



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2610]

A List of Biomarkers Used as Outcomes in Development of FDA-Approved New Molecular Entities and New Biological Therapeutics (October 2007 to December 2015); Establishment of a Public Docket; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled "A List of Biomarkers Used as Outcomes in Development of FDA-Approved New Molecular Entities and New Biological Therapeutics (October 2007 to December 2015); Establishment of a Public Docket" that appeared in the Federal Register of September 19, 2016 (81 FR 64177). The document announced the establishment of a docket to receive suggestions, recommendations, and comments from interested parties (such as academic researchers, regulated industries, consortia, and patient groups) on a list of biomarkers that were used as outcomes to develop FDA-approved new molecular entities (NMEs) and New Biological Therapeutics from October 2007 to December 2015. The document was published without an active Web link. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3330, Silver Spring MD 20993-0002, 301-796-9115, lisa.granger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

In the Federal Register of Monday, September 19, 2016, in FR Doc. 2016-22470, on page 64178 the following correction is made:

On page 64178, in the second column, in the last sentence of the first paragraph under Section I, Background, "Biomarkers Used as Outcomes in Development of FDA-Approved Therapeutics (October 2007 to December 2015)" is corrected to read "<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/ucm483052.htm>".

Dated: September 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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