TABLE 1—NDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued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Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of February 14, 2025. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from table 1.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://*

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.

FOR FURTHER INFORMATION CONTACT: Yan Peng, Office of Nutrition and Food Labeling, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371, or Holli Kubicki, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act) gives FDA the authority to establish definitions and standards of identity (SOIs) for foods whenever such action would promote honesty and fair dealing in the interest of consumers (see section 401 of the FD&C Act (21 U.S.C. 341)). SOIs specify the ingredients, both mandatory and optional, of a standardized food, and sometimes describe the amount or proportion of each ingredient. Many SOIs also prescribe a method of production.

The yogurt SOI is stated at 21 CFR 131.200. There is not a separate SOI for high-protein yogurt, Greek yogurt, or Greek-style yogurt. For purposes of this document, high-protein yogurt, Greek yogurt, or Greek-style yogurt (collectively referred to in this document as ''high-protein yogurt'') generally refers to a dairy product cultured with, at minimum, *Lactobacillus delbrueckii,* subspecies *bulgaricus,* and *Streptococcus thermophilus,* which has undergone a manufacturing method to increase the protein level.

In recent years, the yogurt industry has raised concerns that the existing, single yogurt SOI does not accommodate the current practices or technologies to manufacture high-protein yogurt. Specifically, FDA received comments from the yogurt industry during the FDA 2019 Public Meeting on Horizontal Approaches to Food Standards of Identity Modernization (84 FR 45497, August 29, 2019 (Docket No. FDA–2018–N–2381)), and after the reopening of comments on the FDA 2005 proposed rule titled Food Standards; General Principles and Food Standards Modernization (85 FR 10107, February 21, 2020 (Docket No. FDA–1995–N–0062)), advocating for an additional SOI for strained, high-protein yogurt (which some comments referred to as Greek yogurt). The comments stated that a new SOI for strained, high-protein yogurt should include language that describes the authentic straining process, the characteristics of the product, and the distinguishing compositional nutritional elements of the product.

We understand that since high-protein yogurt was introduced to the U.S. market, this category continues to expand substantially in product availability and variety, along with innovations in formulations and manufacturing processes.

We also understand that there are different methods used by industry to increase the protein level of yogurt, some of which may not be consistent with the yogurt SOI. One method is to concentrate yogurt after culturing to remove liquid whey by a straining process (Refs. 1 and 2). The straining process can be done in a traditional way using cheesecloth, but is more commonly done commercially using a centrifugal separator (Refs. 1 and 2). Many yogurt manufacturers that use the straining process to make high-protein yogurt add cream after culturing and straining to achieve the desired fat content specified for the product. These manufacturers state that cream must be added after culturing and straining due to a variety of challenges that occur if cream is added before culturing, including reduced production efficiency due to clogging of centrifugal separators by fat, loss of fat in acid whey, and reduced ability to recycle acid whey with high fat content.

Another method is the addition of milk-protein ingredients to milk prior to culturing (Refs. 1 and 2). This method is also known as the protein-fortified method, which allows for the production of high-protein yogurt on the same processing equipment used for yogurt not fortified with milk-protein ingredients, without the need for liquid whey removal after culturing (Refs. 1 and 2).

Yet another method is to concentrate protein in milk before or after culturing (*e.g.,* membrane ultrafiltration (Refs. 1 and 2)). (We note that FDA granted a temporary permit to Chobani to market test certain yogurt products deviating from the yogurt SOI by using ultrafiltered nonfat milk as a basic dairy ingredient before culturing (88 FR 18322, March 28, 2023).

II. Issues for Consideration and Request for Information

FDA is issuing this request for information to better understand the current marketplace for high-protein yogurt products. In particular, FDA is interested in information that would help us determine whether there is a need for updating an existing, or establishing a new standard of identity for these products to promote honesty and fair dealing in the interest of consumers. We also request information and data about the various manufacturing processes and ingredients used to make high-protein yogurt. We specifically invite comment in response to the questions below. Please explain your answers and provide references and data, if possible.

1. We seek input from all interested parties related to consumers' understanding and expectations of high-protein yogurt, and the current industry practices and innovations. We are also interested in data and other information regarding usage of the various names for high-protein yogurt.

2. If pasteurized cream is added after culturing, please specify the point at which cream is added during the manufacturing process (*e.g.,* time, temperature, pH). What are the typical amount and the effects of adding pasteurized cream after culturing on yogurt attributes that are required by the SOI (*e.g.,* pH, milk solids not fat level, level of live cultures, including *Lactobacillus delbrueckii subsp. bulgaricus* and *Streptococcus thermophilus*)? Please specify with data. What adjustments are needed, if any, to meet the levels required by the yogurt SOI?

3. How are the characteristics of yogurt impacted by the point at which cream is added during the manufacturing process relative to culturing (*i.e.,* adding cream to milk before culturing compared to adding cream after culturing)? Please explain and provide data (*e.g.,* pH, sensory properties, compositions, levels of live cultures) to compare the yogurt made by adding cream before culturing versus adding cream after culturing.

4. There are different ways to achieve high-protein content in high-protein yogurt, such as membrane concentration of milk protein before culturing, straining of cultured yogurt after culturing, membrane separation of yogurt after culturing, or milk protein fortification. How do the high-protein yogurts made with these different processes differ in characteristics (*e.g.,* pH, sensory properties, compositions, levels of live cultures, nutrient profile)?

Please explain and specify which characteristics differ.

4.a. Membrane filtration (often ultrafiltration) can be used to concentrate milk prior to culturing. What are the specifications of the ultrafiltered milk (*e.g.,* concentration factors; filtered milk pH; compositions, such as total solids, protein, lactose, fat, minerals, vitamins; other pertinent information) used to manufacture high-protein yogurt?

4.b. Straining after culturing removes a portion of the liquid whey from the cultured yogurt to increase protein content in the finished yogurt product. What is the concentration factor or weight ratio of liquid whey versus concentrated yogurt after straining? What are important processing parameters, such as temperature, during the straining process? What are the characteristics of the liquid whey from the yogurt straining process and the concentrated yogurt (*e.g.,* pH; levels of live cultures; compositions, including total solids, total protein, whey protein, casein, lactose, fat, minerals, vitamins; other pertinent information)?

4.c. Membrane filtration of yogurt after culturing removes liquid whey to concentrate yogurt. What is the typical concentration factor or weight ratio of permeate (liquid whey) versus retentate (concentrated yogurt) after membrane filtration? What are important processing parameters, such as temperature, during the membrane filtration process? What are the characteristics of the liquid whey and concentrated yogurt after membrane filtration (*e.g.,* pH; levels of live cultures; compositions, including total solids, total protein, whey protein, casein, lactose, fat, minerals, vitamins; other pertinent information)?

4.d. Dairy protein fortification can also be used to increase the protein level in yogurt. Please describe the types of protein ingredient(s) (*e.g.,* whey protein, casein protein, milk protein, caseinate) added during the manufacturing process to increase the protein level in yogurt. How are the dairy protein ingredients added (*e.g.,* timing of the addition during processing, amounts added)? How are the characteristics of yogurts impacted by fortifying with different types of protein ingredients? Please explain and provide data (*e.g.,* pH, sensory properties, levels of live cultures, composition) to compare the yogurts made by fortifying with different types of protein ingredients.

5. As indicated earlier in this document, high-protein yogurt is also known as or referred to under different names, such as Greek yogurt and Greek-style yogurt. Please provide relevant data and information regarding usage of the various names for high-protein yogurt (*e.g.,* Greek yogurt and Greek-style yogurt). Please also provide relevant data and information regarding the inclusion of the manufacturing process in the names for high-protein yogurt (*e.g.,* ''strained yogurt,'' ''strained Greek yogurt,'' ''ultrafiltered yogurt''). Examples of relevant data and information may include specific firm practices, trade conventions, and consumer studies.

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Chandan, R.C. and A. Kilara, editors, 2013, Manufacturing Yogurt and Fermented Milks, Second Edition, John Wiley & Sons, Inc. Available at *https://doi.org/10.1002/9781118481301.*
2. *Jørgensen, C.E., R.K. Abrahamsen, E. Rukke, et al. ''Processing High-Protein Yoghurt—A Review,'' *International Dairy Journal,* 88: 42–59, 2019. Available at *https://doi.org/10.1016/j.idairyj.2018.08.002.*

Dated: January 8, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00754 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–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; ALHEMO (concizumab-mtci)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that ALHEMO (concizumab-mtci), approved on December 20, 2024, manufactured by Novo Nordisk, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that ALHEMO (concizumab-mtci), manufactured by Novo Nordisk, Inc., meets the criteria for a priority review voucher. ALHEMO (concizumab-mtci) injection is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors and hemophilia B (congenital factor IX deficiency) with FIX inhibitors.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about ALHEMO (concizumab-mtci), go to the ''*Drugs@FDA*'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: January 8, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00750 Filed 1–14–25; 8:45 am]

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