TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued

Application No.	Drug	Applicant
ANDA 207919	Acyclovir Sodium injectable, EQ 50 mg base/mL	Dr. Reddy's Laboratories Inc., 107 College Rd. East, Princeton, NJ 08540.
ANDA 209325	Miglustat capsule, 100 mg	Breckenridge Pharmaceutical, Inc., 15 Massirio Dr., Suite 201, Berlin, CT 06037.
ANDA 209708	Mivacurium Chloride solution, EQ 10 mg base/5 mL (EQ 2 mg base/mL) and EQ 20 mg base/10 mL (EQ 2 mg base/mL).	Woodward Pharma Services, LLC, 47220 Cartier Dr., Suite A, Wixom, MI 48393.
ANDA 211893	Ranitidine HCl capsule, EQ 150 mg base and EQ 300 mg base.	Appco Pharma LLC, 262 Old New Brunswick Rd., Suite M, N, B–1, F, Piscataway, NJ 08854.
ANDA 214428	Niacin extended-release tablet, 500 mg and 1 g	Sciecure Pharma Inc., U.S. Agent for Beijing Sciecure Pharmaceutical Co., Ltd., 138 Glendale Ave., Edison, NJ 08817.
ANDA 215908	Nitisinone capsule, 2 mg, 5 mg, 10 mg, and 20 mg	Torrent Pharma Inc., 106 Allen Rd., Suite 305, Basking Ridge, NJ 07920.
ANDA 217094	Fluphenazine HCl tablet, 1 mg, 2.5 mg, 5 mg, and 10 mg	Torrent Pharma Inc., U.S. Agent for Torrent Pharmaceuticals Ltd., 106 Allen Rd., Suite 305, Basking Ridge, NJ 07920.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of February 14, 2025. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1.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 February 14, 2025 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: January 8, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00742 Filed 1–14–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5851]

Teva Branded Pharmaceutical Products R&D, Inc., et al.; Withdrawal of Approval of 12 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 12 new drug applications (NDAs) 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 February 14, 2025.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@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(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.

TABLE 1—NDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
NDA 009388	Diamox IV (acetazolamide) Injectable, Equivalent to (EQ) 500 milligrams (mg) base per vial.	Teva Branded Pharmaceutical Products R&D, Inc., 145 Brandywine Parkway, West Chester, PA 19380.
NDA 012836	Persantine (dipyridamole) Tablets, 25mg, 50mg, and 75mg	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Road, P.O. Box 368, Ridgefield, CT 06877.
NDA 018817	Calan (verapamil hydrochloride (HCl)) Tablets, 40 mg, 80 mg, 120 mg, and 160 mg.	Pfizer Inc., 66 Hudson Boulevard East, New York, NY 10001.
NDA 021743	Tarceva (erlotinib HCl) Tablets, EQ 25 mg base, EQ 100 mg base, and EQ 150 mg base.	OSI Pharmaceuticals, LLC, 2375 Waterview Dr., Northbrook, IL 60062.
NDA 021785	Invirase (saquinavir mesylate) Tablets, EQ 500 mg base	Hoffmann-La Roche, Inc. c/o Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080.
NDA 021937	Atripla (efavirenz, emtricitabine, and tenofovir disoproxil fumarate) Tablets, 600 mg/200 mg/300 mg.	Gilead Sciences, Inc., 333 Lakeside Dr., Foster City, CA 94404.
NDA 022383	Arcapta Neohaler (indacaterol maleate) Powder for Inhalation, EQ 75 micrograms base.	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936.
NDA 204412	Delzicol (mesalamine), Delayed-Release Capsules, 400 mg	AbbVie Inc., 1 N. Waukegan Rd., North Chicago, IL 60064.
NDA 210875	Kynmobi (apomorphine HCl) Sublingual Film, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg.	Sumitomo Pharma America, Inc., 84 Waterford Dr., Marlborough, MA 01752.

TABLE 1—NDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued

Application No.	Drug	Applicant
NDA 211172	Tegsedi (inotersen sodium) Solution for Injection, EQ 284 mg base/1.5 mL.	Akcea Therapeutics, Inc., 2850 Gazelle Ct., Carlsbad, CA 92010.
NDA 212640	Exservan (riluzole) Oral Film, 50 mg	Aquestive Therapeutics, 30 Technology Dr., Warren, NJ 07059.
NDA 213426	Seglentis (celecoxib and tramadol HCl) 56 mg; 44 mg	Kowa Pharmaceuticals America, Inc., 530 Industrial Park Blvd., Montgomery, AL 36117.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of February 14, 2025. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved NDA 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 February 14, 2025 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: January 6, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00743 Filed 1–14–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5716]

High-Protein Yogurt; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting information and data about the manufacturing processes and ingredients used to make certain dairy products referred to as high-protein yogurt, Greek yogurt, or Greek-style yogurt in this document. We are taking this action, in part, because the yogurt standard of identity may not align with certain manufacturing processes and ingredients used to concentrate protein to manufacture these products. We intend to use the information and data to help determine what type(s) of actions, if any, should be taken.

DATES: Either electronic or written comments on the notice must be submitted by April 15, 2025.

ADDRESSES: You may submit comments and information as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 15, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2024–N–5716 for ''High-Protein Yogurt; Request for Information.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.'' We will review this copy, including the claimed confidential information, in our 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://*