develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on February 18, 2022 (87 FR 9366). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's website.

II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Arsenic trioxide.
Acetaminophen.
Asenapine.
Bupivacaine.
Cedazuridine; Decitabine.
Chlorhexidine gluconate.
Cocaine hydrochloride.
Exenatide synthetic (multiple referenced listed drugs).
Flunisolide.
Halobetasol propionate.
Hydrocortisone; Neomycin sulfate; Polymyxin B sulfate.
Ibuprofen.
Lorezepam.
Naloxone hydrochloride.
Oliceridine.
Palbociclib.
Pralsetinib.
Risdiplam.
Secretin synthetic human.
Solifenacin succinate.
Tegaserod maleate.
Torsemide.
Triheptanoin.

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Acarbose.
Doxorubicin hydrochloride.
Linaclotide.
Metoprolol succinate.
Midostaurin.
Oseltamivir phosphate.
Selinexor.
Solifenacin succinate.
Theophylline.
Tiopronin.
Torsemide.
Trametinib dimethyl sulfoxide.
Uridine triacetate.

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

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

V. 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: May 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–10701 Filed 5–19–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0766]

Hospira, Inc., et al.; Withdrawal of Approval of 21 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 21 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of June 21, 2022.

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, 240–402–6980, *Martha.Nguyen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040140	Diphenhydramine Hydrochloride (HCl) Injection, 50 milligrams (mg)/milliliters (mL).	Hospira, Inc., 275 North Field Dr., Building H1–3S, Lake Forest, IL 60045.
ANDA 040578	Benzphetamine HCl Tablets, 50 mg	ScinoPharm Taiwan, Ltd., 909 N Ford Ave., Fullerton, CA 92832.
ANDA 065267	Cefprozil Tablets, 250 mg, and 500 mg	Bionpharma Inc., 600 Alexander Rd., Suite 2–4B, Princeton, NJ 08540.
ANDA 065284	Cefprozil Oral Suspension, 125 mg/5 mL and 250 mg/5 mL	Do.

Application No.	Drug	Applicant
ANDA 065301	Cefadroxil Tablets, Equivalent to (EQ) 1 gram (g) base	Do.
ANDA 065307	Cefadroxil Oral Suspension, EQ 250 mg base/5 mL and EQ 500 mg base/5 mL.	Do.
ANDA 065309	Cefadroxil Capsules, EQ 500 mg base	Do.
ANDA 065326	Cephalexin Oral Suspension, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL.	Do.
ANDA 076720	Morphine Sulfate Extended Release Tablets, 30 mg, and 60 mg.	Nesher Pharmaceuticals (USA) LLC., 13910 Saint Charles Rock Rd., Bridgeton, MO 63044.
ANDA 076733	Morphine Sulfate Extended Release Tablets, 15 mg	Do.
ANDA 077855	Morphine Sulfate Extended Release Tablets, 100 mg and 200 mg.	Do.
ANDA 080225	Potassium Chloride Injection, 2 milliequivalent (mEq)/mL and 3 mEq/mL.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 202393	Diclofenac Sodium Topical Solution, 1.5%	TWi Pharmaceuticals, Inc., 536 Vanguard Way, Brea, CA 92821.
ANDA 203581	Glyburide Tablets, 1.25 mg, 2.5 mg, and 5 mg	Sunny Pharmtech Inc., 175 SW 166th Ave., Pembroke Pines, FL 33027.
ANDA 204137	Omeprazole and Sodium Bicarbonate Capsules, 20 mg; 1.1 g.	Unicorn Pharmaceuticals, 5 Links Circle, Durham, NC 27707.
ANDA 206588	Dextroamphetamine Sulfate Tablets, 5 mg, and 10 mg	Nesher Pharmaceuticals (USA) LLC.
ANDA 208263	Doxycycline Hyclate Capsules, EQ 50 mg base and EQ 100 mg base.	Do.
ANDA 209111	Dextroamphetamine Sulfate Extended Release Capsules, 5 mg, 10 mg, and 15 mg.	Do.
ANDA 210079	Oxycodone and Acetaminophen Tablets, 325 mg; 2.5 mg, 325 mg; 5 mg, 325 mg; 7.5 mg, 325 mg; 10 mg.	Do.
ANDA 210080	Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Extended Release Capsules, 1.25 mg; 1.25 mg; 1.25 mg; 1.25 mg, 2.5 mg; 2.5 mg; 2.5 mg; 2.5 mg, 3.75 mg; 3.75 mg; 3.75 mg; 3.75 mg, 5 mg; 5 mg; 5 mg; 5 mg, 6.25 mg; 6.25 mg; 6.25 mg; 6.25 mg, 7.5 mg; 7.5 mg; 7.5 mg; 7.5 mg.	Do.
ANDA 211543	Butalbital, Acetaminophen, and Caffeine Tablets, 325 mg; 50 mg; 40 mg.	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of June 21, 2022. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on June 21, 2022, 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: May 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–10924 Filed 5–19–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0277]

Risk Management Plans To Mitigate the Potential for Drug Shortages; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Risk Management Plans to Mitigate the Potential for Drug Shortages.'' This draft guidance is intended to help stakeholders develop, maintain, and implement, as appropriate, risk management plans (RMPs) to proactively assist in the prevention of human drug product and biological product shortages. In March 2020, with the enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), the Federal Food, Drug, and Cosmetic Act (FD&C Act) was amended to require certain manufacturers to develop, maintain, and implement, as appropriate, a ''redundancy risk management plan.'' This draft guidance provides information about the development and content of RMPs for those manufacturers as well as for other stakeholders. This draft guidance recommends a framework and factors to consider that stakeholders can use to develop RMPs. This draft guidance is relevant for all stakeholders, including those with oversight and control responsibilities for drug quality and contract establishments, and for manufacturers of active pharmaceutical ingredients (APIs), approved or licensed drug and biological products, and drug products marketed without an application.

DATES: Submit either electronic or written comments on the draft guidance by July 19, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by July 19, 2022.