Agency Response Letter GRAS Notice No. GRN 000571

Return to inventory listing: **GRAS Notice Inventory (https://wayback.archive-it.org/7993/20171031001515/http://www.fda.gov/grasnoticeinventory)**

See also **Generally Recognized as Safe (GRAS) (https://wayback.archive-it.org/7993/20171031001515/http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/default.htm)** and **about the GRAS Notice Inventory (https://wayback.archive-it.org/7993/20171031001515/http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm)**

CFSAN/Office of Food Additive Safety

November 6, 2015

Gavin Thompson, Ph.D.
Ramboll Environ
2111 East Highland Ave., Suite 402
Phoenix, AZ 85016

Re: GRAS Notice No. GRN 000571

Dear Dr. Thompson:

The Food and Drug Administration (FDA) is responding to the notice, dated March 2, 2015, that you submitted on behalf of Jennewein Biotechnologie, GmbH (Jennewein) in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on March 4, 2015, filed it on March 20, 2015, and designated it as GRAS Notice No. GRN 000571.

The subject of the notice is 2'-fucosyllactose (2'-FL). The notice informs FDA of the view of Jennewein that 2'-FL is GRAS, through scientific procedures, for use as an ingredient in non-exempt, milk-based term infant formulas and in toddler formulas at a maximum level of 2 grams per liter (g/L) of reconstituted formula.

As part of its notice, Jennewein includes the report of a panel of individuals (Jennewein's GRAS panel) that evaluated the data and information that are the basis for Jennewein's GRAS determination. Jennewein considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. Jennewein's GRAS panel evaluated the identity, manufacturing process, specifications, estimated dietary exposure, and published information supporting the safety of 2'-FL. Based on this review, Jennewein's GRAS panel concluded that 2'-FL, produced in accordance with good manufacturing practices, is GRAS under the conditions of its intended use.