

Ave., Bldg. 66, Rm. 5510, Silver Spring, MD 20993-0002, 301-796-4539.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “ICH Q12: Implementation Considerations for FDA-Regulated Products.” ICH Q12 provides a framework to facilitate the management of postapproval CMC changes in a more predictable and efficient manner. It includes regulatory tools and enablers with associated guiding principles that should enhance industry’s ability to manage postapproval changes and increase transparency between industry and regulatory authorities, supporting innovation and continual improvement.

This guidance should be read in conjunction with ICH Q12, which this guidance complements by clarifying how the ICH Q12 tools and enablers can be implemented within the U.S. regulatory system. These guidances apply to drug substances and drug products that are the subject of new drug applications (NDAs), biologics license applications (BLAs), abbreviated new drug applications (ANDAs), and supplements to these applications regulated by CDER and CBER. They also apply to combination products with device constituent parts that are the subject of NDAs, BLAs, ANDAs, and supplements to these applications regulated by CDER and CBER. This guidance provides considerations for implementation of ICH Q12 tools, such as established conditions, postapproval change management protocols, and the product lifecycle management document. The considerations provided follow the order of the sections in ICH Q12 and are specific to FDA’s implementation.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “ICH Q12: Implementation Considerations for FDA-Regulated Products.” 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. Paperwork Reduction Act of 1995**

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–

3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information for the submission of NDAs and ANDAs in 21 CFR 314.50, 314.70, 314.71, 314.94, and 314.97, including supplements, have been approved under OMB control number 0910-0001. The collections of information in 21 CFR parts 210 and 211 have been approved under OMB control number 0910-0139. The collections of information for the submission of BLAs under 21 CFR 601.2 and 601.12 have been approved under OMB control number 0910-0338.

**III. Electronic Access**

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>, or <https://www.regulations.gov>.

Dated: May 14, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-10611 Filed 5-19-21; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2021-D-0131]

**Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients With Type 2 Diabetes Mellitus; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus.” This draft guidance provides recommendations for feasibility and early feasibility clinical studies for

certain medical devices intended to therapeutically improve glycemic control in patients with Type 2 Diabetes Mellitus. These medical devices are intended to therapeutically reduce glycated hemoglobin in Type 2 Diabetes Mellitus patients independent of medication (*e.g.*, insulin) delivery. This draft guidance is not final nor is it in effect at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by July 19, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time 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-

2021–D–0131 for “Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus.” 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a

single hard copy of the draft guidance document entitled “Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus” to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** April Marrone, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2604, Silver Spring, MD 20993–0002, 240–402–6510.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

This draft guidance provides recommendations for the design of feasibility and early feasibility clinical studies for certain medical devices intended to therapeutically improve glycemic control in patients with Type 2 Diabetes Mellitus (T2DM). T2DM is a metabolic disorder that is characterized by high blood sugar levels, insulin resistance, and relative lack of insulin. In 2020, it is estimated that 10.5 percent of the U.S. population, or roughly 34.2 million Americans, have diabetes and that T2DM accounts for 90 percent to 95 percent of all diabetes cases.<sup>1</sup>

Due to the prevalence of T2DM in the United States, many medical device manufacturers and researchers seek to develop therapeutic medical devices that are intended to improve glycemic control in patients with T2DM. While there are several legally marketed devices that help patients manage T2DM, including medical devices intended to measure or monitor blood sugar (e.g., blood glucose monitors, continuous glucose monitors) or dose and deliver insulin (e.g., insulin pens, pumps, syringes), there are currently no legally marketed medical devices in the United States that are intended to therapeutically improve glycemic control in patients with T2DM.

In recent years, medical devices that are therapeutically intended to improve glycemic control in patients with T2DM have become an increasing area of interest, and manufacturers have requested the Agency’s feedback

regarding feasibility and early feasibility clinical studies for these medical devices. This draft guidance represents the Agency’s initial thinking on feasibility and early feasibility clinical studies for these medical devices. FDA’s recommendations may change as more information becomes available.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on feasibility and early feasibility clinical studies for certain medical devices intended to therapeutically improve glycemic control in patients with T2DM. 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 interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This draft guidance document is also available at <https://www.regulations.gov> and at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Persons unable to download an electronic copy of “Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 19045 and complete title to identify the guidance you are requesting.

##### **III. Paperwork Reduction Act of 1995**

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

<sup>1</sup> Center for Disease Control, National Diabetes Statistics Report 2020: Estimates of Diabetes and its Burden in the United States, available at <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.

21 CFR part or guidance	Topic	OMB control No.
807, subpart E .....	Premarket notification .....	0910-0120
814, subparts A through E .....	Premarket approval .....	0910-0231
812 .....	Investigational Device Exemption .....	0910-0078
"Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff".	Q-submissions .....	0910-0756
50, 56 .....	Protection of Human Subjects: Informed Consent; Institutional Review Boards.	0910-0755
56 .....	Institutional Review Boards .....	0910-0130

Dated: May 14, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-10599 Filed 5-19-21; 8:45 am]

**BILLING CODE 4164-01-P**

**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; Correction**

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of March 5, 2021. The document announced the withdrawal of approval of seven abbreviated new drug applications (ANDAs) from multiple applicants as of April 5, 2021. The document indicated that FDA was withdrawing approval of the following five ANDAs, after receiving a withdrawal request from Neopharma, Inc., 211 College Road East, Suite 101, Princeton, NJ 08540: ANDA 078383, Pioglitazone Hydrochloride (HCl) Tablets, Equivalent to (EQ) 15 milligrams (mg) base, EQ 30 mg base, and EQ 45 mg base; ANDA 078953, Irinotecan HCl Injection, 40 mg/2 milliliters (mL) (20 mg/mL) and 100 mg/5 mL (20 mg/mL); ANDA 079049, Alendronate Sodium Tablets, EQ 5 mg base, EQ 10 mg base, EQ 35 mg base, and EQ 70 mg base; ANDA 090732, Anastrozole Tablets, 1 mg; and ANDA 203161, Irbesartan Tablets, 75 mg, 150 mg, and 300 mg. Before FDA withdrew the approval of these ANDAs, Neopharma, Inc., informed FDA that it did not want the approval of the ANDAs withdrawn. Because Neopharma, Inc., timely requested that approval of these ANDAs not be withdrawn, the approval

of ANDAs 078383, 078953, 079049, 090732, and 203161 is still in effect.

**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*.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Friday, March 5, 2021 (86 FR 12950), appearing on page 12950 in FR Doc. 2021-04520, the following corrections are made on pages 12950 and 12951 in the table:

The entries for ANDAs 078383, 078953, 079049, 090732, and 203161 are removed.

Dated: May 14, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-10588 Filed 5-19-21; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2021-P-0162]

**Determination That NORMODYNE (Labetalol Hydrochloride) Injection, 5 Milligrams per Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that NORMODYNE (labetalol hydrochloride) injection, 5 milligrams per milliliter (mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the

product as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:** Christopher Koepke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3600, *Christopher.Koepke@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).