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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: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulation regarding the confidentiality of data and information in and about new animal drug application files to change when certain approval-related information will be disclosed by the Agency. This change will ensure that the Agency is able to update its list of approved new animal drug products within the statutory timeframe. It will 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: This rule is effective July 30, 2014. Submit either electronic or written comments by June 2, 2014. If FDA receives no significant adverse comments within the specified comment period, the Agency will publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the Agency will publish a document in the **Federal Register** withdrawing this direct final rule before its effective date.

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, 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 issuing this direct final rule amending § 514.11 to change the time when certain approval-related information in an NADA file will be publicly disclosed, from when notice of the approval is published in the **Federal Register** to when the application is approved. This change will 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 will 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. Direct Final Rulemaking

FDA has determined that the subject of this rulemaking is suitable for a direct final rule. FDA is amending § 514.11 to change the time when certain approval-related information in an NADA file will be publicly disclosed to ensure that the Agency is able to update the ''Green Book'' within the 30-day statutory timeframe. This 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 proposed rule. The companion proposed rule and this direct final rule are substantively identical. The 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 direct final rule runs concurrently with the comment period of the companion proposed rule. Any comments received in response to the companion proposed rule will also be considered as comments regarding this direct final rule.

FDA is providing a comment period for the direct final rule of 75 days after the date of publication in the **Federal Register**. If FDA receives any significant adverse comment, we intend to withdraw this 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 direct final 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 rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not the subject of a significant adverse comment.

If FDA does not receive significant adverse comment in response to the direct final 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 direct final 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 direct final 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 direct final 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 direct final rule would not impose any compliance costs on the sponsors of animal drug products that are currently marketed or in development, the Agency certifies that this direct final rule will 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 direct final rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the direct final 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, the Agency concludes that the direct final 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 direct final 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, 21 CFR part 514 is 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.

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Dated: March 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–05430 Filed 3–14–14; 8:45 am]

BILLING CODE 4160–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2013–0439; FRL–9907–55–Region 6]

Approval and Promulgation of Air Quality Implementation Plans; Texas; Stage II Vapor Recovery Program and Control of Air Pollution From Volatile Organic Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving revisions to the Texas State Implementation Plan (SIP) that control emissions of volatile organic compounds (VOCs) at gasoline dispensing facilities (GDFs) in Texas. The revisions were submitted to the EPA by the Texas Commission on Environmental Quality (TCEQ) on October 31, 2013 and address the maintenance and removal of Stage II vapor recovery equipment at GDFs. The EPA is also approving related revisions to the Stage II SIP narrative that pertain to the maintenance and removal of Stage II vapor recovery equipment and demonstrate that the absence of Stage II equipment in the Beaumont-Port Arthur (BPA), Dallas-Fort Worth (DFW) and Houston-Galveston Brazoria (HGB) areas, and in El Paso County would not interfere with attainment of the national ambient air quality standards, reasonable further progress or any other requirement of the Clean Air Act (CAA or Act). The EPA is approving these revisions pursuant to sections 110 and 202 of the Act and consistent with the EPA's guidance.

DATES: This final rule is effective on April 16, 2014.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R06–OAR–2013–0439. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. To inspect the hard copy materials, please schedule an appointment with the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below or Mr. Bill Deese at 214–665–7253.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Paige, Air Planning Section (6PD–L); telephone (214) 665–6521; email address *paige.carrie@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' means EPA.

Table of Contents

I. Background

The background for today's final rule is discussed in our December 30, 2013 proposal to approve revisions to the Texas SIP (78 FR 79340). In that action, we proposed to approve the Texas SIP revisions submitted by the TCEQ on October 31, 2013, which specify that new GDFs would not be required to install Stage II equipment and provide removal (decommissioning) procedures that existing GDFs in the 16 counties [1] must complete by August 31, 2018. The revisions to the Stage II SIP describe the removal of Stage II equipment at GDFs and require maintenance of the Stage II equipment until decommissioning occurs. The revisions to the SIP narrative also include a demonstration that the removal of, or failure to install, Stage II equipment in the 16 counties is consistent with section 110(l) of the Act which precludes approval of revisions to the SIP that contribute to nonattainment or interfere with maintenance of any National Ambient Air Quality Standard.

Our December 30, 2013 proposal provides a detailed description of the revisions and the rationale for EPA's proposed actions, together with a

[1] The four areas in Texas where Stage II is required comprise 16 counties: BPA, containing Hardin, Jefferson and Orange counties; DFW, involving Collin, Dallas, Denton and Tarrant counties; El Paso County; and HGB, containing Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery, and Waller counties.