4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-3152]

Postapproval Changes to Drug Substances; Draft Guidance for Industry; Availability; Correction

AGENCY: Food and Drug Administration, HHS

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled "Postapproval Changes to Drug Substances; Draft Guidance for Industry; Availability" that appeared in the *Federal Register* of September 11, 2018. The document announced a draft guidance that provides recommendations to holders of approved new drug applications, abbreviated new drug applications, new animal drug applications, abbreviated new animal drug applications, and holders of drug master files and veterinary master files who may want to make a change to the drug substance manufacturing process during the drug product application postapproval period. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115.

SUPPLEMENTARY INFORMATION:

In the *Federal Register* of Tuesday, September 11, 2018 (83 FR 45944), in FR Doc. 2018-19666, on page 45944, the following correction is made:

On page 45944, in the first column, in the header of the document, and also in the third column under *Instructions*, "Docket No. FDA-2018-D-3151" is corrected to read "Docket No. FDA-2018-D-3152".

Dated: September 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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