development of implanted BCI devices. FDA considered the input provided during this workshop to develop this guidance document. This guidance document provides clinical study design and nonclinical testing recommendations associated with BCI devices.

This is a leapfrog guidance: A type of guidance that serves as a mechanism by which the Agency can share initial thoughts regarding emerging technologies that are likely to be of public health importance early in product development. This leapfrog guidance represents the Agency's initial thinking and our recommendations may change as more information becomes available.

A notice of availability of the draft guidance appeared in the **Federal Register** of February 25, 2019 (84 FR 6007). FDA considered comments received and revised the guidance as appropriate in response to the comments, including the addition of a brief section on Human Factors recommending that usability information be captured early in device development and continue iteratively, and a recommendation in the ''Home Use'' section, to describe the training related to home use of the devices and how the effectiveness of this training will be evaluated. A clarification was also added in the Scope section to highlight that for any BCI devices with technological characteristics, components, or indications for use or patient population not described in the guidance, manufacturers/investigators should submit a pre-submission to seek FDA feedback.

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 ''Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation—Non-Clinical Testing and Clinical Considerations.'' 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 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* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation—Non-clinical Testing and Clinical Considerations '' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500045 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. 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 guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
812	Investigational Device Exemption	0910–0078
''Requests for Feedback on Medical Device Submissions: The Q-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
801	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards.	0910–0755

Dated: May 14, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10622 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–2019–D–2837]

Testing and Labeling Medical Devices for Safety in the Magnetic Resonance Environment; 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 final guidance entitled ''Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment.'' FDA developed this guidance to provide FDA's recommendations on the testing needed for assessing the safety and compatibility of medical devices in the Magnetic Resonance (MR) Environment and the recommended format for Magnetic Resonance Imaging (MRI) Safety Information in medical device labeling. This guidance document is anticipated to aid in consistency of reviews, testing, and MRI safety labeling across a variety of medical devices.

DATES: The announcement of the guidance is published in the **Federal Register** on May 20, 2021.

ADDRESSES: You may submit either electronic or written comments on

Agency guidances 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–2019–D–2837 for ''Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment.'' 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 guidance document entitled ''Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment'' 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: Terry Woods, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2116, Silver Spring, MD 20993–0002, 301–796–2503.

SUPPLEMENTARY INFORMATION:

I. Background

The MR Environment presents unique safety hazards for patients and other persons with devices near or inside an MR system. Ensuring safety and effectiveness for a medical device intended to enter the MR Environment should be an integral part of the device risk management. Appropriate testing and labeling, such as well supported MR Conditional labeling, should form the basis of adequate mitigations for the unique safety hazards in the MR Environment. This guidance document outlines FDA's current thinking on the testing needed for assessing the safety and compatibility of medical devices in the MR Environment and the recommended format for MRI Safety Information in device labeling. This document supersedes FDA Guidance entitled ''Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment'', dated December 11, 2014.

A notice of availability of the draft guidance appeared in the **Federal Register** of August 2, 2019 (84 FR 37886). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarification of approaches for radiofrequency heating assessments and associated labeling. Revisions were also made to provide more guidance about when gradient induced vibration and heating assessments are needed and to include the possibility of magnetically induced force and torque causing equipment to tip over.

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 ''Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment.'' 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 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* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 2019–16505 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 guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''	De Novo classification process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
801 and 809	Medical Device Labeling Regulations	0910–0485

Dated: May 14, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10598 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–2017–D–5767]

Abbreviated New Drug Applications for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of Recombinant Deoxyribonucleic Acid; Guidance for Industry; 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 a final guidance for industry entitled ''ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin.'' This guidance is intended to assist potential applicants in determining when an application for a synthetic peptide drug product that refers to a previously approved peptide drug product of Recombinant Deoxyribonucleic Acid (rDNA) origin should be submitted as an abbreviated new drug application (ANDA) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) rather than as a new drug application (NDA) under the FD&C Act. This guidance finalizes the draft guidance of the same title issued on October 3, 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on May 20, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2017–D–5767 for ''ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin.'' 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