U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: August 14, 2023

From: Denis Wafula, Ph.D., Biologist, Environmental Team, Division of Science and Technology (HFS-255)

To: Stevie N. Bush, Ph.D., Division of Food Contact Substances (HFS-275)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2295

Notifier: Alcresta Therapeutics, Inc

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
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Attached is the FONSI for FCN 2295, which is for the use of a copolymer of ethylene glycol dimethacrylate, butyl methacrylate, and glycidyl methacrylate (CAS Reg. No. 133396-60-8) as a fixing agent for the immobilization of lipase enzyme preparations. This FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

After this FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated April 27, 2023, may be made available to the public. We will post digital transcriptions of the FONSI, and the EA on the agency's public website.

Please let us know if there is any change in the identity or use of the food-contact substance.

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Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2295, submitted by Alcresta Therapeutics, Inc. for the use of a copolymer of ethylene glycol dimethacrylate, butyl methacrylate, and glycidyl methacrylate (CAS Reg. No. 133396-60-8) as a fixing agent for the immobilization of lipase enzyme preparations. The FCS-enzyme complex will be used at a level not to exceed 10.75 g of FCS-enzyme complex/person/day in contact with food type IV-B under Condition of Use E as described in Tables 1 and 2.[1] The use is limited to supplemental enteral nutrition applications only. The FCS-enzyme complex is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

The Office of Food Additive Safety has determined that allowing this notification to become effective will not significantly affect the quality of the human environment and, therefore, an environmental impact statement (EIS) will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA), dated April 27, 2023. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact (FONSI) and is briefly summarized below.

Food-contact articles containing the FCS are expected to be disposed primarily by landfilling or incineration at municipal solid waste (MSW) combustors. Food-contact articles containing the FCS are not expected to be recycled. It is expected that due to EPA's regulations at 40 CFR Part 258, there will be no significant introduction of the FCS or its components into the environment resulting from land disposal of food-contact articles containing the FCS. Incineration of food-contact articles containing the FCS will not significantly alter the emissions from properly operating MSW combustion facilities, and hence will not cause these facilities to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60.

The EA also considered the impact of greenhouse gas (GHG) emissions. Based on information provided in a confidential attachment to the EA, the total estimated GHG emissions resulting from the combustion of food-contact articles manufactured with the FCS in this notification are below 25,000 metric tons CO_2 equivalent, the US EPA threshold for mandatory reporting of GHG emissions (40 CFR 98.2). Therefore, no significant environmental impacts are anticipated.

Although the use of the FCS as intended in this FCN is expected to increase the total amount of the substance produced and used beyond the level currently used in FCN 1498; the FCS will be used in small amounts in finished medical devices. Therefore, the overall amounts of the FCS used will be small and the increases will be insignificant. Consequently, the use of the FCS is not anticipated to result in significant impacts on the use of energy and resources.

No potential adverse environmental effects are identified that would necessitate alternative actions to those proposed. The alternative of not approving the notified action would result in the continued use of other approved substances the FCS would otherwise replace; such action would have no significant environmental impacts. Because no significant impacts are identified, mitigation measures are not required.

[1] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

As evaluated in the EA, the use of the FCS as described in FCN 2295 will not significantly affect the human environment. Therefore, an EIS will not be prepared.

Prepared by

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Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by

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