dissemination strategies, and public information programs; (2) testing health messages, strategies, and program components while they are in developmental form to assess audience comprehension, reactions, and perceptions, as well as after they have been disseminated to consumers; and (3) adding to the tobacco control, public health communication, and regulatory science knowledge base. Quantitative studies play an important role in exploring areas of research and gathering information because they can be used to summarize a population of interest on key variables or reveal systematic relationships between variables.

This foundational research has helped FDA to understand audiences and inform message development and the testing of messages in communicating the risks of tobacco use, how to quit using tobacco products, and FDA's role in regulating tobacco. Obtaining this information has allowed FDA to improve messages, materials and implementation strategies while revisions are still affordable and possible.

The voluntary information collected serves the primary purpose of providing FDA information about various measures of ad performance including, but not limited to, message comprehension, perceived effectiveness, emotional responses and knowledge, attitudes, and behavioral intentions to assess the ability of messages, advertisements, and materials to reach and successfully communicate with their intended audiences. Additionally, this information collection provides FDA with insights into how to best measure public education message performance. Quantitative testing of messages and other materials with a sample of the target audience allows FDA to refine and assess messages, advertisements, and materials directed at consumers.

In addition, quantitative information is collected under this umbrella generic by FDA to track changes in response to policy and regulatory actions and to expand the tobacco regulatory science base by providing information on changing behaviors, knowledge and attitudes about tobacco products, including post-marketing surveillance of tobacco products. In addition, quantitative information is collected by FDA to track changes in response to policy and regulatory actions and to expand the tobacco regulatory science base by providing information on changing behaviors, knowledge, and attitudes about tobacco products, including postmarketing surveillance of tobacco products.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Screener | 1,360,000 | 1 | 1,360,000 | 0.083 (5 minutes) | 113,334 |
| Self-Administered Surveys | 204,000 | 1 | 204,000 | 0.33 (20 minutes) | 68,000 |
| Informed Consent/Assent | 204,000 | 1 | 204,000 | .033 (2 minutes) | 6,800 |
| Total | 1,768,000 | | | | 188,134 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 96,269 hours and a corresponding increase of 1,106,692 responses. We attribute this adjustment to the number of study responses used during the current approval and now estimated for the next 3 years. A greater number of quantitative studies will be conducted over the next 3 years due to the need to develop new creative messages and content. Recent years have seen a dramatic change in media. With the shift to digital media, FDA must adapt to communicate effectively in a digital environment. As digital tobacco use prevention/interventions are still in their infancy, we must better understand the types of digital channels available. To impact public health outcomes, we need to understand how to reach our intended audience. New foundational studies are needed (including those on digital metrics, measurement, and implementation) to support activities and initiatives that will enable the public to receive evidence-based, timely, and clear health communication and education. As a result, we have adjusted our burden estimate and revised the number of respondents to the information collection.

Dated: June 17, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–13644 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–2803]**

### Sandoz Inc., et al.; Withdrawal of Approval of 20 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 20 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 July 22, 2024.

**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:** The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150© (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.

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