| | |
|---|---|
| **From:** | Carlson, Susan |
| **To:** | Morissette, Rachel |
| **Cc:** | Bonnette, Richard; Honigfort, Mical |
| **Subject:** | FW: bLf Levels in Infant Formula |
| **Date:** | Tuesday, March 3, 2020 10:29:45 AM |
| **Attachments:** | Glanbia - Letter re Use of bLf at higher levels 03-02-20.pdf<br>2019-12-17 Bovine lactoferrin GMT transmittal.pdf |

Hi Rachel,

Will you please coordinate a response to this inquiry?

Thank you,
Susan

---

**From:** Cathryn Sacra <csacra@easconsultinggroup.com>
**Sent:** Tuesday, March 3, 2020 10:17 AM
**To:** Carlson, Susan <Susan.Carlson@fda.hhs.gov>
**Subject:** bLf Levels in Infant Formula

Dear Dr. Carlson,

I am attaching a letter on behalf of our client, Glanbia Nutrition, seeking clarification of the use of bovine lactoferrin (bLf) at a level of 600 mg/l in infant formula, as well as a copy of the 12/17/19 letter from Richard Bonnette which was referenced in our letter.

Please let me know if you have any questions.

Best regards,
Cathryn

Cathryn W. Sacra
Director of Labeling and Cosmetic Services
EAS Consulting Group, LLC
1700 Diagonal Road
Suite 750
Alexandria VA, 22314
877-327-9808 (toll free) +1 571-447-5500 (main)  +1 571-447-5505 (direct) 703-548-3270 (fax)
csacra@easconsultinggroup.com
www.easconsultinggroup.com

EAS CONSULTING GROUP

*Specializing in FDA Regulatory Matters*

March 2, 2020

Susan Carlson, Ph.D., Director
FDA/CFSAN/OFAS/DBGNR, HFS-255
5100 Campus Drive
College Park, MD 20740-3835

Dear Dr. Carlson:

On behalf of Glanbia Nutritionals, this letter seeks clarification and confirmation that the use of bovine lactoferrin (bLf) at a level of 600 mg/L is an acceptable level in infant formula (IF) that is marketed in the United States. We are aware that at least one company is currently adding bLf to its IF at this level. Based on our understanding of the past history related to the use of bLf in IF, we understand that this level is permitted.

Based on information that we have obtained through discussions with FDA (OFAS and the Infant Formula Team) and information obtained through Freedom of Information requests, we have received documentation that the Infant Formula Team has acknowledged (with input from OFAS) that a level of 600 mg/L is GRAS and is acceptable in IF. In a letter dated October 3, 2014 (page 3 of 115 pages), Mead Johnson submitted a New Infant Formula Notification (NIFN) to FDA for an Enfinitas Infant formula Powder that contained bovine lactoferrin (lactoferrin whey protein fraction)[1] at a level of 600 mg/L. The amounts of the other components in this IF were essentially the same as those in another MJ IF that is currently marketed, so the major issue related to this new IF was the higher use level of bLf and another component. [Please note that this product is currently marketed as Enfamil Enspire IF.]

FDA has recognized that bLf is GRAS for use in IF in two GRAS Notices (GRNs 465 and 669). In the MJ NIFN, FDA confirmed that the lactoferrin whey protein fraction is "equivalent to" the bLf in GRN 465. This was further supported by a memo from OFAS (Jeremy Mihalov) to Linda Tonucci et al. dated March 19, 2015 (page 75 of 115 pages). On Page 85 of the MJ NIFN, FDA's internal memo accepted lactoferrin as the name for the lactoferrin whey protein product (85 of 115 pages) and recognized lactoferrin as the common or usual name (page 111 of 115 pages).

---

[1] MJ referred to this product as "lactoferrin whey protein fraction." However, FDA has acknowledged that this product is essentially the same as the bLf in GRN 465 and has accepted the common and usual name of lactoferrin.

EAS Consulting Group, LLC
1700 Diagonal Road, Suite 750, Alexandria, Virginia 22314
(877) 327-9808 Toll Free • (571) 447-5500 Local • (703) 548-3270 Fax

In our discussions with FDA, it has also been determined that Glanbia's bLf is equivalent to the bLf produced in GRNs 465 and 669.[2]

In a memo dated April 22, 2015, the Infant Formula Team stated "Based on the information provided, we have not identified issues that would contradict MJ's conclusion that lactoferrin whey protein fraction and complex-lipid-enriched whey are safe for their intended use as per existing regulation (i.e., 21 CFR 184.1979c) or GRAS notifications for similar substances (e.g., GRAS notice 000465)." Pages, 94, 98 of 115 pages).

This memo further stated: "**Summary and Conclusion**: Mead Johnson's proposed product, **Enfinitas Infant**: A milk-based powder infant formula containing lactoferrin and a complex-lipid-enriched whey protein (MFGM) in addition to ARA, DHA, GOS, and PDX, intended for healthy infants 0 to 12 months old, appears to meet the requirements under 21 CFR 107.100; therefore, I do not recommend that we object to the marketing of Mead Johnson's **Enfinitas Infant.**" (Page 100 of 115 pages).

The above statement gives explicit acknowledgement that 600 mg/L of bLF is GRAS and acceptable. As you know, there is no GRAS citation that explicitly covers this higher amount. GRNs 465 and 669 indicated in their submissions that the intended use levels would be in the range of 130 -140 mg/L even though there was data supporting higher use levels. All that is currently available for the higher use level in IF is OFAS's internal statement of five years ago to the IF group stating that it did not identify any issues that would contradict MJ's conclusion of safety and the Infant Formula Team's memo cited above. [NB: Enfamil Enspire with bLF at 600 mg/L has been marketed in the U.S. for several years now.] Therefore, at this time, EAS respectively requests confirmation and consideration by OFAS for an external written memo to Glanbia on its concurrence and "no objection" to the intended use of bLf in IF at 600 mg/L.

Thank you for your prompt consideration of this request. Should you have questions, or need additional clarification, please do not hesitate to contact me

Sincerely,

Cathryn Sacra
Director, Labeling and Cosmetic Consulting Serivces

[2] See: FDA letter attached to email dated December 17, 2019 from Richard Bonnette (FDA) to Cathryn Sacra (EAS).

Cathryn W. Sacra
Director, Labeling and Cosmetic Services
EAS Consulting Group, LLC
1700 Diagonal Road, Suite 750
Alexandria, VA 22314

Dear Ms. Sacra:

The Food and Drug Administration (FDA, we) is declining to file the submission you provided on behalf of Glanbia Nutritionals dated October 7, 2019, regarding a bovine lactoferrin product.

We decline to file this submission because the November 5, 2019, email from Noreen Hobayan of Glanbia Nutritionals did not identify substantive differences in the method of manufacturing between the subject of the October 7, 2019, submission and the subject of previous notices where FDA has responded that we had no questions at that time regarding the notifiers' GRAS conclusions. Further, the submission notes that the intended uses are identical, and there are no differences in specifications or production between the subject of this submission and the subjects of those previous notices.

We will not be evaluating this submission as part of the GRAS notification program.

Sincerely,

Richard E. Bonnette Iii III -S
Digitally signed by Richard E. Bonnette Iii III -S
Date: 2019.12.17 15:36:21 -05'00'

Richard Bonnette, M.S.
Consumer Safety Officer
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740