and a risk assessment entitled ''A Quantitative Assessment of Inorganic Arsenic in Apple Juice'' (the risk assessment document). We gave interested parties an opportunity to submit comments by September 13, 2013.

This guidance finalizes FDA's action level for inorganic arsenic in apple juice of 10 micrograms per kilogram (µg/kg) or 10 parts per billion (ppb) and identifies FDA's intended sampling and enforcement approach. The basis for the action level is set forth in the guidance document, as well as the risk assessment document originally made available on July 15, 2013, that can be accessed in the docket referenced above at *https://www.regulations.gov.* The guidance reviews data on inorganic arsenic levels in apple juice, health effects from exposure to inorganic arsenic, and the ability of manufacturers to achieve different levels of inorganic arsenic in apple juice. It also explains FDA's rationale for identifying an action level of 10 µg/kg or 10 ppb for inorganic arsenic in apple juice.

Arsenic is present in the environment as a naturally occurring substance or as a result of contamination from human activity. In foods, arsenic may be present as inorganic arsenic (the primary toxic form of arsenic) or organic arsenic. Exposure to inorganic arsenic is associated with adverse human health effects, including cancer and neurodevelopmental effects. Apple juice is one source of exposure to arsenic from food, and a greater potential source of exposure for children than adults, because children's dietary patterns are often less varied than those of adults, and they consume more apple juice relative to their body weight than do adults. We expect that the 10 µg/kg or 10 ppb action level, though non-binding, will help protect public health by encouraging manufacturers to reduce levels of inorganic arsenic in apple juice and therefore reduce human exposure to inorganic arsenic. We also expect that this level is achievable by industry with the use of current good manufacturing practices. We intend to consider the action level of 10 µg/kg or 10 ppb inorganic arsenic as an important source of information for determining whether apple juice is adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1)).

In finalizing the guidance, we incorporated data from the supporting document and added an analysis of new data on inorganic arsenic levels in apple juice, health effects from exposure to inorganic arsenic, and the ability of manufacturers to limit inorganic arsenic in apple juice, in evaluating the appropriate action level. We also made changes to the text for clarity, including explaining the term ''added'' in this context and that ''apple juice'' includes apple cider, and we have also revised the title of the guidance to more clearly show that we are setting an action level. In addition, we added information on our understanding of arsenical pesticide use in the United States and expanded the discussion of the rationale for setting an action level based on sampling and testing results and the discussion of FDA's sampling and enforcement approach. We also incorporated new references in support of these changes and to reflect the citation of recently published FDA data and a new reference to FDA's *Closer to Zero* action plan.

We also considered all comments received during the comment period in finalizing the document. Comments on the draft guidance requested that we consider establishing action levels for other foods containing arsenic, such as other apple products, other fruit juices, and rice; that the action level be lower than 10 ppb; that we consider additional risk management approaches; and that questioned the achievability of the action level of 10 ppb in apple juice. We did not receive new data from the comments supporting establishment of either a higher or lower action level. None of the comments caused us to change the approach set out in the draft guidance. We have clarified in the title of the final guidance that the action level of 10 ppb applies to inorganic arsenic.

Other comments suggested modifications to the risk assessment document. We note that the risk assessment report underwent peer review before we made it available to the public. (This can be found at *https://www.fda.gov/science-research/peer-review-scientific-information-and-assessments/completed-peer-reviews.*) None of these comments supported a determination that the risk assessment document needs to be modified. We will continue to monitor research developments on adverse health effects of inorganic arsenic exposure to determine if new data support changes to the guidance.

II. Paperwork Reduction Act of 1995

This final guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: May 30, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–11769 Filed 6–1–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2079]

Hospira, Inc., et al.; Withdrawal of Approval of Eight 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 eight 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 3, 2023.

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 075160	Metoprolol Tartrate Injectable, 1 milligram (mg)/milliliter (mL)	Hospira, Inc., 275 North Field Dr., Bldg. H1–3S, Lake Forest, IL 60045.
ANDA 077029	Calcipotriene Solution, 0.005%	Tolmar, Inc., 701 Centre Ave., Fort Collins, CO 80526.
ANDA 079186	Dorzolamide Hydrochloride (HCl) Solution/Drops, Equivalent to (EQ) 2% base.	American Regent, Inc., 5 Ramsey Rd., Shirley, NY 11967.
ANDA 200457	Ibuprofen Suspension, 100 mg/5 mL	Arise Pharmaceuticals LLC, 12 Roszel Rd., Unit B202, Princeton, NJ 08543.
ANDA 204356	Ammonia N 13 Injectable, 3.75 millicurie (mCi)–260 mCi/mL	Wisconsin Medical Radiopharmacy LLC, 11236 West Lapham St., West Allis, WI 53214.
ANDA 205605	Amikacin Sulfate Injectable, EQ 50 mg base/mL	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 205687	Ammonia N 13 Injectable, 3.75 mCi–260 mCi/mL	Essential Isotopes, LLC, 1513 Research Park Dr., Columbia, MO 65211.
ANDA 210265	Fludeoxyglucose F18 Injectable, 20 mCi/mL–200 mCi/mL ...	University of Texas Southwestern Medical Center, 5323 Harry Hines Blvd., Dallas, TX 75390.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of July 3, 2023. 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 July 3, 2023 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 30, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–11744 Filed 6–1–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1729]

Migraine: Developing Drugs for Preventive Treatment; 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 ''Migraine: Developing Drugs for Preventive Treatment.'' This draft guidance document is intended to assist sponsors in the clinical development of drugs for the preventive treatment of migraine. The draft guidance is intended to complement, not replace, the guidance for industry ''Migraine: Developing Drugs for Acute Treatment,'' and focuses on specific drug development and trial design issues that are unique to the study of drugs for the preventive treatment of migraine. This draft guidance is intended to serve as a focus for continued discussions among FDA's Division of Neurology II, sponsors, the academic community, and the public.

DATES: Submit either electronic or written comments on the draft guidance by August 1, 2023 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–2022–D–1729 for ''Migraine: Developing Drugs for Preventive Treatment.'' 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