SUMMARY is corrected to read: “The Food and Drug Administration (FDA or Agency) Center for Drug Evaluation and Research (CDER) is announcing that FDA will begin supporting the Clinical Data Interchange Standards Consortium (CDISC) for Study Data Tabulation Model version 1.8 (SDTM v1.8), and CDISC Standard for Exchange of Nonclinical Data Implementation Guide—Animal Rule version 1.0 (SENDIG—AR v1.0) on March 15, 2020, and that these new standards will be required in submissions for studies that start after March 15, 2022 (for new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs)), and in submissions for studies that start after March 15, 2023 (for certain investigational new drug applications (INDs)), that are submitted to CDER.”

Dated: June 4, 2021.
Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[Federal Register Doc. 2021–12198 Filed 6–9–21; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2020–N–0315]
Electronic Study Data Submission; Data Standards; Support and Requirement Begin for Study Data Tabulation Model Version 1.8 With Standard for Exchange of Nonclinical Data Implementation Guide—Animal Rule Version 1.0; Correction
AGENCY: Food and Drug Administration, HHS.
ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the Federal Register on March 11, 2020. The document announced that FDA will begin supporting the Clinical Data Interchange Standards Consortium (CDISC) for Study Data Tabulation Model version 1.8 (SDTM v1.8), and CDISC Standard for Exchange of Nonclinical Data Implementation Guide—Animal Rule version 1.0 (SENDIG—AR v1.0) on March 15, 2020, and that these new standards will be required in submissions to FDA effective March 15, 2022. The document omitted the 36-month implementation period for certain investigational new drugs applications (INDs) as required by the guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Standardized Study Data” which is referenced in that document. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, 301–796–0035, email: cderdatastandards@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Correction
In the Federal Register of March 11, 2020 (85 FR 14205), in FR Doc. 2020–04898, the following corrections are made:

1. On page 14205, in the second column, the first sentence of the