Articles Containing Active Pharmaceutical Ingredient(s) Considered to be Poorly Soluble in Aqueous Media, That Exhibit Little to No Systemic Bioavailability, and Are Locally Acting.'' 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 section 512(n)(1) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: June 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13690 Filed 6–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–N–4066; FDA–2023–N–0918; FDA–2023–N–4259; FDA–2023–N–4849; and FDA–2021–N–0471]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
FDA Recall Regulations	0910–0249	6/30/2027
Food Labeling Regulations	0910–0381	5/31/2027
Export Certificates for FDA Regulated Products	0910–0498	6/30/2027
Food Allergen Labeling and Reporting	0910–0792	6/30/2027
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption—Agricultural Water	0910–0816	6/30/2027

Dated: June 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13638 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–2017–D–0154]

Considerations in Demonstrating Interchangeability With a Reference Product: Update; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Considerations in Demonstrating Interchangeability With a Reference Product: Update.'' This draft guidance describes considerations regarding a switching study or studies intended to support a demonstration that a proposed therapeutic protein product is interchangeable with a reference product for the purposes of submitting a marketing application or supplement under the Public Health Service Act (PHS Act). After considering any comments received in the docket for this draft guidance, we intend to revise the final guidance for industry entitled ''Considerations in Demonstrating Interchangeability With a Reference Product'' issued on May 14, 2019, to amend sections in that document regarding the subject addressed in this draft guidance.

DATES: Submit either electronic or written comments on the draft guidance by August 20, 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–2017–D–0154 for ''Considerations in Demonstrating Interchangeability With a Reference Product: Update.'' 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; or 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. 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: Mustafa Unlu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1139, Silver Spring, MD 20993, 301–796–3396; 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Considerations in Demonstrating Interchangeability With a Reference Product: Update.'' This draft guidance describes considerations regarding a switching study or studies intended to support a demonstration that a proposed therapeutic protein product is interchangeable with a reference product for the purposes of submitting a marketing application or supplement under section 351(k) of the PHS Act (42 U.S.C. 262(k)). After considering any comments received in the docket for this draft guidance, we intend to revise the final guidance for industry entitled ''Considerations in Demonstrating Interchangeability With a Reference Product'' (Interchangeability Guidance) issued on May 14, 2019 (84 FR 21342) to amend sections in that document regarding the subject addressed in this draft guidance.

FDA issued the Interchangeability Guidance before receiving and reviewing any biologics license applications submitted under section 351(k) of the PHS Act for a proposed interchangeable biosimilar product. Since publication of the Interchangeability Guidance, experience has shown that for the products approved as biosimilars to date, the risk in terms of safety or diminished efficacy is insignificant following single or multiple switches between a reference product and a biosimilar product. Accordingly, FDA's scientific approach to when a switching study or studies may be needed to support a demonstration of interchangeability has evolved.

This draft guidance is not intended to be finalized as a standalone guidance. Instead, the recommendations in this draft guidance, when finalized, are intended to revise the Interchangeability Guidance and to replace sections in that document, such as sections VI.A and VII, to reflect FDA's current thinking regarding the subject addressed in this guidance. FDA is issuing this draft guidance to seek public comment through the accompanying docket.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). 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 for the submission of a biologics license application or supplemental application under section 351(k) of the PHS Act have been approved under OMB control number 0910–0718. The collections of information in 21 CFR part 312 for the

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–