DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 207

[Docket No. FDA–2005–N–0464]

RIN 0910–AA49

Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs; Corrections

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule; correcting amendments.

SUMMARY: On August 31, 2016, the Food and Drug Administration (FDA or Agency) published an amended final rule that listed inaccurate cross-references to FDA's drug establishment registration and drug listing regulations. This document corrects the inaccurate cross-references used in the final regulations.

DATES: This rule is effective April 1, 2021.

FOR FURTHER INFORMATION CONTACT: Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3521.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 31, 2016 (81 FR 60170), FDA published the final rule entitled ''Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs.'' That final rule amended current regulations in part 207 (21 CFR part 207) concerning who must register establishments and list human drugs, human drugs that are also biological products, and animal drugs.

II. Description of the Technical Amendments

FDA is amending its regulations in part 207 to correct inaccurate cross-references used in the August 31, 2016, final rule. This document amends the Agency's regulations in part 207 through minor technical amendments to update references in §§ 207.1, 207.3, 207.13, 207.49, and 207.53 (21 CFR 207.1, 207.3, 207.13, 207.49, and 207.53) by replacing all cross-references to ''§ 207.1(b)'' with ''§ 207.1''.

III. Notice and Public Comment

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (APA) (5 U.S.C. 553). Section 553 of the APA exempts ''rules of agency organization, procedure, or practice'' from proposed rulemaking (*i.e.,* notice and comment rulemaking) (5 U.S.C. 553(b)(3)(A)). Rules are also exempt when an Agency finds ''good cause'' that notice and comment rulemaking procedures would be ''impracticable, unnecessary, or contrary to the public interest'' (5 U.S.C. 553(b)(3)(B).)

FDA has determined that this rulemaking meets the notice and comment exemption requirements in 5 U.S.C. 553(b)(3)(A) and (B). FDA's revisions make only technical changes to correct inaccurate cross-references. FDA does not believe public comment is necessary for these minor revisions.

The APA allows an effective date less than 30 days after publication as ''provided by the agency for good cause and published with the rule'' (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do 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 the amendments to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 207

Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, 21 CFR part 207 is amended as follows:

PART 207—REQUIREMENTS FOR FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN DRUGS, INCLUDING DRUGS THAT ARE REGULATED UNDER A BIOLOGICS LICENSE APPLICATION, AND ANIMAL DRUGS, AND THE NATIONAL DRUG CODE

■ 1. The authority citation for part 207 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

§ 207.1 [Amended]

■ 2. Amend § 207.1 in the definition of *Bulk drug substance* by removing ''§ 207.1(b)'' and adding in its place ''this section''.

§ 207.3 [Amended]

■ 3. Amend § 207.3 by removing ''§ 207.1(b)'' and adding in its place ''§ 207.1''.

§ 207.13 [Amended]

■ 4. Amend § 207.13(l)(1) by removing ''§ 207.1(b)'' and adding in its place ''§ 207.1''.

§ 207.49 [Amended]

■ 5. Amend § 207.49(a)(15)(i), (a)(15)(ii)(A) and (B), and (a)(15)(iii)(A) and (B) by removing ''§ 207.1(b)'' and adding in its place ''§ 207.1''.

§ 207.53 [Amended]

■ 6. Amend § 207.53(d)(1), (d)(2)(i) and (ii), and (d)(3)(i) and (ii) by removing ''§ 207.1(b)'' and adding in its place ''§ 207.1''.

Dated: March 25, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 528, and 558

[Docket No. FDA–2020–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, Department of Health and Human Services.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during October, November, and December 2020. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve the accuracy and readability of the regulations.

DATES: This rule is effective April 1, 2021.