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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, Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a final rule to require electronic submission of certain postmarketing safety reports for approved new animal drugs. The final rule also provides a procedure for requesting a temporary waiver of the electronic submission requirement.

DATES: This rule is effective August 28, 2020. For the applicable compliance date, please see section V, ''Effective and Compliance Dates'' in **SUPPLEMENTARY INFORMATION**.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

The purpose of this rulemaking is 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.

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 (21 CFR 514.80)). An applicant is defined as a person or entity who owns or holds on behalf of the owner the approval for a new animal drug application (NADA) or an abbreviated new animal drug application (ANADA) and is responsible for compliance with applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and regulations (see § 514.3 (21 CFR 514.3)). In addition, a nonapplicant, 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)).

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.

Finalizing this rule will improve our systems for collecting and analyzing postmarketing safety reports. The change will 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 amendments will facilitate international harmonization and exchange of safety information. This rule also provides a procedure for requesting a temporary waiver of the electronic submission requirement.

B. Summary of the Major Provisions of the Final Rule

The rule amends the records and reports regulation in part 514 (21 CFR part 514) to include the following:

- Procedures relating to the electronic submission of certain postmarketing safety reports for approved new animal drugs; and
- Procedures for requesting a temporary waiver of the electronic submission requirement.

The final rule requires electronic submission for the following reports for approved new animal drugs: (1) 3-day alert reports that applicants elect to submit as a courtesy copy 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; (2) 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; and (3) 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 are replacing the current paper submission process with the electronic submission requirement and a procedure for requesting a temporary waiver of the electronic submission requirement. Finally, the final rule clarifies where to submit reports not required to be submitted electronically. Under the final rule, we continue to require 3-day alert reports to be submitted to the appropriate FDA District Office or local FDA resident post on paper. 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 as a ''courtesy copy,'' the applicant will be required to submit the ''courtesy copy'' of 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 FD&C Act (21 U.S.C. 321, 331, 351, 352, 360b, and 371).

D. Costs and Benefits

The quantifiable benefit of this rule is annual cost savings of $7,908 from reduced data entry time for CVM. The other benefits of this final rule would be to animal health and are not quantifiable. The main cost of this rule is a one-time upfront cost to industry of $73,500 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 $161 per year, for processing the waivers to the electronic reporting requirement. Annualizing these costs over a 15-year time horizon (from 2018 to 2033), we estimate total annualized costs to be $6,139 at a 3 percent discount rate, and total annualized costs of $7,703 at a 7 percent discount rate. The annualized net benefit of this rule is −$880 at a 3 percent discount rate and −$2,444 at a 7 percent discount rate. The present value of the net benefits is −$10,504 at a 3 percent discount rate and −$22,262 at a 7 percent discount rate over a 15-year time horizon.

II. Background

A. Need for the Regulation

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.

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.

In the **Federal Register** of February 14, 2018 (83 FR 6480), we proposed to amend our existing animal drug records and reports regulation in part 514 to 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 (83 FR 6480 at 6484). We set forth the rationale that 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 (83 FR 6480 at 6482).

Electronic submission of postmarketing safety reports:

- Expedites our access to safety information and provides us data in a format that will support more efficient and comprehensive reviews;
- Enhances 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
- Eliminates or reduces 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.

Electronic submission of postmarketing safety reports allows us to be more responsive to rapidly occurring changes in the technological environment. Consistent with our current practice for voluntarily provided electronic submissions, the final rule requires 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 final rule allows 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 *https://www.fda.gov/animal-veterinary/report-problem/veterinary-adverse-event-reporting-manufacturers* (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 final 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 final 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 final 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 final rule will enhance industry's global pharmacovigilance practices by allowing it to use common data elements and transmission standards when submitting ICSRs to multiple regulators.

B. Summary of Comments to the Proposed Rule

We received two comment letters on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from industry and an individual. Some comments support our rulemaking and our ongoing efforts to improve our systems for collecting and analyzing postmarketing safety reports. Some comments offer suggestions for specific changes for us to consider making to the subject regulations.

C. General Overview of the Final Rule

This final rule amends our animal drug records and reports regulation at part 514 to require electronic submission of certain postmarketing safety reports for approved new animal drugs. In addition, the rule provides a procedure for requesting a temporary waiver of the requirement. In this rulemaking, we finalize the provisions in the proposed rule.

III. Legal Authority

Our legal authority for issuing this final rule is provided by section 512(*l*) of the FD&C Act relating to records and reports concerning approved new animal drugs and section 701(a) of the FD&C Act. Section 512(*l*) of the FD&C Act requires that, following approval of an 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. 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 final rule's amendments to this regulation will further efficient enforcement of section 512(*l*) by permitting records and reports to be reported electronically.

IV. Comments on the Proposed Rule and FDA Response

A. Introduction

This section summarizes comments we received in response to the proposed rule and our response to those comments. Both commenters support our rulemaking and our ongoing efforts to improve our systems for collecting and analyzing postmarketing safety reports. Some of the comments offer suggestions for additional changes to the subject regulations. We considered the comments we received in response to the proposed rule in preparing this final rule. After considering these comments, we are not making any changes to the codified language that was included in the proposed rule.

In sections IV.B. through IV.C., we describe the comments received on the proposed rule and provide our responses. To make it easier to identify the comments and our responses, the word ''Comment,'' in parentheses, appears before the comment's description, and the word ''Response,'' in parentheses, appears before our response. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Description of General Comments and FDA Response

Two comments make general remarks supporting the proposed rule without focusing on a particular proposed provision.

(Comment 1) Comments generally support our efforts to require electronic submission of certain postmarketing safety reports for approved new animal drugs. One comment recognizes that the requirement of electronic submission would greatly benefit the Agency and animal health by supporting quicker access to postmarketing safety information. Another comment applauds our efforts to improve our systems for collecting and analyzing postmarketing safety reports and to facilitate international harmonization and exchange of safety information.

(Response 1) We appreciate the general support that the comments express. As noted in section II.A., we expect this rule to expedite our access to safety information and provide us data in a format that will support more efficient and comprehensive reviews. This will 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.

C. Specific Comments and FDA Response

Several comments make specific remarks regarding particular proposed provisions. In this section, we discuss and respond to such comments.

(Comment 2) One comment states that, although in favor of electronically reporting 3-day alerts to CVM in addition to reporting to the appropriate FDA District Office or local resident post, until such time that this can be accomplished via a single mechanism (*i.e.,* electronic reporting to both segments of the Agency simultaneously), this places an undue burden on industry both in time and resources as this would require reporting electronically to CVM while continuing to file paper Form FDA 1932 to District Offices or local resident posts.

(Response 2) We currently require 3-day alert reports to be submitted to the appropriate FDA District Office or local FDA resident post on paper (see § 514.80(b)(1)). However, if in addition to that report an applicant elects to submit a 3-day field alert report directly to CVM (*i.e.,* a ''courtesy copy''), we proposed to require the applicant to submit that additional copy of the report to CVM electronically (see proposed § 514.80(b)(1)). At this time FDA District Offices do not have the technology to receive Form FDA 1932 electronically, so we cannot mandate electronic reporting to FDA District Offices at this time. In addition, the FDA District Offices and local FDA resident posts use a different database for tracking such reports, and do not have direct access to the CVM Adverse Drug Event (ADE) database (which receives ADE information in part from Form FDA 1932). We agree that development of a single mechanism to report 3-day alert reports via electronic Form FDA 1932 to both the FDA District Office (or local FDA resident post) and CVM is ideal, and we are interested in developing this capacity; however, this effort is preliminary and investigatory at this time. As there is currently no requirement to provide a ''courtesy copy'' of 3-day alert reports to CVM, the required electronic submission of such copies would only burden those applicants that choose to provide them despite any additional time and resources needed to do so. Therefore, in this final rule, we are keeping the language of the final rule as proposed at

§ 514.80(b)(1). CVM will continue to collaborate with the FDA District Office or local resident post to followup as appropriate in response to 3-day field alert reports submitted directly to the FDA District Office or local resident post.

(Comment 3) One comment notes that, since the implementation of electronic reporting capability, postmarketing safety reports may be submitted to us via Extensible Markup Language (XML), which is designed to store and transport data and be both human-readable and machine-readable. Therefore, there is no official Form FDA 1932 version of these reports to provide to an inspector during manufacturing site FDA inspections. In addition, the comment continues, inspectors are not well versed in reading the XML formats created from electronically submitted reports. The comment suggests that we provide training to inspectors to help them better understand how to read the XML format for case data or that we provide industry with guidance for an alternative form that could be generated from the database that satisfies the inspectors' needs during site inspections.

(Response 3) We recognize the comment's concerns with regard to utility of the XML format information during inspections. We appreciate the commenter's interest in either preparing more easily readable versions of electronically submitted reports for inspectors or providing training to inspectors in reading the XML format of electronically submitted reports. We intend to consider these suggestions so that inspectors are better able to access the information they need during an inspection. However, the comment did not request any changes to the language in proposed § 514.80(b)(1), nor do we see a reason to make any changes based on the concerns and suggestions included in the comment.

(Comment 4) One comment notes that, while the proposed rule provides a procedure for requesting a temporary waiver of the electronic submission requirement for ''good cause'' (*i.e.,* crisis situations that impact an applicant's or nonapplicant's ability to report electronically, such as natural disasters, pandemics, and terrorism), the proposed rule does not change the content, frequency, or timeline for submission of the postmarketing safety reports to the Agency. The comment suggests that, when the Agency's Electronic Submission Gateway or Safety Reporting Portal is down, we should grant a temporary waiver of the electronic submission requirement for the amount of time the Agency website or portal is down.

(Response 4) We disagree that the Agency should automatically grant a temporary waiver from the electronic submission requirement for the amount of time that the Agency's Electronic Submission Gateway or Safety Reporting Portal is down. As stated in the proposed rule, 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 (83 FR 6480 at 6482). We also stated in the proposed rule that an applicant or nonapplicant experiencing technical difficulty that temporarily prevents 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 (83 FR 6480 at 6485). It is highly unlikely that both the Agency's Electronic Submission Gateway or Safety Reporting Portal would be down at the same time. In the unlikely event that the Agency experiences a prolonged system outage or other major technical problem (which would include the highly unlikely situation where both the Agency's Electronic Submission Gateway or Safety Reporting Portal are down), the Agency does not intend to enforce the requirement to submit reports electronically so long as an applicant or nonapplicant submits reports in an alternate format (most likely on paper using Form FDA 1932).

We are not waiving the required content, frequency, or timeline for submission of the postmarketing safety reports to the Agency, and are finalizing proposed § 514.80(d) without change. The rule requires applicants and nonapplicants to submit a waiver request to us in writing. The initial request for a waiver 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). Applicants and nonapplicants should be prepared to comply with an Agency request for submission in an alternate format by maintaining the capability to submit paper reports using Form FDA 1932, if needed.

In addition to the comments specific to this rulemaking that we addressed previously in this preamble, we received general comments expressing views about matters that are not related to this rulemaking. Therefore, these general comments do not require a response.

V. Effective and Compliance Dates

This rule is effective August 28, 2020. Applicants and nonapplicants must comply with the electronic submission requirement in the final rule when submitting their reports beginning on July 29, 2021.

VI. Economic Analysis of Impacts

We have examined the impacts of the final 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.'' This final rule is not an economically 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 certify that the final 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 issuing ''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 $156 million, using the most current (2019) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

Currently, most submitters have chosen, voluntarily, to use electronic submission for the reports that would be affected by this final rule. As of 2016, 99.7 percent of postmarketing safety reports eligible for electronic submission were electronically submitted. Thus, this final rule would affect a small proportion of these reports.

The quantifiable benefit of this rule is annual cost savings of $5,259 from reduced data entry time for CVM. The other benefits of this final rule would be to animal health and are not quantifiable. The main cost to this rule is a one-time upfront cost to industry of $73,500 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 $161 per year, for processing the waivers to the electronic reporting requirement. Annualizing these costs over a 15-year time horizon (from 2018 to 2033), we estimate total annualized costs to be $6,139 at a 3 percent discount rate, and total annualized costs of $7,703 at a 7 percent discount rate. The annualized net benefit of this rule is −$880 at a 3 percent discount rate and −$2,444 at a 7 percent discount rate. The present value of the net benefits is −$10,504 at a 3 percent discount rate and −$22,262 at a 7 percent discount rate over a 15-year time horizon.

TABLE 1—SUMMARY OF BENEFITS AND COSTS IN 2017 DOLLARS OVER A 15-YEAR TIME HORIZON

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized	$5,259			2017	7	15	
Monetized $/year	5,259			2017	3	15	
Annualized					7		
Quantified					3		
Qualitative							
Costs:							
Annualized	7,703			2017	7	15	
Monetized $/year	6,139			2017	3	15	
Annualized					7		
Quantified					3		
Qualitative							
Transfers:							
Federal					7		
Annualized Monetized $/year					3		
From/To	From:			To:			
Other					7		
Annualized Monetized $/year					3		
From/To	From:			To:			
Effects:							
State, Local or Tribal Government:							
Small Business:							
Wages:							
Growth:							

In line with Executive Order 13771, in table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. Based on these cost-savings this final rule would be considered a deregulatory action under Executive Order 13771. Our primary estimate for the present value of the net costs over an infinite time horizon is −$3,837 (or a cost savings of $3,837) at a 7 percent discount rate and −$96,287 at a 3 percent discount rate in 2016 dollars.

TABLE 2—EXECUTIVE ORDER 13771 SUMMARY TABLE

[In 2016 dollars over an infinite time horizon]

	Primary (7%)	Lower bound (7%)	Upper bound (7%)	Primary (3%)	Lower bound (3%)	Upper bound (3%)
Present Value of Costs	$69,720			$75,346		
Present Value of Cost Savings	110,711			258,326		
Present Value of Net Costs	(40,991)			(182,980)		
Annualized Costs	4,880			2,260		
Annualized Cost Savings	7,750			7,750		
Annualized Net Costs	(2,869)			(5,489)		

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

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 final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the one-time and recurring reporting and recordkeeping 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.

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

Description: This final rule revises 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 requires that they be submitted in an electronic form. The rule also provides a procedure for requesting a temporary waiver of the requirement.

Description of Respondents: Respondents to the information collection provisions of this 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) through (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 final rule revises 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 as a ''courtesy copy'' 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)).

We currently require 3-day alert reports to be submitted to the appropriate FDA District Office or local FDA resident post on paper (see § 514.80(b)(1)). As noted previously, the regulation does not require electronic submission of 3-day field alert reports (§ 514.80(b)(1)). These reports will continue to be submitted on paper Form FDA 1932 directly to the appropriate 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 as a ''courtesy copy,'' the applicant will be required to submit the report electronically. This will 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 final rule also revises these requirements to allow applicants or nonapplicants to request a temporary waiver from the electronic submission requirement for ''good cause'' shown. We anticipate that temporary waivers will only be needed in rare circumstances that impact an applicant's or nonapplicant's ability to report electronically, such as natural disasters, pandemics, and terrorism.

In the February 14, 2018, proposed rule, we included an analysis of the information collection provisions of the proposal under the PRA and requested comments on four topics relevant to that analysis (83 FR 6480 at 6487 through 6488). We have summarized and responded to these comments in sections IV.B. through IV.C., but have made no changes to the burden estimate in our proposed rule.

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

TABLE 3—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 § 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, § 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 3 shows the estimated recurring reporting burden associated with the final rule. In section II.F. of the Final Regulatory Impact Analysis (FRIA), we estimated that 15 firms submitted a paper Form FDA 1932 report from 2011 to 2015 and thus will be affected by the rule's requirement to submit electronically. As stated in the FRIA, 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 FRIA, we also estimated the burdens associated with submission of waiver requests. We expect very few waiver requests (see section II.F.2. of the FRIA), estimating that one firm will request a waiver annually under § 514.80(d)(2). We assume a waiver request takes 1 hour to prepare and submit to us. Together, this results in a total of 271 hours and 271 responses. We are also adding 1 hour to the paper reporting collection to reflect the new waiver request process under § 514.80(d)(2).

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

TABLE 4—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 4 shows the estimated one-time recordkeeping burden associated with the final 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.F. of the FRIA, we estimated that approximately 15 firms will be affected by this rule. We assume it will take an average of 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 rule (*i.e.,* applicants and nonapplicants in the pharmaceutical industry already have the computer and internet capacity necessary to electronically submit postmarketing safety reports).

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the 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.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive order and, consequently, a

tribal summary impact statement is not required.

XI. References

1. Economic Analysis of Impacts; also available at: *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.

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, 21 CFR part 514 is 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); the fifth sentence of 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?.	514.80(b)(4) Periodic drug experience report.
How do I petition to change the date of submission or frequency of submissions?	
* * * * *	* *
What reports must be submitted to FDA electronically?	514.80(d) Format for Submissions.
How can I apply for a waiver from the electronic reporting requirements?	
How do I obtain Form FDA 1932 and Form FDA 2301?	
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 paragraphs (b)(1) and (2) of this section 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.

* * * * *

(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), (2), and (3) and (b)(4)(iv)(A) and (C) of this section, the method of analysis, and the interpretation of the results. * * *

* * * * *

(d) *Format for submissions*—(1) *Electronic submissions.* Except as provided in paragraph (d)(2) of this section, 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) of this section and to FDA under paragraph (d)(2) of this section, and a computer-generated equivalent of Form FDA 2301 may be used for reports submitted to FDA under paragraph (b)(4) of this section. 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.

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Dated: July 2, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

[FR Doc. 2020–15441 Filed 7–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 120

[Public Notice: 11157]

International Traffic in Arms Regulations: Notification of Temporary Suspension, Modification, or Exception to Regulations

AGENCY: Department of State.

ACTION: Extension of temporary suspensions, modifications, and exceptions.

SUMMARY: The Department of State is issuing this document to inform the public of an extension to certain temporary suspensions, modifications, and exceptions for the durations described herein to certain provisions of the International Traffic in Arms Regulations (ITAR) in order to provide for continued telework operations during the current SARS–COV2 public health emergency. These actions are taken in order to ensure continuity of operations within the Directorate of Defense Trade Controls (DDTC) and among members of the regulated community.

DATES: This document is issued July 29, 2020.

FOR FURTHER INFORMATION CONTACT: Sarah Heidema, Office of Defense Trade Controls Policy, U.S. Department of State, telephone (202) 663–1282, or email *DDTCResponseTeam@state.gov.* ATTN: Extension of Suspension, Modification, and Exception.

SUPPLEMENTARY INFORMATION: On May 1, 2020, the Directorate of Defense Trade Controls (DDTC) published in the **Federal Register** a notification of certain temporary suspensions, modifications, and exceptions to the ITAR, necessary in order to ensure continuity of operations within DDTC and among entities registered with DDTC pursuant to part 122 of the ITAR (85 FR 25287). These actions were taken pursuant to ITAR § 126.2, which allows for the temporary suspension or modification of provisions of the ITAR, and ITAR § 126.3, which allows for exceptions to provisions of the ITAR. These actions were taken in the interest of the security and foreign policy of the United States and warranted as a result of the exceptional and undue hardships and risks to safety caused by the public health emergency related to the SARS–COV2 pandemic. The President declared a national emergency on March 13, 2020, as a result of this public health crisis.[1]

Subsequently, on June 10, 2020 (85 FR 35376), DDTC published in the **Federal Register** a request for comment from the regulated community regarding the efficacy and termination dates of the temporary suspensions, modifications, and exceptions provided in 85 FR 25287, and requesting comment as to whether additional measures should be considered in response to the public health crisis. DDTC received comments from several individual entities and from an industry association. DDTC appreciates the efforts expended by those commenters and took all comments under consideration. In the interest of providing this notice as expeditiously as possible, DDTC will not address each of the comments in turn, but will provide this abridged response. Of the four temporary suspensions, modifications, and exceptions to the ITAR announced in the May 1 notice referenced above, DDTC is allowing number 1 (extension of registrations) and number 2 (duration of ITAR licenses and agreements) to terminate in accordance with the timelines provided therein. The remaining two temporary suspensions, modifications, and exceptions, number 3 (§ 120.39(a)(2) allowance for remote work) and number 4 (authorization to allow remote work under technical assistance agreement, manufacturing agreement, or exemption) are extended and shall terminate on December 31, 2020.

The majority of the commenters requested that the telework provisions (numbers 3 and 4) be extended and DDTC agrees. Based upon continued public health recommendations and as informed by responses to request for public comment, it is apparent to DDTC that regulated entities will continue to engage in social distancing measures for the foreseeable future. In order to accommodate teleworking and decentralized workplaces, several commenters recommended extending these temporary modifications through at least the end of October or this calendar year. DDTC is extending the temporary modifications through the end of the calendar year in order to provide regulated entities with staffing flexibilities in the immediate term. DDTC will use this period to fully investigate the possibility and ramifications of making this modification, or a variation thereof, a permanent revision to the ITAR. If necessary, this extension will provide an opportunity to utilize notice and comment rulemaking and to address potential revisions through the interagency process. An extension of

[1] Proclamation 9994 of March 13, 2020, 85 FR 15337 (Mar. 18, 2020).