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 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).

2. On page 14206, in the first column, the last sentence of the document is corrected to read as follows: "FDA will begin supporting SDTM v1.8 and SENDIG–AR v1.0 on March 15, 2020, and the use of 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.

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FOR FURTHER INFORMATION CONTACT:
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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 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.”

The Animal Rule refers to FDA’s regulations for the approval of new drugs and biological products when human efficacy studies are not ethical or feasible (see 21 CFR 314.600–650 for drugs and 21 CFR 601.90–95 for biologics).
and purity characteristics they purport or are represented to possess, and are labeled with adequate warnings and instructions for use.

The pharmaceutical or drug quality-related regulations appear in several parts of Title 21 Code of Federal Regulations (CFR) (Food and Drugs), including sections in parts 1 through 99, 200 through 299, 300 through 499, 600 through 799, and 800 through 1,299. The regulations enable a common understanding of the regulatory process by describing requirements to be followed by drug manufacturers, applicants, and FDA. Under part 211 (21 CFR part 211; see 21 CFR 211.94(e)(1)), specific requirements for medical gas containers and closures are also found in the regulations. Finally, the information collection also supports regulations codified under parts 610 and 680 (21 CFR parts 610 and 680), which reference certain CGMP regulations in part 211 (see §§ 610.12(g), 610.13(a)(2), 610.18(d), 680.2(f), and 680.3(f)).

These regulations set forth information collection requirements that allow FDA to meet its public health protection responsibilities. Products that fail to comply with CGMP requirements may be rendered adulterated under section 501(a)(2)(B) of the FD&C Act. To demonstrate that their products comply with the requirements of section 501(a)(2)(B), API manufacturers must maintain CGMP records; therefore, we have counted them among respondents who incur burden for the information collection. In the table below, we have included an additional 1,260 respondents to reflect API manufacturers not included in our previous submission for renewal.

To assist respondents with the information collection requirements for medical gases, we developed a draft guidance for industry entitled “Current Good Manufacturing Practice for Medical Gases.” This guidance, when finalized, will discuss our recommendations regarding compliance with applicable requirements found in the regulations as they apply to these products. The guidance is available for download from our internet site at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/current-good-manufacturing-practice-medical-gases. We believe the recommendations, if followed, will help respondents focus their information collection activities most efficiently with regard to demonstrating regulatory compliance.

In the Federal Register of March 3, 2021 (86 FR 12466), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received requesting clarification on FDA’s basis in calculating its burden estimate. At the same time, the comment offered no formula or method upon which burden for the information collection. In the table below, we have included an additional 1,260 respondents to reflect API manufacturers not included in our previous submission for renewal.

We retain our estimate of the information collection burden, which is as follows:

<table>
<thead>
<tr>
<th>Section 501(a)(2)(B) of the FD&amp;C Act; Parts 210 and 211</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGMP API Manufacturers</td>
<td>1,260</td>
<td>256</td>
<td>322,560</td>
<td>0.82 (49.2 minutes)</td>
<td>264,499</td>
</tr>
<tr>
<td>CGMP Finished Pharmaceuticals Manufacturers (excludes medical gases)</td>
<td>3,270</td>
<td>299</td>
<td>977,730</td>
<td>0.64 (38 minutes)</td>
<td>625,747</td>
</tr>
<tr>
<td>CGMP Medical Gases Manufacturers</td>
<td>2,284</td>
<td>280</td>
<td>639,520</td>
<td>0.62 (37 minutes)</td>
<td>396,502</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>1,939,810</td>
<td></td>
<td>1,286,748</td>
</tr>
</tbody>
</table>

1. There are no capital or operating and maintenance costs associated with the information collection.
2. Records and burden per activity have been averaged and rounded.

Our estimated burden for the information collection reflects an overall decrease of 29,073 hours and 1,762 records annually for CGMP for finished pharmaceutical manufacturers, excluding those manufacturers of medical gases. Our estimated burden for the information collection also reflects an overall decrease of 486 hours and 1,574 records annually for medical gas manufacturers. Our inclusion of API manufacturers in this collection represents an addition of 264,499 hours and 322,560 records prepared.

Dated: June 2, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

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3 See also, “Q” Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients; Guidance for Industry” (September 2016).