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Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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document announced the withdrawal of approval of 30 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of April 29, 2024.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withdrew the approval of these ANDAs, Target Health LLC, informed FDA that it did not want the approval of the ANDAs withdrawn.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Target Health LLC, timely requested that approvals of ANDAs 076280, 077021, 077310, 077517, 206672, and 209550 not be withdrawn, the approvals are still in effect.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–