4164-014-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20, 201, 207, 314, 514, 515, 601, 607, and 1271

[Docket No. FDA-2005-N-0464 (formerly Docket No. 2005N-0403)]

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; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a 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 appeared in the Federal Register of August 31, 2016 (81 FR 60169). That final rule amended current regulations concerning who must register establishments and list human drugs, human drugs that are also biological products, and animal drugs. The final rule was published with an incorrect statement in the preamble about the rule's effect on establishments at which investigational drugs are manufactured. This document corrects that error.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: David Joy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6254, Silver Spring, MD 20993-0002, 301-796-2242.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 31, 2016 (81 FR 60169), FDA published the final rule "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." The final rule published with an incorrect statement in the preamble about the rule's effect on establishments at which investigational drugs are manufactured. Under the amended regulations, manufacturers, repackers, relabelers, or salvagers who manufacture, repack, relabel, or salvage drugs solely for use in research, teaching, or chemical analysis and not for sale are exempt from the establishment registration requirement under 21 CFR 207.13(e) if they do not engage in other activities that require them to register.

In the Federal Register of August 31, 2016, in FR Doc. 2016-20471, the following correction is made: On page 60185, in the first column, in the third paragraph under "2. When must initial registration information be provided? (§ 207.21)," the following sentence is removed: "Accordingly, an establishment at which an investigational drug is manufactured is subject to the establishment registration requirement."

Dated: December 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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