

access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Erin Stone, M.A., Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H16-2, Atlanta, Georgia, 30329; Email: [IPCGuidelines@cdc.gov](mailto:IPCGuidelines@cdc.gov); Telephone: (404) 639-4000.

**SUPPLEMENTARY INFORMATION:**

**Public Participation**

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data related to the *Draft Guideline*.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted in preparation of the final *Infection Control in Healthcare Personnel: Epidemiology and Control of Selected Infections Transmitted Among Healthcare Personnel and Patients* and may revise the *Draft Guideline* as appropriate.

**Background**

On February 26, 2020, CDC published a notice in the **Federal Register** requesting public comment on the ‘Draft Infection Control in Healthcare Personnel: Epidemiology and Control of Selected Infections Transmitted Among

Healthcare Personnel and Patients: Diphtheria, Group A *Streptococcus*, Meningococcal Disease, and Pertussis Sections’ (85 FR 11084). Because the original notice was published in the early days of the COVID-19 pandemic, interested persons may not have had the opportunity to provide comment. For this reason, CDC has decided to re-open the comment period to provide the public with additional time to review the draft document and provide comment.

The *Draft Guideline* updates four sections of the *Guideline for Infection Control in Health Care Personnel, 1998* (“1998 Guideline”), *Part E: Epidemiology and Control of Selected Infections Transmitted Among Health Care Personnel and Patients*, and their corresponding recommendations in Part II of the *1998 Guideline*: “4. Diphtheria;” “9. Meningococcal Disease;” “12. Pertussis;” and “18. *Streptococcus*, group A infection.” The updated recommendations in the *Draft Guideline* are intended for use by the leaders and staff of Occupational Health Services (OHS) to facilitate providing occupational infection prevention and control (IPC) services to healthcare personnel (HCP) for the management of exposed or infected HCP who may be contagious to others in the workplace.

Since 2015, the Healthcare Infection Control Practices Advisory Committee (HICPAC) has worked with national partners, academicians, public health professionals, healthcare providers, and other partners to develop this *Draft Guideline* as a recommendation for CDC to update sections of the *1998 Guideline*. HICPAC includes representatives from public health, infectious diseases, regulatory and other federal agencies, professional societies, and other stakeholders.

The updated draft recommendations in this *Draft Guideline* are informed by reviews of the *1998 Guideline*; current CDC resources, guidance, and guidelines; and new resources and evidence, when available. This *Draft Guideline* and the updated final *Guideline* will not be a federal rule or regulation.

Dated: March 1, 2021.

**Sandra Cashman,**

*Executive Secretary, Centers for Disease Control and Prevention.*

[FR Doc. 2021-04515 Filed 3-4-21; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2021-N-0033]

**Morton Grove Pharmaceuticals Inc. et al.; Withdrawal of Approval of Seven Abbreviated New Drug Applications**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of seven abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of April 5, 2021.

**FOR FURTHER INFORMATION CONTACT:** Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, [Martha.Nguyen@fda.hhs.gov](mailto:Martha.Nguyen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 065428 .....	Cefprozil Tablets, 250 milligrams (mg) and 500 mg .....	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC., 6451 Main St., Morton Grove, IL 60053.
ANDA 077699 .....	Mefloquine Hydrochloride (HCl) Tablets, 250 mg .....	Hikma Pharmaceuticals USA Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 078383 .....	Pioglitazone HCl Tablets, Equivalent to (EQ) 15 mg base; EQ 30 mg base; EQ 45 mg base.	Neopharma Inc., 211 College Road East, Suite 101, Princeton, NJ 08540.
ANDA 078953 .....	Irinotecan HCl Injection, 40 mg/2 milliliters (mL) (20 mg/mL) and 100 mg/5 mL (20 mg/mL).	Do.
ANDA 079049 .....	Alendronate Sodium Tablets, EQ 5 mg base; EQ 10 mg base; EQ 35 mg base; EQ 70 mg base.	Do.

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