specific question posed by the FAA, and fully explain the rationale for any comment, include supporting data, if applicable. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time. The FAA requests that all comments be submitted in English.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this ANPRM. Before acting on this ANPRM, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The Agency may change its potential proposals in light of the comments it receives.

Proprietary or Confidential Business Information: Do not file proprietary or confidential business information in the docket. Such information must be sent or delivered directly to any of the persons identified in the **FOR FURTHER INFORMATION CONTACT** section of this document, and marked as proprietary or confidential. If submitting information on a disk or CD ROM, mark the outside of the disk or CD ROM, and identify electronically within the disk or CD ROM the specific information that is proprietary or confidential.

Under 14 CFR 11.35(b), if the FAA is aware of proprietary information filed with a comment, the Agency does not place it in the docket. It is held in a separate file to which the public does not have access, and the FAA places a note in the docket that it has received it. If the FAA receives a request to examine or copy this information, it treats it as any other request under the Freedom of Information Act (5 U.S.C. 552). The FAA processes such a request under Department of Transportation procedures found in 49 CFR part 7.

B. Availability of Rulemaking Documents

Electronic copies of rulemaking documents may be obtained from the Internet by—

1. Searching the Federal eRulemaking Portal (*http://www.regulations.gov*);

2. Visiting the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies* or

3. Accessing the Government Printing Office's Federal Digital System at *http://www.gpo.gov/fdsys/.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680. Commenters must identify the docket or notice number of this rulemaking.

All documents the FAA considered in developing this ANPRM, including economic analyses and technical reports, may be accessed from the Internet through the Federal eRulemaking Portal referenced in item (1) above.

Issued in Washington, DC, under the authority set forth in 49 U.S.C. 44733 on: March 5, 2014.

James R. Fraser,

Federal Air Surgeon.

[FR Doc. 2014–05653 Filed 3–14–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA–2014–N–0108]

New Animal Drug Applications; Confidentiality of Data and Information in a New Animal Drug Application File

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing to amend its regulation regarding the confidentiality of data and information in and about new animal drug application files to change when certain approval-related information would be disclosed by the Agency. This change would ensure that the Agency is able to update its list of approved new animal drug products within the statutory timeframe. It would also permit more timely public disclosure of approval-related information, increasing the transparency of FDA decision making in the approval of new animal drugs.

DATES: Submit either electronic or written comments by June 2, 2014. If FDA receives any significant adverse comments, the Agency will publish a document in the **Federal Register** withdrawing the direct final rule within 30 days after the comment period ends. FDA will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2014–N–0108, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand Delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2014–N–0108 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Scott Fontana, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0656.

SUPPLEMENTARY INFORMATION:

I. Background

Section 512(i) (21 U.S.C. 360b(i)) was added to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by the Animal Drug Amendments of 1968 (Pub. L. 90–399). Section 512(i) requires the conditions and indications of use of a new animal drug to be published in the **Federal Register** upon approval of a new animal drug application (NADA) filed under section 512(b) of the FD&C Act.

In 1974, FDA revised its regulations regarding the confidentiality of information in applications in § 135.33a (21 CFR 135.33a) to include provisions of the Freedom of Information Act (Pub. L. 89–487). That revision established that public disclosure by the Agency of certain data and information in an NADA file could not occur before the **Federal Register** notice of approval

published (39 FR 44653, December 24, 1974). Shortly thereafter, § 135.33a was redesignated as § 514.11 (21 CFR 514.11) (40 FR 13802 at 13825, March 27, 1975).

In 1988, the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) added section 512(n)(4)(A) of the FD&C Act, which states that the Agency shall publish a list of approved new animal drug products and revise that list every 30 days to include each new animal drug that has been approved during that 30-day period. This list, as well as related patent information and marketing exclusivity periods, is contained in a document generally known as the ''Green Book,'' available at the Agency's public Web site at *http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts*.

The editorial and clearance processes for publishing the **Federal Register** notice announcing the approval of an NADA varies from 1 to 2 months after the approval letter is issued to the applicant. Consequently, the addition of newly approved product information to the ''Green Book'' and public disclosure of certain other approval-related information at the Agency's public Web site is delayed until after that **Federal Register** notice is published. Such other approval-related information may include the summary of information forming the basis for approval (known also as the Freedom of Information Summary) and documentation of environmental review. Trade and proprietary information in the application file remains confidential and is not disclosed.

FDA is proposing to amend § 514.11 to change the time when certain approval-related information in an NADA file would be publicly disclosed, from when notice of the approval is published in the **Federal Register** to when the application is approved. This change would ensure that the Agency is able to update the ''Green Book'' within the 30-day statutory timeframe (see section 512 (n)(4)(A)(ii) of the FD&C Act). It would also permit more timely public disclosure of certain approval-related information following sponsor notification of application approval, increasing the transparency of Agency decision making in the approval of new animal drugs.

II. Companion Document to Direct Final Rulemaking

This proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**. FDA proposes to amend § 514.11 to change the time when certain approval-related information in an NADA file would be publicly disclosed to ensure that the Agency is able to update the ''Green Book'' within the 30-day statutory time frame. This proposed rule is intended to make noncontroversial changes to existing regulations. The Agency does not anticipate receiving any significant adverse comment on this rule.

Consistent with FDA's procedures on direct final rulemaking, we are publishing elsewhere in this issue of the **Federal Register** a companion direct final rule. The direct final rule and this companion proposed rule are substantively identical. This companion proposed rule provides the procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for this proposed rule runs concurrently with the comment period of the companion direct final rule. Any comments received in response to the companion direct final rule will also be considered as comments regarding this proposed rule.

FDA is providing a comment period for the proposed rule of 75 days after the date of publication in the **Federal Register.** If FDA receives a significant adverse comment, we intend to withdraw the direct final rule before its effective date by publication of a notice in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants withdrawing a direct final rule, the Agency will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (5 U.S.C. 553).

Comments that are frivolous, insubstantial, or outside the scope of the proposed rule will not be considered significant or adverse under this procedure. For example, a comment recommending a regulation change in addition to those in the proposed rule would not be considered a significant adverse comment unless the comment states why the proposed rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this proposed rule and that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the proposed rule that are not the subject of a significant adverse comment.

If FDA does not receive significant adverse comment in response to the proposed rule, the Agency will publish a document in the **Federal Register** confirming the effective date of the final rule. The Agency intends to make the direct final rule effective 30 days after publication of the confirmation document in the **Federal Register.**

A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466). The guidance document may be accessed at: *http://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm*.

III. Legal Authority

FDA is issuing this proposed rule under section 512(c) of the FD&C Act. This section gives the Secretary of Health and Human Services the authority to approve new animal drug applications. In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

IV. Environmental Impact

FDA has 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.

V. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, 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 Agencies 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). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any

significant impact of a rule on small entities. Because this proposed rule would not impose any compliance costs on sponsors of animal drug products that are currently marketed or in development, the Agency proposes to certify that the proposed rule if finalized would not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies 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 $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would 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, the Agency tentatively concludes that the proposed 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.

VII. Paperwork Reduction Act of 1995

This proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

VIII. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

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, it is proposed that 21 CFR part 514 be amended as follows:

PART 514—NEW ANIMAL DRUG APPLICATIONS

■ 1. The authority citation for 21 CFR part 514 continues to read as follows:

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

■ 2. In § 514.11, revise paragraphs (b), (d), (e) introductory text, and (e)(2)(ii) introductory text to read as follows:

§ 514.11 Confidentiality of data and information in a new animal drug application file.

* * * * *

(b) The existence of an NADA file will not be disclosed by the Food and Drug Administration before the application has been approved, unless it has been previously disclosed or acknowledged.

* * * * *

(d) If the existence of an NADA file has been publicly disclosed or acknowledged before the application has been approved, no data or information contained in the file is available for public disclosure, but the Commissioner may, in his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, i.e., at an open session of a Food and Drug Administration advisory committee or pursuant to an exchange of important regulatory information with a foreign government.

(e) After an application has been approved, the following data and information in the NADA file are immediately available for public disclosure unless extraordinary circumstances are shown:

* * * * *

(2) * * *

(ii) For an NADA approved after July 1, 1975, a summary of such data and information prepared in one of the following two alternative ways shall be publicly released when the application is approved.

* * * * *

Dated: March 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–05432 Filed 3–14–14; 8:45 am]

BILLING CODE 4160–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52, 62, and 70

[EPA–R07–OAR–2013–0724; FRL 9907–78-Region 7]

Approval and Promulgation of Implementation Plans, State Plans for Designated Facilities and Pollutants, and Operating Permits Program; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Missouri State Implementation Plan (SIP), the 40 CFR part 62 state plans for designated facilities and pollutants (111(d)), and the 40 CFR part 70 operating permits program, which were received on August 25, 2011, May 8, 2012, and February 11, 2013, respectively. The revisions submitted by the state move definitions currently in individual rules into one rule and eliminates the risk of the same term being defined differently for different rules. This action provides more clarity for the regulated public. These revisions do not have an adverse affect on air quality. EPA's proposed approval of these rule revisions is being done in accordance with the requirements of the Clean Air Act (CAA).

DATES: Comments on this proposed action must be received in writing by April 16, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2013–0724, by mail to Paula Higbee, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Paula Higbee, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at 913–551–7028, or by email at *higbee.paula@epa.gov.*