Impurities.'' The notice gave interested persons an opportunity to submit comments by August 13, 2018.

After consideration of the comments received, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in March 2019.

The guidance revises the existing guidance for industry ''Q3D Elemental Impurities'' and provides an updated permitted daily exposure (PDE) for the cadmium inhalation route of exposure. The revision was initiated following identification of a calculation error in the original text. The updated PDE of 3 µg/day is based on a modifying factor approach that is consistent with the method used for calculating the PDEs for the oral and parenteral routes of exposure.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Q3D(R1) Elemental Impurities.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: March 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04995 Filed 3–10–20; 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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: 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 to FDA effective March 15, 2022. An update will be made to the FDA Data Standards Catalog (Catalog) to reflect these changes.

DATES: Submit either electronic or written comments at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–0315 for ''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.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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:

I. Background

On December 17, 2014, FDA published final guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' (eStudy Data guidance), posted on FDA's Study Data Standards Resources web page at *https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.* The eStudy Data guidance implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k–1(a)) for study data contained in new drug applications, abbreviated new drug applications, biologics license applications, and investigational new drug applications submitted to CDER or the Center for Biologics Evaluation and Research by specifying the format for electronic submissions. The eStudy Data guidance states that a **Federal Register** notice will specify any new standard version updates that will be added to the Catalog and will specify when support for the new standard begins or ends, and when the requirement to submit data using the new standard begins or ends. FDA will begin supporting SDTM v1.8 and SENDIG–AR v1.0 on March 15, 2020, and such Animal Rule [1] submissions will be required to use the new standard effective March 15, 2022.

Dated: March 5, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04898 Filed 3–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1482]

Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is reopening the comment period for the notice that appeared in the **Federal Register** of April 3, 2019, and extending it indefinitely. The notice announced a public hearing to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds. In addition, it notified the public that FDA was establishing a docket for public comment on this hearing and that the docket would close on July 2, 2019. On June 20, 2019, a notice that appeared in the **Federal Register** extended the comment period to July 16, 2019. To provide a public and transparent way for stakeholders to provide new and emerging information to us in real time as it becomes available, we are reopening the comment period and extending it indefinitely to allow interested parties to continue to comment. We are particularly interested in data that may help to address uncertainties and data gaps related to the safety of cannabidiol (CBD).

DATES: FDA is reopening the comment period and extending it indefinitely on the notice published in the **Federal Register** of April 3, 2019 (84 FR 12969).

ADDRESSES: You may submit either electronic or written comments as follows.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–1482 for ''Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

[1] 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).