submissions of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for the submissions of new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 for the submissions of biologics license application and supplemental applications have been approved under OMB control number 0910–0338.

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Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: June 13, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13429 Filed 6–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0020]

SpecGX, LLC, et al.; Withdrawal of Approval of 30 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on March 29, 2024. The document announced the withdrawal of approval of 30 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of April 29, 2024. The document indicated that FDA was withdrawing approval of the following ANDAs after receiving withdrawal requests from Target Health LLC, U.S. Agent for CASI Pharmaceuticals, Inc., 450 Commerce Blvd., Carlstadt, NJ 07072: ANDA 076280, Tizanidine Hydrochloride (HCl) Tablets, Equivalent to (EQ) 2 milligrams (mg) base and EQ 4 mg base; ANDA 077021, Cilostazol Tablets, 100 mg; ANDA 077310, Cilostazol Tablets, 50 mg; ANDA 077517, Ondansetron HCl Tablets, EQ 4 mg base, EQ 8 mg base, and EQ 24 mg base; ANDA 206672, Entecavir Tablets, 0.5 mg and 1 mg; and ANDA 209550, Tenofovir Disoproxil Fumarate Tablets, 300 mg. Before FDA withdrew the approval of these ANDAs, Target Health LLC, informed FDA that it did not want the approval of the ANDAs withdrawn. Because Target Health LLC, timely requested that approvals of ANDAs 076280, 077021, 077310, 077517, 206672, and 209550 not be withdrawn, the approvals are still in effect. This notice corrects that error.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, March 29, 2024 (89 FR 22155), appearing on page 22155 in FR Doc. 2024–06730, the following correction is made:

On page 22155, in the table, the entries for ANDAs 076280, 077021, 077310, 077517, 206672, and 209550 are removed.

Dated: June 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13658 Filed 6–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0710]

Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection; Guidance for Industry, Revision 1; 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, ''Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection.'' The FDA Reauthorization Act of 2017 (FDARA) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) so that, as is the case with a drug, a device is deemed to be adulterated if the owner, operator, or agent of the factory, warehouse, or establishment at which the device is manufactured, processed, packed, or held delays, denies, or limits an FDA inspection. This final guidance describes, for both drugs and now devices, the types of behaviors (actions, inactions, and circumstances) that FDA considers to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection. This guidance finalizes the draft guidance of the same title issued on December 16, 2022, and supersedes the October 2014 final guidance entitled, ''Circumstances That Constitute Delaying, Limiting, or Refusing a Drug Inspection.''

DATES: The announcement of the guidance is published in the **Federal Register** on June 21, 2024.

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–

2013–D–0710 for ''Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection.'' 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 a single hard copy of the guidance entitled ''Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection'' to the Office of Policy, Compliance and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Drive, Element Building, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lola Burford, Office of Regulatory Affairs, Division of Operational Policy, Food and Drug Administration, 12420 Parklawn Drive, Element Building, Rockville, MD 20857, *Lola.Burford@fda.hhs.gov,* 240–402–5865.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) added section 501(j) to the FD&C Act (21 U.S.C. 351(j)) to deem adulterated a drug that ''has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.'' Section 707(b) of FDASIA required the Food and Drug Administration to issue guidance that defined the circumstances that would constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, for purposes of section 501(j). In the **Federal Register** of October 22, 2014 (79 FR 63130), FDA announced the availability of a guidance for industry entitled, ''Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection'' (hereinafter, 2014 guidance).

Subsequently, on August 18, 2017, FDARA (Pub. L. 115–52) was signed into law. Section 702 of FDARA amended the scope of section 501(j) of the FD&C Act to provide that, as the case with drugs, devices are deemed to be adulterated if an FDA inspection is delayed, denied, limited, or refused by the owner, operator, or agent of the establishment at which the device is manufactured, processed, packed, or held. This final guidance supersedes the 2014 final guidance to incorporate devices and to explain the circumstances that FDA would consider to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, resulting in a drug or device manufactured in the facility being deemed adulterated.

This final guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). FDA considered the comments received on the draft guidance and did not make substantial changes from the draft to the final guidance. This final guidance represents the current thinking of FDA on ''Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection'' 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

This 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 either *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/search-general-and-cross-cutting-topics-guidance-documents* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection'' may send an email request to *ORAPolicyStaffs@fda.hhs.gov* to receive an electronic copy of the document.

Dated: June 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13674 Filed 6–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0783]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products and Licensed Devices

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