



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0529]

Qualification Process for Drug Development Tools; Guidance for Industry; Availability;
Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled “Qualification Process for Drug Development Tools; Guidance for Industry; Availability” that appeared in the *Federal Register* of November 25, 2020. The document announced the availability of a final guidance for industry and FDA staff that met the 21st Century Cures Act’s requirement to issue guidance on this qualification process and elaborated on the new qualification process and transparency requirements and discusses the taxonomy for biomarkers and other drug development tools. The document was published with incorrect information in the Paperwork Reduction Act of 1995 section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Chris Leptak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6461, Silver Spring, MD 20993-0002, 301-796-0017; or Stephen Ripley, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002; 240-402-7911.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of November 25, 2020 (85 FR 75334), in FR Doc. 2020-26051, the following correction is made:

On page 75336, in the first 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 pertaining to submissions of investigational new drug applications have been approved under OMB control number 0910-0014; the collections of information pertaining to submissions of new drug applications and abbreviated new drug applications have been approved under OMB control number 0910-0001; and the collections of information pertaining to submissions of biologics license applications in 21 CFR part 601 have been approved under OMB control number 0910-0338."

Dated: December 8, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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