ''Instructions for Electronic Submission of Mandatory Adverse Event Reports to FDA CVM''). As necessary, we will revise the technical specifications referenced in our technical documents to address changing technical specifications or any additional specifications needed for electronic submission. Using guidance documents and technical documents to communicate these technical specifications will permit us to be more responsive to rapidly occurring changes in the technological environment.

The proposed rule is also an important step in our continuing efforts to harmonize our postmarketing safety reporting regulations with international standards for submitting safety information. Currently, the technical specifications referenced in our guidance documents supporting the voluntary electronic submission processes rely upon and adopt certain safety reporting and transmission standards recommended by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). VICH was formed to facilitate the harmonization of technical requirements for the marketing authorization or ''registration'' of veterinary medicinal products among three regions: The European Union, Japan, and the United States. Our electronic submission specifications allow applicants or nonapplicants to submit postmarketing safety reports using the Health Level 7 (HL7) Individual Case Safety Report (ICSR) standard that has been adopted worldwide by VICH. In this proposed rule, we reaffirm our intention to continue to rely on these VICH-recommended standards. We believe the continued use of VICH standards will promote harmonization of safety reporting among regulatory agencies and facilitate the international exchange of postmarketing safety information. Accordingly, this proposed rule is consistent with our ongoing initiatives to encourage the widest possible use of electronic submission and to promote international harmonization of safety reporting for animal drug products through reliance on VICH standards. We anticipate that the proposed rule would enhance industry's global pharmacovigilance practices by allowing it to use common data elements and transmission standards when submitting ICSRs to multiple regulators.

B. Current Regulatory Framework

The current postmarketing safety reports required under § 514.80 for approved NADAs and approved ANADAs are summarized below. The proposed electronic submission requirement would leave the substantive aspects of these reports largely unchanged.

1. Description and Timing of Safety Reports

Under section 512(*l*) of the FD&C Act, we may require holders of approved NADAs to submit reports regarding postapproval experiences with their animal drugs. Our implementing regulation at § 514.80 requires applicants to submit to us postmarketing safety reports of adverse drug experiences and product/manufacturing defects. As stated previously, an applicant is defined as ''a person or entity who owns or holds on behalf of the owner the approval for an NADA or an ANADA, and is responsible for compliance with applicable provisions of the act and regulations.'' (See § 514.3.) In addition, nonapplicants, defined in § 514.3 as ''any person other than the applicant whose name appears on the label and who is engaged in manufacturing, packing, distribution, or labeling of the product,'' may elect to submit adverse drug experience reports directly to us (§ 514.80(b)(3)).

Specifically, § 514.80(b) requires the following adverse drug experience reports, among other reports:

- Three-day field alert reports (§ 514.80(b)(1)). Applicants must submit a report to the appropriate FDA District Office or local resident post with information pertaining to product and manufacturing defects that may result in serious adverse drug events within 3 working days of first becoming aware that a defect may exist.
- Fifteen-day alert reports (§ 514.80(b)(2)(i)) and followup reports (§ 514.80(b)(2)(ii)). Applicants must submit a report to us for each postmarketing adverse drug event that is both serious and unexpected within 15 working days of first receiving the information about the adverse drug event. A followup report must be submitted within 15 working days of receipt of significant new information or as requested by us.
- Nonapplicant reports (§ 514.80(b)(3)). Nonapplicants are required to forward reports of adverse drug experiences *to the applicant* within 3 working days of first receiving the information. A nonapplicant may choose to also submit an additional report *directly to us* within 15 working days of first receiving the information, but must still provide the report to the applicant. (As noted above, a ''nonapplicant'' is any person other than the applicant whose name appears on the label of the approved new animal drug product and who is engaged in the manufacturing, packing, distribution, or labeling of that drug product. 21 CFR 514.3.)
- Reports of product/manufacturing defects and adverse drug experiences submitted as part of the periodic drug experience report (§ 514.80(b)(4)(iv)(A) and (C)). Applicants are required to submit a periodic report every 6 months for the first 2 years following approval (6-month periodic drug experience reports) and yearly thereafter (yearly

periodic drug experience report). The periodic drug experience report must contain, among other things, reports for each product/manufacturing defect and adverse drug experience not previously reported as 3-day field alert reports under § 514.80(b)(1) or 15-day alert or followup reports under § 514.80 (b)(2) (*i.e.,* the periodic drug experience report must contain reports of all expected or nonserious adverse drug events and product/manufacturing defects that did not result in an adverse drug event report). This also includes previously not reported adverse drug experiences that occur in postapproval studies.

2. Current Methods for the Submission of Postmarketing Safety Reports

As noted, for over 25 years we have received postmarketing safety reports on paper. Currently, § 514.80 requires that applicants and nonapplicants submit to us reports of adverse drug experiences and product/manufacturing defects on paper Form FDA 1932. It further requires that 3-day field alert reports must be submitted to the appropriate FDA District Field Office or local FDA resident post while 15-day alert reports and followup reports, periodic drug experience reports, and nonapplicant reports must be submitted to CVM (§ 514.80(b)(1) to (3), (b)(4)(iv)(A) and (C), and (g)).

As noted earlier in this preamble, since May 2010 we have provided industry with the option of submitting certain postmarketing safety reports electronically. Since that time, the majority of submitters have chosen, voluntarily, to utilize electronic submission. As of 2016, approximately 99.7 percent of postmarketing safety reports eligible for electronic submission were electronically submitted.

Reports that may be submitted electronically include 15-day alert reports and followup reports (§ 514.80(b)(2)(i) and (ii)); nonapplicant reports of adverse drug experiences submitted directly to FDA (§ 514.80(b)(3)); and reports of product/manufacturing defects and adverse drug experiences submitted as part of the periodic drug experience report (§ 514.80(b)(4)(iv)(A) and (C)). At this time, 3-day field alert reports (§ 514.80(b)(1)) must be submitted on paper Form FDA 1932 to the appropriate FDA District Office or local resident post. CVM collaborates with the FDA District Office or local resident post to follow up as appropriate in response to 3-day field alert reports. If an applicant elects to submit a 3-day field alert report directly to CVM, the applicant would be required to submit the report electronically. However, this would not alleviate the applicant's responsibility to submit this report to the FDA District Field Office or local FDA resident post on paper Form FDA 1932.

Electronic reports may be submitted through FDA's Electronic Submission Gateway or through the FDA-National Institutes of Health Safety Reporting Portal (Safety Reporting Portal). The Electronic Submission Gateway allows applicants or nonapplicants to submit postmarketing safety reports using the HL7 ICSR standard, which, as discussed earlier in this preamble, has been adopted worldwide by VICH. The Electronic Submission Gateway provides industry with gateway-to-gateway access to transmit an HL7 ICSR message using the FDA electronic submission standard. The Safety Reporting Portal provides applicants or nonapplicants a means to submit individual postmarketing safety reports without having to make financial investments in the technical infrastructure needed to access the Electronic Submission Gateway. Any person who has internet access can use the Safety Reporting Portal to submit reports through a user-friendly, interactive questionnaire available at *https://www.safetyreporting.hhs.gov/*.

For applicants or nonapplicants that submit large numbers of reports, sending an HL7 ICSR electronic file is more cost effective because the information from the reports is transmitted directly from the submitter's database to FDA, eliminating the need for additional resources for collating, copying, storing, retrieving, and mailing paper copies. For applicants or nonapplicants that submit a small number of reports, the use of the web-based Safety Reporting Portal may be more cost effective than implementing a system to send an HL7 ICSR message through the FDA Electronic Submission Gateway.

III. Legal Authority

Section 512(*l*) of the FD&C Act requires that, following approval of a NADA or ANADA, applicants must establish and maintain records and make reports to the Agency of data related to experience, as prescribed by regulation or order. FDA has general rulemaking authority under section 701(a) of the FD&C Act, which permits the Secretary of Health and Human Services to promulgate regulations for the efficient enforcement of the FD&C Act. In order to implement section 512(*l*) of the FD&C Act, FDA promulgated regulations for records and updates concerning experience with new animal drugs (see § 514.80). The proposed amendments to this regulation will further efficient enforcement of section 512(*l*) by permitting records and reports to be reported electronically.

IV. Description of the Proposed Rule

We are proposing to amend our regulations in part 514 (21 CFR part 514). The proposed rule would require electronic submission of certain postmarketing safety reports for approved new animal drugs and provide a procedure for requesting a temporary waiver of the requirement. This action is intended to improve our systems for collecting and analyzing postmarketing safety reports.

A. Scope

The proposed rule would amend § 514.80 to require electronic submission of the following postmarketing safety reports for approved new animal drugs:

- Three-day alert reports that applicants elect to submit directly to CVM in addition to the requirement they have to submit these reports on paper Form FDA 1932 to the appropriate FDA District Office or local FDA resident post (§ 514.80(b)(1);
- Fifteen-day alert reports (§ 514.80(b)(2)(i)) and followup reports (§ 514.80(b)(2)(ii));
- Product/manufacturing defects and adverse drug experience reports submitted by nonapplicants who elect to report adverse drug experiences directly to FDA under § 514.80(b)(3) in addition to providing these reports to the applicant; and
- Product/manufacturing defects and adverse drug experience reports (including reports of previously not reported adverse drug experiences that occur in postapproval studies) required to be submitted as part of the periodic drug experience report (§ 514.80(b)(4)(iv)(A) and (C)).

At this time, we are not proposing to require electronic submission of 3-day field alert reports (§ 514.80(b)(1)) to the appropriate FDA District Office or local resident post because, as noted previously, we currently do not have the information technology systems in place to share with FDA District Offices or local resident posts reports submitted electronically through the Electronic Submission Gateway or Safety Reporting Portal. Under this proposed rule, these reports would continue to be submitted on paper Form FDA 1932 directly to the appropriate FDA District Office or local resident post. CVM will continue to collaborate with the FDA District Office or local resident post to follow up as appropriate in response to

3-day field alert reports submitted directly to the FDA District Office or local resident post. However, as noted, if an applicant elects to submit a 3-day field alert report directly to CVM, the applicant would be required to submit the report electronically. This would not alleviate the applicant's responsibility to submit this report to the FDA District Field Office or local FDA resident post on paper Form FDA 1932.

B. Proposed Provisions

1. Electronic Submission Requirement

We are proposing that applicants would continue to have the obligation to submit 3-day field alert reports directly to the appropriate FDA District Office or local resident post within 3 working days of first becoming aware that a defect may exist. However, if applicants choose to also report directly to CVM in addition to reporting to the appropriate FDA District Office or local resident post, they would be required to submit the report to CVM electronically, unless we grant a waiver permitting an alternate submission method or we otherwise request an alternate submission method. (See proposed § 514.80(b)(1).)

We are proposing that 15-day alert reports and followup reports would be required to be submitted to us electronically, unless we grant a waiver permitting an alternate submission method (see section IV.B.2 of this document) or we otherwise request an alternate submission method (see section IV.B.3 of this document). (See proposed § 514.80(b)(2)(i) and (ii).)

We are proposing that nonapplicants would continue to have the obligation of forwarding reports of adverse drug experiences to the applicant within 3 working days of first receiving the information. Nonapplicants would also continue to have the option of choosing to report directly to us in addition to reporting to the applicant. However, if nonapplicants opt to report directly to us, they would be required to submit the report electronically, unless we grant a waiver permitting an alternate submission method or we otherwise request an alternate submission method. (See proposed § 514.80(b)(3).)

We are proposing that reports of product/manufacturing defects and adverse drug experiences required to be submitted as part of the periodic drug experience report would be required to be submitted to us electronically, unless we grant a waiver permitting an alternate submission method or we otherwise request an alternate submission method. (See proposed § 514.80(b)(4)(iv)(A) and (C).) This includes reports of defects and experiences not previously reported under § 514.80(b)(1) and (2) and previously not reported adverse drug experiences that occur in postapproval studies. These reports could be submitted individually at any time within the timeframe for submitting the periodic drug experience report under current § 514.80(b)(4).

We are proposing that reports submitted to us under § 514.80(b)(1), (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) and (C) be submitted in an electronic format that FDA can process, review, and archive, and that data submitted in electronic submissions conform to the data elements in Form FDA 1932 and our technical documents on how to provide electronic submissions (*e.g.,* method of transmission and processing, media, file formats, preparation and organization of files). The proposed rule would allow us to issue updated technical documents, as necessary. (See proposed § 514.80(d)(1).)

2. Waivers

We are proposing to allow applicants or nonapplicants to request a temporary waiver from the electronic submission requirement for ''good cause'' shown. Examples of circumstances that could constitute ''good cause'' for granting waivers of the electronic submission requirement include crisis situations that impact an applicant's or nonapplicant's ability to report electronically, such as natural disasters, pandemics, and terrorism. The proposed rule would require applicants and nonapplicants to submit a waiver request to us in writing. The initial request, however, could be made by telephone or email to CVM's Division of Veterinary Product Safety, with prompt written followup submitted as a letter to the application. If we grant the request for a temporary waiver, the applicant or nonapplicant would be required to follow the conditions for reporting that we specify upon granting the waiver. (See proposed § 514.80(d)(2).)

We anticipate that temporary waivers of the electronic submission requirement will only be needed in rare circumstances such as natural disasters, pandemics, and terrorism, as noted. An applicant or nonapplicant experiencing technical difficulties that temporarily prevent use of the Electronic Submission Gateway could, as a backup, electronically submit reports using the Safety Reporting Portal. An applicant or nonapplicant that relies on the Safety Reporting Portal but experiences a short-term, temporary interruption of internet services could, as a backup, electronically submit reports from any other computer with access to a working internet connection.

3. FDA Request for Alternate Submission Method

We may require an applicant or nonapplicant to submit reports that would otherwise be required to be submitted electronically to be submitted in an alternate format, such as on paper using Form FDA 1932. We anticipate that we would request the submission of reports through an alternate method only in the event that we experience a prolonged system outage or other major technical problem. During such an event, we would provide advice on the desired method for submission (most likely on paper using Form FDA 1932) and the types of reports that should be submitted using the alternate method. Applicants and nonapplicants should be prepared to comply with such a request by maintaining the capability to submit paper reports using Form FDA 1932 if needed. (See proposed § 514.80(b)(1) to (3), and (b)(4)(iv)(A) and (C).)

4. Mailing Addresses

Finally, we propose to clarify where to submit reports not required to be submitted electronically. Under the proposed rule, we would continue to require 3-day alert reports to be submitted to the appropriate FDA District Office or local FDA resident post. (See proposed § 514.80(g).)

V. Proposed Effective and Compliance Dates

We propose that any final rule based on this proposal become effective 30 days after the date on which it is published in the **Federal Register**. Although we are proposing that the final rule become effective 30 days after the date of publication in the **Federal Register**, we are proposing to provide additional time before applicants and nonapplicants would be required to comply with the electronic submission requirement. We propose that the compliance date would be 12 months after the publication date of the final regulation. The Safety Reporting Portal currently is capable of receiving all of the affected reports and is available to any applicant or nonapplicant with access to the internet. We tentatively conclude that applicants and nonapplicants not currently submitting the affected reports electronically would, in 12 months, be able to make changes to their business practices that would be needed to come into compliance with the proposed requirements.

VI. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the costs of the rule are minimal in both absolute value and in comparison to average yearly sales of small firms in this industry, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

The purpose of this proposed rule is to require electronic submission of certain postmarketing safety reports for approved new animal drugs. The rule, if finalized, would also provide a procedure for requesting a temporary waiver of the electronic reporting requirement for ''good cause'' shown, such as a natural disaster. As currently proposed, this rule would not change the content of the postmarketing safety reports or the frequency of the reporting requirements.

The major benefits of this proposed rule, if finalized, would be to animal health and the Agency in the form of quicker access to postmarketing safety information; the annual cost savings to the Agency is estimated at $7,535. The present value of these benefits over 10 years is $64,272 at a 3 percent discount rate, and $52,920 at a 7 percent discount rate.

Total one-time costs to industry would be $61,311 for changing SOPs and training employees to electronically submit postmarketing safety reports in accordance with the new SOPs. Recurring costs to the Agency would be $153 per year, for processing the waivers to the electronic reporting requirement. Annualizing these costs over a 10-year period, we estimate total annualized costs to be $7,131 at a 3 percent discount rate, and $8,310 at a 7 percent discount rate. The present value of these costs over 10 years is $60,823 at a 3 percent discount rate, and $58,368 at a 7 percent discount rate.

SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized	$7,535			2016	7	10	
Monetized $/year	7,535			2016	3	10	
Annualized					7		
Quantified					3		
Qualitative							
Costs:							
Annualized	7,131			2016	7	10	
Monetized $/year	8,310			2016	3	10	
Annualized					7		
Quantified					3		
Qualitative							
Transfers:							
Federal					7		
Annualized Monetized $millions/year					3		
From/To	From:			To:			
Other Annualized					7		
Monetized $millions/year					3		
From/To	From:			To:			

Effects:
State, Local or Tribal Government:
Small Business: Will not have a significant impact on a substantial number of small entities.
Wages:
Growth:

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in the docket (FDA–2017–N–6381) for this proposed rule and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). A description of these provisions is given in the *Description* section of this document with an estimate of the one-time and recurring reporting burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each 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.

Title: Records and Reports Concerning Experience with Approved New Animal Drugs—OMB Control Number 0910–0284—Revision

Description: This proposed rule would revise the existing information collection requirements in the postmarketing safety reporting regulations for approved new animal drugs to require electronic submission of certain postmarketing safety reports for approved new animal drugs. This rule does not change the content of these postmarketing reports. It only proposes to require that they be submitted in an electronic form. We are also proposing to provide a procedure for requesting a temporary waiver of the requirement.

Description of Respondents: Respondents to the information collection provisions of this proposed rule are applicants and nonapplicants.

Reporting: Currently, the postmarketing safety reporting regulations for approved new animal drugs include requirements to submit to us postmarketing safety reports of adverse drug experiences and product/manufacturing defects. Section 514.80 requires applicants and nonapplicants to keep records of and report to us data, studies, and other information concerning experience with new animal drugs for each approved NADA and ANADA. Following complaints from animal owners or veterinarians, or following their own detection of a problem, applicants or nonapplicants are required to submit adverse event reports and product/manufacturing defect reports under § 514.80(b)(1) to (3) and (b)(4)(iv)(A) and (C) on Form FDA 1932. Form FDA 1932 may be submitted on paper or electronically via the Electronic Submission Gateway or Safety Reporting Portal. Form FDA 1932a (the voluntary reporting form) is used by veterinarians and the public to submit adverse event reports, product defects, and lack of effectiveness complaints directly to FDA. Form FDA 1932a may be submitted on paper or may be submitted electronically by completing and emailing a fillable PDF form. Form FDA 2301 is used to submit the required transmittal of periodic reports (§ 514.80(b)(4)); special drug experience reports (§ 514.80(b)(5)(i)); promotional material for new animal drugs (§ 514.80(b)(5)(ii)); and distributor statements (§ 514.80(b)(5)(iii)). Form FDA 2301 may be submitted on paper, may be submitted electronically by completing and emailing a fillable PDF form, or may be submitted electronically via CVM's eSubmitter. We review the records and reports required in § 514.80 and the voluntary reports to facilitate a determination under section 512(e) of the FD&C Act as to whether there may be grounds for suspending or withdrawing approval of the new animal drug.

The proposed rule will revise these requirements to require electronic submission of the following postmarketing safety reports for approved new animal drugs:

- Three-day alert reports that applicants elect to submit directly to CVM in addition to the requirement that they have to submit these reports on paper Form FDA 1932 to the appropriate FDA District Office or local FDA resident post (§ 514.80(b)(1);
- Fifteen-day alert reports (§ 514.80(b)(2)(i)) and followup reports (§ 514.80(b)(2)(ii));
- Product/manufacturing defects and adverse drug experience reports submitted by nonapplicants who elect to report adverse drug experiences directly to FDA under § 514.80(b)(3) in addition to providing these reports to the applicant; and
- Product/manufacturing defects and adverse drug experience reports (including reports of previously not reported adverse drug experiences that occur in postapproval studies) required to be submitted as part of the periodic drug experience report (§ 514.80(b)(4)(iv)(A) and (C)).

At this time, we are not proposing to require electronic submission of 3-day field alert reports (§ 514.80(b)(1)) to the appropriate FDA District Office or local resident post because, as noted previously, we currently do not have the information technology systems in place to share with the FDA District Office or local resident post reports submitted electronically through the Electronic Submission Gateway or Safety Reporting Portal. These reports would continue to be submitted on paper Form FDA 1932 directly to the appropriate FDA District Office or local resident post. CVM will continue to collaborate with the FDA District Office or local resident post to follow up as appropriate in response to 3-day field alert reports submitted directly to the FDA District Office or local resident post. However, as noted, if an applicant elects to submit a 3-day field alert report directly to CVM, the applicant would be required to submit the report electronically. This would not alleviate the applicant's responsibility to submit this report to the FDA District Field Office or local FDA resident post on paper Form FDA 1932.

The proposed rule will also revise these requirements to allow applicants or nonapplicants to request a temporary waiver from the electronic submission requirement for ''good cause'' shown. Examples of circumstances that could constitute ''good cause'' for granting waivers of the electronic submission requirement include crisis situations that impact an applicant's or nonapplicant's ability to report electronically, such as natural disasters, pandemics, and terrorism. The proposed rule would require applicants and nonapplicants to submit a waiver request to us in writing. The initial request, however, could be made by telephone or email to CVM's Division of Veterinary Product Safety, with prompt

written followup submitted as a letter to the application.

The continuous monitoring of new animal drugs affords the primary means by which we obtain information regarding problems with the safety and efficacy of marketed approved new animal drugs, as well as product/manufacturing problems. Postapproval marketing surveillance is important to ensure the continued safety and effectiveness of new animal drugs. Drug effects can change over time and other effects may not manifest until years after the approval.

We estimate the reporting burden of this collection of information as follows:

TABLE 1—ESTIMATED RECURRING REPORTING BURDEN [1]

21 CFR section	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic submission of postmarketing safety reports under proposed § 514.80(b)(1), (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) and (C)	1932	15	18	270	1	270
Request for waiver, proposed § 514.80(d)(2)	N/A	1	1	1	1	1
Total				271		271

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 1 shows the estimated recurring reporting burden associated with the proposed rule. In section II.C. of the Preliminary Regulatory Impact Analysis (PRIA), we estimated that 15 firms submitted a paper Form FDA 1932 report from 2011 to 2015 and thus would be affected by the proposed rule's requirement to submit electronically. As stated in the PRIA, we estimate that in 2016 CVM received 270 of the affected postmarketing safety reports on paper. We calculate the number of responses per respondent as the total annual responses divided by the number of respondents. We estimate that, on average, it will take 1 hour to submit electronic postmarketing safety reports for approved new animal drugs, for a total of 270 hours. We base our estimate of 1 hour per report on our experience with electronic postmarketing safety reporting. In the PRIA, we also estimated the burdens associated with submission of waiver requests. We expect very few waiver requests (see section II.E. of the PRIA), estimating that approximately one firm would request a waiver annually under proposed § 514.80(d)(2). We estimate that a waiver request would take approximately 1 hour to prepare and submit to us. Together, this results in a total of 271 hours and 271 responses. If this rule is finalized as proposed, we would reduce the paper reporting collection approved under OMB control number 0910–0284 by 270 hours and increase the electronic reporting collection approved under OMB control number 0910–0645 by 270 hours.

Recordkeeping: We estimate the recordkeeping burden of this collection of information as follows:

TABLE 2—ESTIMATED ONE-TIME RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Write New SOPs	15	1	15	20	300
Training	15	1	15	20	300
Total			30		600

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2 shows the estimated one-time recordkeeping burden associated with the proposed rule. This burden includes both the one-time burden of creating new SOPs to submit the reports electronically and the one-time cost of training employees to electronically submit postmarketing safety reports to CVM in accordance with the new SOPs. In section II.E. of the PRIA, we estimated that approximately 15 firms would be affected by this proposed rule, if finalized. We also estimated that it would take approximately 20 hours per firm to create new SOPs for electronic submission of postmarketing safety reports and approximately 20 hours per firm to complete the training of employees to electronically submit postmarketing safety reports in accordance with the new SOPs. Together, this results in a total of 600 hours and 30 records. We assume that there are no capital costs associated with firms implementing this proposed rule (*i.e.,* applicants and nonapplicants in the pharmaceutical industry already have the computer and internet capacity necessary to electronically submit postmarketing safety reports).

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the PRA (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have

substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 514 be amended as follows:

PART 514—NEW ANIMAL DRUG APPLICATIONS

■ 1. The authority citation for part 514 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 354, 356a, 360b, 360ccc, 371, 379e, 381.

■ 2. Section 514.80 is amended as follows:

■ a. Revise the entries in the table for paragraphs (b)(4), (d), (e), and (g);

■ b. Add a fifth sentence to paragraph (b)(1); and

■ c. Revise the last sentence of paragraph (b)(2)(i); the third sentence of paragraph (b)(2)(ii); the last sentence of paragraph (b)(3); paragraphs (b)(4)(iv)(A) and (C); paragraph (b)(4)(v); and paragraphs (d) and (g).

The addition and revisions read as follows:

§ 514.80 Records and reports concerning experience with approved new animal drugs.

* * * * *

Purpose	21 CFR paragraph and title
* * * * *	*
What are the general requirements for submission of periodic drug experience reports, *e.g.,* method of submission, submission date and frequency, when is it to be submitted, how many copies? How do I petition to change the date of submission or frequency of submissions?	514.80(b)(4) Periodic drug experience report.
* * * * *	*
What reports must be submitted to FDA electronically? How can I apply for a waiver from the electronic reporting requirements? How do I obtain Form FDA 1932 and Form FDA 2301?	514.80(d) Format for Submissions.
How long must I maintain records and reports required by this section?	514.80(e) Records to be maintained.
* * * * *	*
Where do I mail reports that are not required to be submitted electronically?	514.80(g) Mailing addresses.
* * * * *	*

* * * * *

(b) * * *

(1) * * * If the applicant elects to also report directly to the FDA's Center for Veterinary Medicine (CVM), the applicant must submit the report to CVM in electronic format as described in paragraph (d)(1) of this section, unless the applicant obtains a waiver under paragraph (d)(2) of this section or FDA requests the report in an alternate format.

(2) * * *

(i) * * * The report must be submitted to FDA in electronic format as described in paragraph (d)(1) of this section, unless the applicant obtains a waiver under paragraph (d)(2) of this section or FDA requests the report in an alternate format.

(ii) * * * A followup report must be submitted to FDA in electronic format as described in paragraph (d)(1) of this section, unless the applicant obtains a waiver under paragraph (d)(2) of this section or FDA requests the report in an alternate format. * * *

(3) * * * If the nonapplicant elects to also report directly to FDA, the nonapplicant must submit the report to FDA in electronic format as described in paragraph (d)(1) of this section, unless the nonapplicant obtains a waiver under paragraph (d)(2) of this section or FDA requests the report in an alternate format.

(4) * * *

(iv) * * *

(A) Product/manufacturing defects and adverse drug experiences not previously reported under § 514.80(b)(1) and (b)(2) must be reported individually to FDA in electronic format as described in paragraph (d)(1) of this section, unless the applicant obtains a waiver under paragraph (d)(2) of this section or FDA requests the report in an alternate format.

(B) * * *

(C) Reports of previously not reported adverse drug experiences that occur in postapproval studies must be reported individually to FDA in electronic format as described in paragraph (d)(1) of this section, unless the applicant obtains a waiver under paragraph (d)(2) of this section or FDA requests the report in an alternate format.

(v) * * * The summaries must state the time period on which the increased frequency is based, time period comparisons in determining increased frequency, references to any reports previously submitted under paragraphs (b)(1), (b)(2), (b)(3), and (b)(4)(iv)(A) and (C) of this section, the method of analysis, and the interpretation of the results. The summaries must be submitted in a separate section within the periodic drug experience report.

* * * * *

(d) *Format for submissions.*—(1) *Electronic submissions.* Except as provided in paragraph (d)(2), reports submitted to FDA under paragraphs (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) and (C) of this section and reports submitted to CVM under paragraph (b)(1) of this section must be submitted in an electronic format that FDA can process, review, and archive. Data provided in electronic submissions must be in conformance with the data elements in Form FDA 1932 and FDA technical documents describing transmission. As necessary, FDA will issue updated technical documents on

how to provide the electronic submission (*e.g.,* method of transmission and processing, media, file formats, preparation, and organization of files). Unless requested by FDA, paper copies of reports submitted electronically should not be submitted to FDA.

(2) *Waivers.* An applicant or nonapplicant may request, in writing, a temporary waiver of the electronic submission requirements in paragraph (d)(1) of this section. The initial request may be by telephone or email to CVM's Division of Veterinary Product Safety, with prompt written followup submitted as a letter to the application(s). FDA will grant waivers on a limited basis for good cause shown. If FDA grants a waiver, the applicant or nonapplicant must comply with the conditions for reporting specified by FDA upon granting the waiver.

(3) *Paper forms.* If approved by FDA before use, a computer-generated equivalent of Form FDA 1932 may be used for reports submitted to the appropriate FDA District Office or local FDA resident post under paragraph (b)(1) and to FDA under (d)(2), and a computer-generated equivalent of Form FDA 2301 may be used for reports submitted to FDA under paragraph (b)(4). Form FDA 1932 may be obtained on the FDA website, by telephoning CVM's Division of Veterinary Product Safety, or by submitting a written request to the following address: Food and Drug Administration, Center for Veterinary Medicine, Division of Veterinary Product Safety (HFV–240), 7500 Standish Pl., Rockville, MD 20855–2764. Form FDA 2301 may be obtained on the FDA website, by telephoning CVM's Division of Surveillance (HFV–210), or by submitting a written request to the following address: Food and Drug Administration, Center for Veterinary Medicine, Division of Surveillance (HFV–210), 7500 Standish Pl., Rockville, MD 20855–2764.

* * * * *

(g) *Mailing addresses.* Three-day alert reports must be submitted to the appropriate FDA District Office or local FDA resident post. Addresses for District Offices and resident posts may be obtained on the FDA website. Other reports not required to be submitted to FDA in electronic format must be submitted to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855–2764.

* * * * *

Dated: February 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–02757 Filed 2–13–18; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50 and 51

[EPA–HQ–OAR–2016–0347; FRL–9974–55–OAR]

RIN 2060–AT35

Response to June 1, 2016, Clean Air Act Section 126(b) Petition From Connecticut

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public hearing.

SUMMARY: The Environmental Protection Agency (EPA) is announcing that a public hearing will be held on the EPA's proposed response to a June 1, 2016, petition submitted by the state of Connecticut pursuant to section 126 of the Clean Air Act (CAA). The petition requests that the EPA make a finding that the Brunner Island Steam Electric Station located in York County, Pennsylvania, emits air pollution in amounts that significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone national ambient air quality standard (NAAQS) in Connecticut. The hearing will be held on February 23, 2018, in Washington, DC. The EPA will issue its proposed response in the near future.

DATES: The public hearing will be held on February 23, 2018, in Washington, DC. Please refer to **SUPPLEMENTARY INFORMATION** for additional information on the public hearing.

ADDRESSES:

Public Hearing. The February 23, 2018 public hearing will be held at the EPA, William Jefferson Clinton East Building, Room 1153, 1201 Constitution Avenue NW, Washington, DC 20004. Identification is required. If your driver's license is issued by Michigan, Minnesota, New York, Vermont or the state of Washington, you must present an additional form of identification to enter (*see* **SUPPLEMENTARY INFORMATION** for additional information on this location).

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 EPA Docket Center Reading Room, William Jefferson Clinton West Building, 1301 Constitution Avenue NW, Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The phone number for the Public Reading Room is (202) 566–1744.

FOR FURTHER INFORMATION CONTACT: If you would like to speak at the public hearing, please contact Ms. Pamela Long, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards (OAQPS), Air Quality Planning Division (C504–01), Research Triangle Park, NC 27711, telephone (919) 541–0641, fax number (919) 541–5509, email address *long.pam@epa.gov,* no later than February 21, 2018. If you have any questions relating to the public hearing, please contact Ms. Long at the above number.

If you have questions concerning the June 1, 2016 petition, please contact Mr. Lev Gabrilovich, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards (OAQPS), Air Quality Planning Division, (C539–01), Research Triangle Park, NC 27711, telephone (919) 541–1496, email address *gabrilovich.lev@epa.gov.*

SUPPLEMENTARY INFORMATION: The public hearing will provide interested parties the opportunity to present data, views, or arguments concerning the EPA's proposed response to the June 1, 2016, petition. The EPA may ask clarifying questions during the oral presentations, but will not respond to the presentations at that time. Written statements and supporting information that are submitted during the comment period will be considered with the same weight as any oral comments and supporting information presented at the public hearing. Written comments must be postmarked by the last day of the comment period.

The public hearing will convene at 9:00 a.m. and end at 6:00 p.m. Eastern Time (ET) or at least two hours after the last registered speaker has spoken. The EPA will make every effort to accommodate all individuals interested in providing oral testimony. A lunch break is scheduled from 12:00 p.m. until 1:00 p.m. Please note that this hearing will be held at a U.S. government facility. Individuals planning to attend the hearing should be prepared to show valid picture identification to the