effective date for a proposed ban.[1] However, the SMDA did not eliminate the informal hearing provision for a proposed ban issued with a special effective date. Thus, section 516(b) of the FD&C Act continues to require that FDA ''provide reasonable opportunity for an informal hearing'' on a proposed ban with a special effective date (21 U.S.C. 360f(b)) while subsection (a), the general rule for medical device bans, does not (see 21 U.S.C. 360f(a)).

On December 10, 1992 (57 FR 58400), FDA published a final rule implementing the SMDA. The final rule of 1992 amended § 895.21(d), which covers the procedures for issuing a ban without a special effective date, by removing the requirement that FDA provide an opportunity for an informal hearing when there is no special effective date.[2] FDA incorrectly removed the same language from § 895.30, which covers the procedures for issuing bans with special effective dates; the Agency issued a technical amendment restoring this language in the **Federal Register** of June 2, 2015 (80 FR 31299). However, FDA did not correct the language in § 16.1 to list section 516(b) of the FD&C Act and § 895.30(c) as the provisions that provide for regulatory (informal) hearings, nor did the Agency remove the reference to § 895.21(d). FDA does so now.

FDA finds good cause for issuing this amendment to § 16.1(b)(1) as a final rule without notice and comment because this amendment corrects the regulations to restate the statute (5 U.S.C. 553(b)(B)). ''[W]hen regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary.'' *Gray Panthers Advocacy Committee* v. *Sullivan,* 936 F.2d 1284, 1291 (D.C. Cir. 1991); see also *Komjathy* v. *Nat. Trans. Safety Bd.,* 832 F.2d 1294, 1296 (D.C. Cir. 1987) (when a rule ''does no more than repeat, virtually verbatim, the statutory grant of authority,'' notice-and-comment procedures are not required). Further, the change to remove the erroneous cross-reference to § 895.21(d) and add the correct cross-reference to§ 895.30(c) is merely technical, insignificant in nature and impact, and inconsequential to industry and the public. See *Mack Trucks, Inc.* v. *EPA,* 682 F.3d 87, 94 (D.C. Cir. 2012). This is because this correction in no way changes when FDA is required to provide an opportunity for a hearing, which is determined by section 516 of the FD&C Act and part 895, nor does it impact the availability of such a hearing to any entity impacted by the proposed ban. It merely corrects a citation error to avoid confusion. This amendment to § 16.1(b) thus merely corrects the references to the applicable requirements of the FD&C Act and its implementing regulations, making notice-and-comment procedures unnecessary in this case. Therefore, publication of this document constitutes final action on this change under the Administrative Procedure Act (APA) (5 U.S.C. 553).

In addition, FDA finds good cause for this amendment to become effective on the date of publication of this action. The APA allows an effective date less than 30 days after publication as ''provided by the agency for good cause found and published with the rule'' (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendment to § 16.1 does not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for this correction to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 16 is amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 2. Amend § 16.1 as follows:

■ a. In paragraph (b)(1), remove from the list the entry ''Section 516 of the act relating to a proposed banned device regulations (see § 895.21(d) of this chapter).'' and add in its place ''Section 516(b) of the act regarding a proposed regulation to ban a medical device with a special effective date.''

■ b. In paragraph (b)(2), add an entry in numerical sequence for ''§ 895.30(c), regarding a proposed regulation to ban a medical device with a special effective date.''

Dated: August 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18787 Filed 8–10–16; 8:45 am]

BILLING CODE 4164–01–P

[1] Specifically, the SMDA deleted the then-last sentence of section 516(a). See Public Law 101–629, section 18(d)(2) (''Section 516(a) (21 U.S.C. 360f(a)) is amended . . . by striking out the last sentence.''); 21 U.S.C. 360f(a) (1989) (stating, in the last sentence, ''The Secretary shall afford all interested persons opportunity for an informal hearing on a regulation proposed under this subsection.'').

[2] Although the hearing provision was validly removed from § 895.21(d)(8) in 1992, the removed language erroneously reappeared in the Code of Federal Regulations beginning in 1994. On March 5, 2015 (80 FR 11865), the Office of the Federal Register published a correction document fixing this publication error.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA–2016–N–1943]

New Animal Drug Applications; Contents of Notice of Opportunity for a Hearing; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correcting amendments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is making technical corrections to its regulations for hearing procedures for denial of approval or withdrawal of approval of new animal drug applications. The Agency is taking this action to harmonize terminology and to improve the organization and clarity of the regulations.

DATES: This rule is effective August 11, 2016.

ADDRESSES: 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 final rule 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: Vernon Toelle, Center for Veterinary Medicine (HFV–234), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5637, *vernon.toelle@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background

This regulation is intended to make technical amendments to § 514.200 (21 CFR 514.200) to harmonize the terminology with part 12 (21 CFR part 12), as well as to update § 514.200 in accordance with plain language principles to make it easier for the public to understand and follow.

When the Agency issued procedural regulations for formal evidentiary public hearings, originally published in part 2 (21 CFR part 2) and later redesignated to part 12,[1] we intended those provisions to apply to all formal evidentiary hearings on new product applications, including new animal drug applications. As explained in the proposed rule, once the specific provisions in 21 CFR parts 511 and 514 relating to investigational and marketed new animal drugs were revised in the same way as their counterpart provisions relating to investigational and marketed new drugs, to refer to the new procedural provisions in part 2, the prior procedural provisions relating to hearings would be revoked.[2]

Consequently, when part 12 was finalized, we revised the regulations specific to new animal drugs. These revisions included revoking certain provisions and revising 21 CFR 514.201 to state that hearings related to new animal drugs under section 512(d) and (e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(d) and (e)) shall be governed by part 12 of this chapter. However, when we made these revisions to part 514, we neglected to update § 514.200 to match the terminology used in part 12.

Therefore, we are now revising § 514.200 to make its language and terminology consistent with the language and terminology of the procedural regulations for hearings in part 12. Specifically, we are changing the references to ''administrative law judge'' in current § 514.200 to the term ''presiding officer'', which is defined in 21 CFR 10.3 [3] and further explained in 21 CFR 12.60 as the presiding officer in a hearing will be the Commissioner, a member of the Commissioner's office to whom the responsibility for the matter involved has been delegated, or an administrative law judge qualified under 5 U.S.C. 3105. Since the term ''presiding officer'' is used throughout part 12, we are updating the language of § 514.200 to use the same terminology. We are also updating the language in current § 514.200 from ''written appearance'' to ''objections and request for a hearing'' since the latter terminology is used throughout part 12. Finally, we are updating the language in § 514.200 on the contents of the objections and request for hearing and the contents of the Commissioner's notice granting a hearing to match the language of part 12 and to make clear what is required. These updates will eliminate confusion that could be caused by use of different terms to refer to the same procedural requirements and allow the reader to obtain necessary information in one place. We anticipate these technical changes will make § 514.200 easier for the public to understand and follow.

Since we are revising § 514.200 to harmonize the language and terminology with part 12, we are also taking this opportunity to update the language of § 514.200 in accordance with the Plain Writing Act of 2010 (Pub. L. 111–274) and Executive Order 13563. The Plain Writing Act of 2010 requires that all Federal agencies use ''clear government communication that the public can understand and use.'' Executive Order 13563 mandates that all regulations be ''accessible, consistent, written in plain language, and easy to understand.'' Therefore, we are eliminating gender-specific pronouns, passive voice, complicated sentence structure, and archaic language, and updating the language to make it more reader-friendly and accessible. We anticipate that these changes will make § 514.200 clearer and easier to read. Additionally, we are updating the title of that section from ''Contents of notice of opportunity for a hearing'' to ''Notice of opportunity for hearing; notice of participation and requests for hearing; grant or denial of hearing'' because the latter title more accurately describes the type of information found in § 514.200. The latter title also harmonizes with an analogous section for new drug applications in 21 CFR 314.200.

All of these corrections are nonsubstantive, technical amendments designed to harmonize the language and terminology of § 514.200 with the governing regulation on formal evidentiary public hearings in part 12 and to make the language of § 514.200 easier for the public to understand and follow. We are taking this action as a part of our Retrospective Review Initiative [4] to clarify and harmonize the regulations and to update the language in accordance with the Plain Writing Act of 2010 and Executive Order 13563.

II. Legal Authority

FDA is issuing these regulations under section 512(e) of the FD&C Act. This section gives the Secretary of Health and Human Services the authority to grant approval, deny approval, or withdraw approval of 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.

Section 6 of Executive Order 13563 states that FDA is under a continuing obligation to review its existing regulations periodically to determine whether any such regulations should be modified, streamlined, expanded, or repealed to improve regulatory effectiveness and reduce public burden. The Plain Writing Act of 2010 mandates that all regulations be written in clear language that is easy for the public to understand and use.

This rule makes technical amendments to § 514.200 to harmonize the language and terminology with the governing regulation on administrative hearings in part 12 and to update the language in accordance with the Plain Writing Act of 2010 and Executive Order 13563. Publication of this document constitutes final action on these changes under the Agency's original intent with respect to the hearing provisions for new animal drug applications. Therefore, for good cause, FDA finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary.

III. Effective Date

These regulations are effective upon publication.

IV. Economic Analysis of Impacts

We have examined the impacts of the 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 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). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant

[1] See 41 FR 51706, November 23, 1976, and 42 FR 4680, January 25, 1977.

[2] See 40 FR 40682 at 40716, September 3, 1975.

[3] ''*Presiding officer* means the Commissioner or the Commissioner's designee or an administrative law judge appointed as provided in 5 U.S.C. 3105.''

[4] See E.O. 13563, section 6.

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 this rule is making only technical amendments, 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 $146 million, using the most current (2015) 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.

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(i) 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.

VI. Paperwork Reduction Act of 1995

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

VII. 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.

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:

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

■ 2. Revise § 514.200 to read as follows:

§ 514.200 Notice of opportunity for hearing; notice of participation and requests for hearing; grant or denial of hearing.

(a) The notice to the applicant of opportunity for a hearing on a proposal by the Commissioner to refuse to approve an application or to withdraw the approval of an application will be published in the **Federal Register** together with an explanation of the grounds for the proposed action. The notice will describe how to request a hearing. An applicant has 30 days after publication of the notice to request a hearing.

(b) If the applicant fails to request a hearing within the 30-day timeframe, the Commissioner, without further notice, will publish a final order denying or withdrawing approval of the application.

(c) If the applicant desires to request a hearing:

(1) Within 30 days after publication of the notice of opportunity for hearing, the applicant must submit to the Division of Dockets Management written objections and a request for a hearing in accordance with §§ 12.20 and 12.22. This request for a hearing must include each specific objection to the proposal on which a hearing is requested, together with a detailed description and analysis of the factual information (including all relevant clinical and other investigational data) the applicant will present in support of that objection. A request for a hearing may not rest upon mere allegations or denials or general descriptions of positions or contentions, but must set forth specific reliable evidence showing there is a genuine and substantial issue of fact that requires a hearing.

(2) If the Commissioner determines upon review of the data and information submitted in the objections and request for a hearing that a hearing is not justified because no genuine and substantial issue of fact precludes the refusal to approve the application or the withdrawal of approval of the application (for example, the applicant has not identified any adequate and well-controlled clinical investigations to support the claims of effectiveness), the Commissioner will enter an order denying the hearing and stating the final findings and conclusions.

(3) If the Commissioner determines upon review of the data and information submitted in the objections and request for a hearing that a hearing is justified, the Commissioner will publish a notice setting forth the following:

(i) The regulation or order that is the subject of the hearing;

(ii) A statement specifying any part of the regulation or order that has been stayed by operation of law or in the Commissioner's discretion;

(iii) The parties to the hearing;

(iv) The specific issues of fact for resolution at the hearing;

(v) The presiding officer, or a statement that the presiding officer will be designated in a later notice; and

(vi) The date, time, and place of the prehearing conference, or a statement that the date, time, and place will be announced in a later notice. However, in the case of a denial of approval, the hearing must not occur more than 90 days after expiration of the 30-day time period in which to request a hearing, unless the presiding officer and the applicant otherwise agree; and in the case of withdrawal of approval, the hearing will occur as soon as practicable.

(d) The hearing will be open to the public; however, if the Commissioner finds that portions of the application which serve as a basis for the hearing contain information concerning a method or process entitled to protection as a trade secret, the part of the hearing involving such portions will not be public, unless the respondent so specifies in the request for a hearing.

Dated: August 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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