

fusion or other rearrangement as detected by an FDA-approved test. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Subsequent to this approval, the USPTO received a patent term restoration application for Truseltiq (U.S. Patent No. 8,552,002) from QED Therapeutics, Inc. (agent of Novartis AG), and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 18, 2023, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of Truseltiq 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 Truseltiq is 4,258 days. Of this time, 4,016 days occurred during the testing phase of the regulatory review period, while 242 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* October 2, 2009. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 2, 2009.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* September 29, 2020. FDA has verified the applicant's claim that the new drug application (NDA) for Truseltiq (NDA 214622) was initially submitted on September 29, 2020.

3. *The date the application was approved:* May 28, 2021. FDA has verified the applicant's claim that NDA 214622 was approved on May 28, 2021.

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 1,516 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: December 1, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–26885 Filed 12–6–23; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2015–D–3539]

#### Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act; 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 “Interim Policy on Compounding Using Bulk Drug Substances Under section 503B of the Federal Food, Drug, and Cosmetic Act” (draft guidance or 2023 503B Interim Policy Draft Guidance) to describe FDA's interim policy regarding the use of bulk drug substances in compounding by outsourcing facilities while FDA develops the list of bulk drug substances that outsourcing facilities can use in compounding under

the applicable section of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This draft guidance, when finalized, will replace the guidance for industry entitled, “Interim Policy on Compounding Using Bulk Drug Substances Under section 503B of the Federal Food, Drug, and Cosmetic Act” issued in January 2017 (2017 503B Interim Policy Guidance).

**DATES:** Submit either electronic or written comments on the draft guidance by January 8, 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–

2015–D–3539 for “Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B 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 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. 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:**

Rechelle Buford, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–0447.

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act.” This draft guidance, when finalized, will replace the 2017 503B Interim Policy Guidance, available at <https://www.fda.gov/media/94402/download>.

Section 503B of the FD&C Act (21 U.S.C. 353b) describes the conditions that must be satisfied for human drug products compounded by an outsourcing facility to be exempt from the following three sections of the FD&C Act: (1) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications); (2) section 502(f)(1) (21 U.S.C. 352(f)(1) (concerning the labeling of drugs with adequate directions for use); and (3) section 582 (21 U.S.C. 360eee–1) (concerning drug supply chain security requirements). One of the conditions that must be met for a drug product compounded by an outsourcing facility to qualify for these exemptions is that the outsourcing facility does not compound a drug using a bulk drug substance unless: (1) the bulk drug substance appears on a list established by the Secretary of Health and Human Services identifying bulk drug substances for which there is a clinical need (the 503B bulks list) (see section 503B(a)(2)(A)(i)) or (2) the drug compounded from such bulk drug substances appears on the drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) at the time of compounding, distribution, and dispensing (see section 503B(a)(2)(A)(ii) of the FD&C Act).

This draft guidance, when finalized, will revise FDA’s current interim policy with respect to categorization of certain substances nominated for inclusion on the 503B bulks list. The guidance, when finalized, would end the categorization of bulk drug substances into Categories 1, 2, or 3 for those bulk drug substances nominated on or after the date of publication of the final guidance.

The 2017 503B Interim Policy Guidance describes the conditions

under which FDA does not intend to take action against an outsourcing facility for compounding a drug using certain bulk drug substances that are not eligible for use in compounding under section 503B because they do not appear on the 503B bulks list and that are not used to compound a drug that appears on the FDA drug shortage list at the time of compounding, distribution, and dispensing. One of those conditions is that the bulk drug substance appears in Category 1. If the 2023 503B Interim Policy Draft Guidance is finalized in its current form, a substance nominated on or after the date of publication of that final guidance would not be categorized and would not be within the scope of the policy for substances that appear in Category 1.<sup>1</sup> However, FDA would consider the substance for inclusion on the 503B bulks list in accordance with the process and clinical need standard established in the FD&C Act (see section 503B(a)(2)(A)(i) of the FD&C Act). Substances that already appear in Category 1 (including substances nominated with adequate supporting information prior to the date of publication of the final guidance) may continue to be eligible for the policy that applies to Category 1 substances, as described in the final guidance, until FDA makes a final determination whether they will be placed on the 503B bulks list in accordance with section 503B(a)(2)(A)(i) of the FD&C Act or unless the Agency removes the substances from Category 1 based on, for example, information about safety risks.

FDA encourages interested parties to focus their comments on the limited revisions to the interim policy included, for public comment, in the 2023 503B Interim Policy Draft Guidance.

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 the “Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act.” 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.

<sup>1</sup> FDA recognizes that some compounders and other stakeholders may currently be in the process of compiling a nomination for the 503B bulks list for submission to the Agency. FDA intends to categorize nominations of bulk drug substances received prior to the date in which FDA announces the availability of the final guidance. FDA believes that this will provide a sufficient amount of time in which to submit nominations that are currently in progress.

## II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## 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>, or <https://www.regulations.gov>.

Dated: December 1, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–26845 Filed 12–6–23; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–D–3462]

#### Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs; 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 “Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs.” The guidance addresses the verification systems that manufacturers, repackagers, wholesale distributors, and dispensers must have in place to comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Drug Supply Chain Security Act (DSCSA). Specifically, the guidance covers the statutory verification systems requirements that include the quarantine and investigation of a product determined to be suspect and the quarantine and disposition of a product determined to be illegitimate. The guidance also addresses the statutory requirement for notification to the Agency of a product that has been cleared by a manufacturer, repackager, wholesale distributor, or dispenser (also referred to as “trading partners”) after a suspect product investigation because it is determined that the product is not an

illegitimate product. Finally, the guidance addresses the statutory requirement for responding to requests for verification and processing saleable returns. The guidance finalizes the revised draft guidance “Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs,” issued on March 10, 2022.

**DATES:** The announcement of the guidance is published in the **Federal Register** on December 7, 2023.

**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–2018–D–3462 for “Verification Systems Under the Drug Supply Chain Security

Act for Certain Prescription Drugs; Guidance for Industry; Availability.” 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 this 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; or to Office of Communication, Outreach and Development, Center for