

Application No.	Drug	Applicant
ANDA 090732	Anastrozole Tablets, 1 mg	Do.
ANDA 203161	Irbesartan Tablets, 75 mg, 150 mg, and 300 mg	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of April 5, 2021. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on April 5, 2021 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: February 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-04520 Filed 3-4-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2354]

Data Standards; Requirement Begins for the Clinical Data Interchange Standards Consortium Version 1.1 of the Standard for Exchange of Nonclinical Data Developmental and Reproductive Toxicology Implementation Guide and Version 1.6 of the Study Data Tabulation Model; Clarification to Food and Drug Administration Data Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is announcing the date that support will begin for version 1.1 of the Clinical Data Interchange Standards Consortium (CDISC) Standard for Exchange of Nonclinical Data Developmental and Reproductive Toxicology Implementation Guide (SENDIG-DART) and version 1.6 of the Clinical Data Interchange Standards

Consortium (CDISC) Study Data Tabulation Model (SDTM) and the dates when such new standard and version update will be required in certain submissions. The Agency will update the FDA Data Standards Catalog (Catalog) to reflect these changes. An additional note is added to the Catalog clarifying the requirements for the submission of a simplified trial summary dataset to determine a study start date at the point of submission at the electronic gateway.

DATES: Support for version 1.1 of the CDISC SENDIG-DART and version 1.6 of the CDISC SDTM will begin on March 15, 2021. The requirement for electronic submissions to be submitted using version 1.1 of the CDISC SENDIG-DART will begin March 15, 2023, for new drug applications (NDAs), abbreviated new drug applications (ANDAs), and certain biologics license applications (BLAs), and March 15, 2024, for certain investigational new drug applications (INDs). The requirement for electronic submissions to be submitted using version 1.6 of the CDISC SDTM will begin on March 15, 2022.

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-235 for "Data Standards; Requirements Begin for the Clinical Data Interchange Standards Consortium Version 1.1 of the Standard for Exchange of Nonclinical Data Developmental and Reproductive Toxicology Implementation Guide and Version 1.6 of the Study Data Tabulation Model. Clarification to the FDA Data Standards Catalog." 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, 240-402-7500.

- **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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Bryan Spells, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993-0002, 240-402-6511, email: cderndatastandards@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA’s CDER is issuing this **Federal Register** notice to announce the date that support will begin for version 1.1 of the CDISC SENDIG–DART and version 1.6 of the CDISC SDTM and the dates when such new standard and version update will be required in certain submissions. The FDA guidance for industry “Providing Regulatory Submissions in Electronic Format—Standardized Study Data” (October 2020) (eStudy Data guidance), posted on FDA’s Study Data Standards Resources web page at <https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>, 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 NDAs, ANDAs, certain BLAs, and certain INDs 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 standards and version updates to FDA-supported study data standards that will be added to the Catalog, when the support for such standards and version updates begins or ends, and when the requirement to use such standards and version updates in submissions begins or ends.

Support for version 1.1 of the CDISC SENDIG–DART and version 1.6 of the CDISC SDTM will begin on March 15, 2021, the transition date. The requirement for electronic submissions

to be submitted using version 1.1 of the CDISC SENDIG–DART will begin March 15, 2023, for NDAs, ANDAs and certain BLAs, and March 15, 2024, for certain INDs. The requirement for electronic submissions to be submitted using version 1.6 of the CDISC SDTM will begin on March 15, 2022.

Dated: February 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-04609 Filed 3-4-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0180]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the generic clearance for the collection of quantitative data on tobacco products and communications.

DATES: Submit either electronic or written comments on the collection of information by May 4, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 4, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 4, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service

acceptance receipt is on or before that date.

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–2018–N–0180 for “Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240-402-7500.

- **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