determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NUCYNTA (tapentadol hydrochloride) solution, eq 20 mg base/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to NUCYNTA (tapentadol hydrochloride) solution, eq 20 mg base/mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05582 Filed 3–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1774]

Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.'' This draft guidance document provides an overview of the mechanisms available to submitters through which they can request interactions with FDA related to medical device submissions. This draft guidance, when finalized, is intended to supersede the document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' issued on June 2, 2023, and provides clarification and additional information on the scope of Q-Submission (Q-Sub) types, better delineation of how to obtain feedback for different types of questions (*i.e.,* informal communication vs. Pre-Submission or other Q-Submission types), and improved examples. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by May 14, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2018–D–1774 for ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.'' 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 ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' to the Office of Policy, 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: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2438, Silver Spring, MD 20993–0002, 301–796–5640 or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

As part of the Medical Device User Fee Amendments of 2022, the Agency committed to issuing a draft guidance to provide additional information to assist in identifying the circumstances in which an applicant's question is most appropriate for informal communication instead of a Pre-Submission and to provide an opportunity for the public to comment on the updated guidance. This draft guidance reflects such additional information and further clarifies other elements of the Q-Sub Program.

This draft guidance provides an overview of the mechanisms available to submitters through which they can request interactions with FDA, including written feedback and/or a meeting regarding medical device Investigational Device Exemption applications, Premarket Approval applications, Humanitarian Device Exemption applications, De Novo requests, 510(k) submissions, Clinical Laboratory Improvement Amendments (CLIA) Waiver by Applications, Dual 510(k) and CLIA Waiver by Application submissions, Accessory Classification Requests, and certain Investigational New Drug applications and Biologics License Applications submitted to the Center for Biologics Evaluation and Research.

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 ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.'' 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 guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00001677 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

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
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
''Administrative Procedures for CLIA Categorization'' and ''Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''.	CLIA Administrative Procedures; CLIA Waivers	0910–0607
''Medical Device Accessories—Describing Accessories and Classification Pathways''.	Accessories	0910–0823
Form FDA 3601 ''Medical Device User Fee Cover Sheet''; Form FDA 3601(a), the ''Device Facility User Fee Cover Sheet;'' ''FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act''.	Medical Device User Fee Cover Sheet and Device Facility User Fee Cover Sheet—Form FDA 3601 and Form 3601(a); 513(g) Request for Information.	0910–0511
''Center for Devices and Radiological Health Appeals Processes''	Appeals Process	0910–0738
''Emergency Use Authorization of Medical Products and Related Authorities''.	Emergency Use Authorization	0910–0595
312	Investigational New Drug Application	0910–0014
601	Biologics License Application	0910–0338

Dated: March 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05580 Filed 3–14–24; 8:45 am]

BILLING CODE 4164–01–P