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.*

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## 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.*

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