thickness thermal burns. Subsequent to this approval, the USPTO received a patent term restoration application for NEXOBRID (U.S. Patent No. 8,540,983) from MediWound, Ltd., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 30, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of NEXOBRID represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for NEXOBRID is 7,427 days. Of this time, 6,514 days occurred during the testing phase of the regulatory review period, while 913 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* August 30, 2002. The applicant claims August 29, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 30, 2002, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* June 29, 2020. FDA has verified the applicant's claim that the biologics license application (BLA) for NEXOBRID (BLA 761192) was initially submitted on June 29, 2020.

3. *The date the application was approved:* December 28, 2022. FDA has verified the applicant's claim that BLA 761192 was approved on December 28, 2022.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: December 13, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31022 Filed 12–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5016]

Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices; Draft 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 draft guidance for industry entitled ''Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices.'' This draft guidance provides recommendations to assist sponsors, clinical investigators, and institutional review boards (IRBs) in defining, identifying, and reporting protocol deviations. The guidance provides definitions for protocol deviations and important protocol deviations. In addition, the guidance provides a recommended classification system for sponsors to report protocol deviations to FDA in clinical study reports for drugs, biological products, and devices; for investigators to report protocol deviations to sponsors and to IRBs; and for IRBs to evaluate protocol deviations.

DATES: Submit either electronic or written comments on the draft guidance by February 28, 2025 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–2023–D–5016 for ''Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices.'' 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)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or 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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993, 240–402–8926; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Soma Kalb, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G318, Silver Spring, MD 20993–0002, 301–796–6359.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices.'' Protocols document the study design, objectives, population, planned procedures, investigational product management, method(s) of data capture, monitoring and oversight plans, and statistical analysis plans either directly or by reference to associated investigational plans. In the conduct of a clinical investigation, some deviations from the specifics outlined in the protocol may occur.

This guidance provides recommendations to assist sponsors, clinical investigators, and IRBs in defining, identifying, and reporting protocol deviations. FDA regulations do not include a definition of the term protocol deviation or provide a system for classifying the various types of deviations that may occur during the conduct of a clinical investigation. A system that applies consistent classification, reporting, and documentation standards is important to assure the most interpretable and useful information emerges from the reporting of protocol deviations. To address these considerations, this guidance includes (1) definitions for protocol deviations and important protocol deviations, (2) recommendations on the types of protocol deviations that sponsors should report to FDA in clinical study reports, (3) recommendations on the types of protocol deviations that investigators should report to sponsors and to IRBs, and (4) recommendations for IRBs in their evaluation of protocol deviations.

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 ''Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices.'' 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. 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 21 CFR part 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 320 have been approved under OMB control number 0910–0291; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231.

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/regulatory-information/search-fda-guidance-documents, 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: December 17, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31261 Filed 12–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2149]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; De Novo Classification Process (Evaluation of Automatic Class III Designation)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 29, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0844. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

De Novo Classification Process (Evaluation of Automatic Class III Designation)—21 CFR Part 860, Subpart D

OMB Control Number 0910–0844—Revision

This information collection supports FDA regulations and information collection discussed in associated guidance. Sections 201(h), 513(a) and (f), 701(a), and 704 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(h), 360c(a) and (f), 371(a), and 374) establish a comprehensive system for the regulation of medical devices intended for human use. Section 513(f)(2) of the FD&C Act provides for a ''De Novo'' classification process, most recently amended by section 3101 of the 21st Century Cures Act (Pub. L. 114–255). The final rule ''Medical Device De Novo Classification Process'' (86 FR 54826), established part 860, subpart D (21 CFR part 860, subpart D) (§§ 860.200 through 860.260) to implement provisions in section 513(f)(2) of the FD&C Act. These regulations govern format and content elements for De Novo device classification requests, as well as withdrawal of the requests, and explain FDA procedures for acceptance, review, and granting or denying a request.

FDA's guidance for industry and FDA staff, ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'', provides guidance on the process for the submission and review of a De Novo classification request under section 513(f)(2) of the FD&C Act, also known as the De Novo classification process. This process provides a pathway to class I or class II classification for medical devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

In addition to regulatory requirements set forth in part 860, subpart D, the guidance document entitled ''Acceptance Review for De Novo Classification Requests'' communicates our thinking on criteria set out in § 860.230, in assessing whether a De Novo request should be accepted for substantive review. The guidance document includes an ''Acceptance Checklist'' to assist respondents in this regard.

The guidance document ''Electronic Submission Template for Medical Device De Novo Requests,'' provides the standards for the submission of De Novo requests by electronic format, a timetable for establishment of these standards, and criteria for waivers of and exemptions from the requirements to meet a statutory requirement. This guidance is also intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process.

The collections of information described by this notice are necessary to satisfy the previously mentioned statutory requirements for administration of this voluntary submission program. FDA uses the information to evaluate whether a medical device may be reclassified from class III into class I or II and, if applicable, to determine the general and/or special controls necessary to sufficiently regulate the medical device. Respondents to this information collection are private sector or other for-profit businesses.

In the **Federal Register** of May 29, 2024 (89 FR 46402), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR part 860, subpart D; information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 860.210, 860.220, 860.230; De Novo requests—format, content, and acceptance elements.	79	1	79	182	14,378
§ 860.230; FDA acceptance of request (*GFI Acceptance Checklist;* Appendix A) [1].	79	1	79		