



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-5739]

Formal Meetings Between the Food and Drug Administration and Abbreviated New Drug Application Applicants of Complex Products Under Generic Drug User Fee Amendments; Guidance for Industry; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is correcting a notice entitled “Formal Meetings Between the Food and Drug Administration and Abbreviated New Drug Application Applicants of Complex Products Under Generic Drug User Fee Amendments; Guidance for Industry; Availability” that appeared in the *Federal Register* of November 25, 2020. The document announced the availability for a guidance for industry. The document was published with incorrect information in the Paperwork Reduction Act of 1995 section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993-0002, 240-402-7930, elizabeth.giaquinto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of November 25, 2020 (85 FR 75336), in FR Doc. 2020-26050, the following correction is made:

On page 75337, in the third column, under the heading, "II. Paperwork Reduction Act of 1995", the paragraph is corrected to read:

"While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management

and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information for meetings related to generic drug development have been approved under OMB control number 0910-0797."

Dated: November 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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