

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.

FOR FURTHER INFORMATION CONTACT:

Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM. ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM is indicated in conjunction with cataract surgery for the reduction of intraocular pressure in adult patients with mild to moderate primary open angle glaucoma. Subsequent to this approval, the USPTO received patent term restoration applications for ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (U.S. Patent Nos.

7,867,186; 9,301,875; and 9,597,230) from Glaukos Corporation, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated June 21, 2019, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM 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 ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM is 2,508 days. Of this time, 2,330 days occurred during the testing phase of the regulatory review period, while 178 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* August 11, 2011. FDA has verified the applicant's claim that the date the investigational device exemption for human tests to begin, as required under section 520(g) of the FD&C Act became effective, was August 11, 2011.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* December 26, 2017. The applicant claims December 21, 2017, as the date the premarket approval application (PMA) for ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (PMA 170043) was initially submitted. However, FDA records indicate that PMA 170043 was submitted on December 26, 2017.

3. *The date the application was approved:* June 21, 2018. FDA has verified the applicant's claim that PMA 170043 was approved on June 21, 2018.

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 applications for patent extension, this applicant seeks 1,345 days, 496 days, or 1,783 days 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: July 10, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-15295 Filed 7-14-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-3769]

Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act; 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 a final guidance entitled "Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act." Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the FDA Reauthorization Act of 2017 (FDARA) require that certain pre-submissions and submissions for devices be submitted in

electronic format specified by FDA beginning on such date as specified in final guidance. It also mandates that FDA issue draft guidance not later than October 1, 2019, and a final guidance not later than 1 year after the close of the public comment period, providing for further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements. In addition, in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter from the Secretary of Health and Human Services to Congress, FDA committed to developing electronic submission templates, and issuing a draft guidance on the topic. No later than 12 months after the close of the public comment period, the Agency will issue a final guidance. This guidance is intended to satisfy the final guidance documents referenced in the FDA&C Act and the MDUFA IV Commitment Letter.

DATES: The announcement of the guidance is published in the **Federal Register** on July 15, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidance documents 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-3769 for "Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act." 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 § 10.115 (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 "Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act" 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, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT:

Jacqueline Gertz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1655, Silver Spring, MD 20993-0002, 240-402-9677 or Stephen Ripley, 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

Section 745A(b) of the FD&C Act (21 U.S.C. 379k-1(b)), amended by section 207 of FDARA (Pub. L. 115-52), requires that pre-submissions and submissions for devices under section 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f), 520(g), 520(m), or 564 of the FD&C Act (21 U.S.C. 360(k), 360c(f)(2)(A), 360e(c), 360e(d), 360e(f), 360j(g), 360j(m), or 360bbb-3) or section 351 of the Public Health Service Act (42 U.S.C. 262) and any supplements to such pre-submissions or submissions, including appeals of those submissions, be submitted in electronic format specified by FDA beginning on such date as specified by FDA in final guidance. It also mandates that FDA issue a draft guidance not later than

October 1, 2019, providing for further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements. In addition, in the MDUFA IV Commitment Letter¹ from the Secretary of Health and Human Services to Congress, FDA committed to developing “electronic submission templates that will serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process” and “by FY [fiscal year] 2020, the Agency will issue a draft guidance document on the use of the electronic submission templates.” No later than 12 months after the close of the public comment period, the Agency will issue a final guidance. This guidance is intended to satisfy the final guidance documents referenced in section 745A(b)(3) of the FD&C Act and the MDUFA IV Commitment Letter.

The Agency has concluded that it is not feasible to describe and implement the electronic format(s) that would apply to all the submissions covered by section 745A(b) of the FD&C Act in one guidance document. Accordingly, this guidance describes how FDA interprets and plans to implement the requirements of section 745A(b)(3) of the FD&C Act, while individual guidances will be developed to specify the formats for specific submissions and corresponding timetables for implementation. Specifically, this guidance discusses: (1) The submission types that must be submitted electronically, (2) criteria for waivers of and exemptions from the submissions in electronic format requirements, and (3) the timetable and process for implementing the requirements.

A notice of availability for the draft guidance appeared in the **Federal**

Register of November 25, 2019 (84 FR 50850). FDA considered the comments received and revised the guidance as appropriate in response to the comments, including an update to add real-time review Premarket approval application (PMA) supplements and a clarification that we intend to consider the time period necessary to transition to use of the electronic format when identifying the date on which electronic format will be required.

In section 745A(b) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the statutory requirement for electronic submissions solely in electronic format by providing standards, a timetable, and criteria for waivers and exemptions. To the extent that this document provides such requirements under section 745A(b)(3) of the FD&C Act (*i.e.*, standards, timetable, criteria for waivers of and exemptions), indicated by the use of the mandatory words, such as must or required, this document is not subject to the usual restrictions in FDA’s good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. (See § 10.115(d).)

However, this document also contains guidance on additional submission types for which submission in electronic format is not required. To the extent that this guidance describes recommendations that are not standards, timetable, criteria for waivers of, or exemptions under section 745A(b)(3), it is being issued in accordance with FDA’s good guidance practices regulation (§ 10.115). This guidance represents the Agency’s current thinking on this topic, and do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used for these

recommendations if such an approach satisfies the requirements of the applicable statutes and regulations. This final guidance contains both binding and nonbinding provisions.

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 is also available at <https://www.regulations.gov> or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>. Persons unable to download an electronic copy of “Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 19031 to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

| 21 CFR part or guidance | Topic | OMB control No. |
|---|---|-----------------|
| 807, subpart E | Premarket Notification Submission | 0910–0120 |
| 814, subparts A through E | Premarket Approval Application | 0910–0231 |
| 814, subpart H | Humanitarian Use 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 |
| “FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act”. | 513(g) Request for Information | 0910–0705 |
| “Requests for Feedback on Medical Device Submissions: The Q-Submission Program and Meetings with Food and Drug Administration Staff”. | Pre-Submissions | 0910–0756 |
| 800, 801, and 809 | Medical Device Labeling Regulations | 0910–0485 |
| 820 | Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation. | 0910–0073 |

¹ <https://www.fda.gov/media/102699/download>.

| 21 CFR part or guidance | Topic | OMB control No. |
|---|---|-----------------|
| "Humanitarian Device Exemption Regulation: Q&As" | Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements. | 0910-0661 |
| "Emergency Use Authorization of Medical Products" | Emergency Use Authorization | 0910-0595 |
| 601 | Biologics License Applications | 0910-0338 |
| "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices". | CLIA Waiver Applications | 0910-0598 |
| "Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization". | Administrative Procedures for CLIA Categorizations | 0910-0607 |

Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-15250 Filed 7-14-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1396]

Use of Data From Foreign Investigational Studies To Support Effectiveness of New Animal Drugs; 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 (GFI) #265 entitled "Use of Data from Foreign Investigational Studies to Support Effectiveness of New Animal Drugs." The draft guidance, if finalized, will describe FDA's current thinking with respect to assisting sponsors in incorporating data from foreign countries into proposed clinical investigational protocols and applications for new animal drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by October 13, 2020 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-2020-D-1396 for "Use of Data from Foreign Investigational Studies to Support Effectiveness of New Animal Drugs." 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 guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See