TABLE—ANDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
ANDA 040118	Carisoprodol, Aspirin and Codeine Phosphate Tablets, 325 milligrams (mg), 200 mg, and 16 mg.	Sandoz Inc., 100 College Rd. West, Princeton, NJ 08540.
ANDA 040291	Fluorouracil Injection, 50 mg/milliliters (mL)	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 071849	Morphine Sulfate Injectable, 0.5 mg/mL	Hospira, Inc., 275 North Field Dr., Building H1–3S, Lake Forest, IL 60045.
ANDA 074133	Metoprolol Tartrate Injectable, 1 mg/mL	Do.
ANDA 076648	Nitrofurantoin (Monohydrate/Macrocrystals) Capsules, 75 mg, and 25 mg.	Aurobindo Pharma USA Inc., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520.
ANDA 077387	Ondansetron Hydrochloride (HCl) Preservative Free Injection, Equivalent to (EQ) 2 mg base/mL.	American Regent, Inc., 5 Ramsey Rd., Shirley, NY 11967.
ANDA 077582	Ondansetron HCl Injectable, EQ 2 mg base/mL	Do.
ANDA 079039	Ondansetron HCl Injection, EQ 2 mg base/mL	Do.
ANDA 087440	Dexamethasone Sodium Phosphate Injection, EQ 4 mg phosphate/mL.	Do.
ANDA 088388	Mepivacaine HCl and Levonordefrin Injection, 0.05 mg/mL; 2%.	ICON Clinical Research, LLC, U.S. Agent for Deproco, Inc., 4130 ParkLake Ave., Suite 400, Raleigh, NC 27612.
ANDA 090578	Ampicillin and Sulbactam For Injection, EQ 10 grams(g) base/vial and EQ 5 grams (g) base/vial.	EAS Consulting Group, LLC, U.S. Agent for Astral SteriTech Pvt. Ltd., 1700 Diagonal Rd., #750, Alexandria, VA 22314.
ANDA 090579	Ampicillin and Sulbactam For Injection, EQ 1 g base/vial, EQ 500 mg base/vial, EQ 2 g base/vial, and EQ 1 g base/vial.	Do.
ANDA 090723	Duloxetine HCl Capsules, Delayed-Release Pellets, EQ 20 mg base, EQ 30 mg base, and EQ 60 mg base.	Marksans Pharma, Inc., U.S. Agent for Marksans Pharma Ltd., 150 Motor Pkwy., Suite 401, 4th Floor, Rm. 430, Hauppauge, NY 11788.
ANDA 207266	Bupivacaine HCl Injectable, 0.75%	Baxter Healthcare Corp., One Baxter Pkwy., Deerfield, IL 60015.
ANDA 207794	Busulfan Injection, 6 mg/mL	Nexus Pharmaceuticals, Inc., 400 Knightsbridge Pkwy., Lincolnshire, IL 60069.
ANDA 209068	Chlorthalidone Tablets, 25 mg and 50 mg	Elity LLC, U.S. Agent for Sunny Pharmtech Inc., 175 SW 166th Ave., Pembroke Pines, FL 33027.
ANDA 212223	Captopril Tablets, 12.5 mg, 25 mg, 50 mg, and 100 mg	Pharmobedient Consulting, LLC, U.S. Agent for Seton Pharmaceuticals, LLC, 642 North East 3rd Ave., Fort Lauderdale, FL 33304.
ANDA 212287	Piperacillin and Tazobactam For Injection, EQ 2 g base/vial, EQ 250 mg base/vial, EQ 3 g base/vial, EQ 375 mg base/vial, EQ 4 g base/vial, and EQ 500 mg base/vial.	EAS Consulting Group, LLC.
ANDA 212721	Cefepime HCl For Injection, EQ 1 g base/vial and EQ 2 g base/vial.	Do.
ANDA 213552	Succinylcholine Chloride Injection, 20 mg/mL	Nexus Pharmaceuticals, Inc.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of July 22, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on July 22, 2024 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: June 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13660 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–2023–D–1275]

Demonstrating Bioequivalence for Type A Medicated 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; 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 (GFI) #279 entitled ''Demonstrating Bioequivalence

for Type A Medicated 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.'' This final guidance describes an approach to satisfy the requirements for the completion of the Bioequivalence technical section for generic Type A medicated articles (TAMAs) containing poorly soluble, locally acting, active pharmaceutical ingredients (APIs) that have little to no systemic absorption, and for which blood level studies are not considered appropriate to demonstrate product bioequivalence. The suggested approach described in this guidance uses a combination of in vitro and in vivo data to support a determination of bioequivalence to address the unique challenges associated with demonstrating bioequivalence of TAMAs containing poorly soluble, locally acting APIs that have little to no systemic absorption.

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

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–2023–D–1275 for ''Demonstrating Bioequivalence for Type A Medicated 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.'' 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 the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Ian Hendricks, Center for Veterinary Medicine (HFV–172), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0853, *Ian.Hendricks@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 8, 2023 (88 FR 37551), FDA published the notice of availability for a draft guidance entitled ''Demonstrating Bioequivalence for Type A Medicated 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,'' giving interested persons until August 7, 2023, to comment on the draft guidance. In response to a request for an extension, we extended the comment period for the draft guidance to October 16, 2023 (August 16, 2023, 88 FR 55702).

FDA received two comment submissions on the draft guidance and those comments were considered as the guidance was finalized. For example, we revised the final guidance to clearly state that it does not cover APIs that are systemically absorbed because they are already addressed in other guidances. In addition, several editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated June 8, 2023.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Demonstrating Bioequivalence for Type A Medicated

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