June 22, 2022

Sussy Kraus
U.S. Representative for Global-Group UK
Global Kosher Ltd.
Unit 1, The Quad
Great Marlings
Luton LU2 8DL, United Kingdom
sussy@focussgroup.com

Re: Request Number(s): 001.016

Dear Sussy Kraus:

This letter is in response to your request dated May 19, 2022, providing information relevant to the safety and nutritional adequacy of Kendamil Stage 1 Infant Formula with Iron Mehadrin Grade (Kendamil Mehadrin) and requesting that the Food and Drug Administration (FDA or we) exercise enforcement discretion with respect to the import, sale, and distribution of the formula. Information provided to FDA by Global Kosher Ltd. is contained in Request Number(s) 001.016, which is incorporated by reference into this response. Among other things, this file includes:

1. **Product Name:**
   Kendamil Stage 1 Infant Formula with Iron, Mehadrin Grade (Kendamil Mehadrin Infant Milk), 800 grams (g)
   Product Code: 77000346
   CUC 5056000501639
   TUC 05056000501653

2. **Countries of Product Sale:**
   The Kendamil Mehadrin formula has been marketed in many countries that have kosher consumers since 2015, including the United Kingdom.

3. **Quantity of Product Intended for Initial Introduction to Commerce:**
   25,000 Cases (6 cans per case 800g)
   Available product is labeled for the foreign market but will be relabeled with the label provided in this request.

EPN	PRODUCT	BATCH	MANUFACTURE DATE	BEST BEFORE DATE
77000207	Kendamil Mehadrin One 6x800g	L22116KCA01	26/04/22	26/04/24
77000207	Kendamil Mehadrin One 6x800g	L22117KCA01	27/04/22	27/04/24
77000344	Kendamil One Mehadrin 6x800g	L22123KCA02	03/05/22	03/05/24
77000344	Kendamil One Mehadrin 6x800g	L22124KCA01	04/05/22	04/05/24

4. **Product to be Manufactured:**
   About 50,000 to 75,000 cases are expected to be shipped per month.
   Shelf life is 24 months.

5. **Manufacturing Facility Location:**
   Kendal Nutricare Ltd
   Mint Bridge Road
   Kendal, Cumbria LA9 6NL
   United Kingdom
   FDA Registration No. 18373050946

6. **Distribution Plan:**
   A distribution plan was provided in the request.

7. **Quantitative Formulation:**
   A full quantitative formulation of the product was provided in the request.

8. **Copy of the Product Label(s):**

9. **Product Packaging Description:**
   A description of the product packaging was provided in the request.

10. Nutrition Information and Nutrient Test Results:

All nutrients required by 21 CFR 107.100 are included on the label for Kendamil Mehadrin, and the label nutrient declarations meet specified minimum and maximum levels. Nutrient test results were provided for Kendamil Mehadrin, EPN number 77000207, batch 22116KCA01 and Kendamil Mehadrin, EPN number 77000344, batch 22123KCA02 for 7 nutrients required by 21 CFR 107.100. All results meet minimum and maximum requirements and also support the label declarations.

11. Summary of Test Results for *Cronobacter* spp. and *Salmonella* spp.

Global Kosher Ltd provided microbiological testing results for *Cronobacter* spp. and *Salmonella* spp. for EPN 77000207 - batches L20339KCA01, L22116KCA01 and L22117KCA01, EPN 77000297 - batch L22115KRO01, and EPN 77000344 - batches L22123KCA02 and L22124KCA01. Global Kosher Ltd. also provided information on microbiological test methods. Based on the information provided by the firm, the sampling plans for *Cronobacter* spp. is in conformance with those recommended in FDA's Guidance for Industry: Infant Formula Enforcement Discretion Policy (FDA's Guidance).[1] However, the sampling plan for Salmonella does not conform with FDA's guidance, as the certificates of analysis (COAs) indicate that a total of 750g of sample was analyzed rather than 1500g sample.

See below for additional information about FDA's expectations for additional microbiological testing for *Salmonella* spp. on the batches of Kendamil Mehadrin prior to shipping and distributing the product, in conformance with the recommendation in FDA's Guidance.

12. Good Manufacturing Practices and Controls:

Adequate information regarding current good manufacturing practices and controls, along with a process flow diagram and process description, were provided. Additional helpful information (e.g., complete HACCP plan, environmental monitoring plan and results, and supplier control plan) was also supplied.

13. Inspection Data:

Inspection data and UK Food Safety Certification from BRCGS were provided in the request. The facility has not undergone FDA inspection. A summary and complete inspection report from BRCGS, conducted on June 22-24, 2021, were included in the request. No need for major corrective actions was noted in the report.

We have evaluated your request to determine whether Kendamil Mehadrin Infant milk raises any concerns regarding safety or nutritional adequacy. Based on our review of the information

[1] FDA's Guidance is available at https://www.fda.gov/media/158476/download.

provided, we do not have any questions at this time about the information regarding the safety and nutritional adequacy of the product included in your request.

Based on the information Global Kosher Ltd. has presented to FDA and provided that Global Kosher Ltd. takes the additional steps outlined below in this letter, FDA does not intend to object to the import, sale, or distribution of Kendamil Mehadrin Infant milk through November 14, 2022:

1. Global Kosher Ltd. will ensure that batches of Kendamil Mehadrin destined for the U.S. market are tested at 1500g sample size for Salmonella. Global Kosher Ltd. will provide the results for the first batch intended for the U.S. before shipping. Global Kosher will conduct this testing for subsequent batches of product intended for shipment to the U.S., retain records of the test results, and make such records available to FDA on request.

2. Global Kosher Ltd. will provide nutrient testing results to FDA for all nutrients listed as required in 21 CFR 107.100 for the first batch of Kendamil Mehadrin intended for the U.S. Global Kosher Ltd. will complete such testing and provide the results to FDA as soon as possible; conducting such testing and providing the results to FDA are not prerequisites to shipping.

3. Global Kosher Ltd. will ensure all nutrients listed as required in 21 CFR 107.100 are included in any nutrient testing going forward for subsequent batches of product intended for export to the U.S. Global Kosher will retain records of the test results and make them available to FDA on request.

We do not consider the marketing of products under any such temporary exercise of enforcement discretion to alter the status of such products as "new infant formula" under Title 21 of the Code of Federal Regulations, section 106.3 (21 CFR 106.3) for purposes of the applicability of the new infant formula registration and submission requirements under section 412(c) and (d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 United States Code (U.S.C.) 350a(c) and (d)) and 21 CFR 106.110 and 106.120.

FDA reserves the right to suspend this exercise of enforcement discretion, as appropriate, if, for example, we become aware of information that raises a concern about the safety or nutritional adequacy of the product.

Sincerely,

Leslie Kux -S

Digitally signed by Leslie Kux -S
Date: 2022.06.22 12:31:27 -04'00'

Leslie Kux, J.D.
Deputy Director for Nutrition, Regulatory Policy, and Engagement
Center for Food Safety and Applied Nutrition

U.S. FOOD & DRUG ADMINISTRATION

June 22, 2022

Sussy Kraus
U.S. Representative for Global Group UK
Global Kosher Ltd.
Unit 1, The Quad
Great Marlings
Luton LU2 8DL, United Kingdom

Re: Request Number(s): 001.016

Dear Sussy Kraus:

This letter is in response to your request dated May 19, 2022, providing information relevant to the safety and nutritional adequacy of Kendamil Formula with Iron Mehadrin Grade (Kendamil Mehadrin) and requesting that the Food and Drug Administration (FDA or we) exercise enforcement discretion with respect to the import, sale, and distribution of the formula. Information provided to FDA by Global Kosher Ltd. is contained in Request Number(s) 001.016, which is incorporated by reference into this response. Among other things, this file includes:

1. **Product Name:**
   Kendamil Stage 1 Infant Formula with Iron, Mehadrin Grade (Kendamil Mehadrin Infant Milk), 800 grams (g)
   Product Code: 77000207
   Kendamil Stage 2 Toddler Formula, Mehadrin Grade (Kendamil Mehadrin Infant Milk), 800 grams (g)
   Product Code: 77000208

2. **Countries of Product Sale:**
   The Kendamil Mehadrin formula has been marketed in many countries that have kosher consumers since 2015, including the United Kingdom.

3. **Quantity of Product Intended for Initial Introduction to Commerce:**
   6 cans per case 800g
   Available product is labeled for the foreign market but will be relabeled prior to sale with the label provided in this request.

4. **Addditonal product to be Manufactured:**
   About 50,000 – 75,000 cases are expected to be shipped per month.
   Shelf life is 24 months.

5. **Manufacturing Facility Location:**
   Kendal Nutricare Ltd
   Mint Bridge Road
   Kendal, Cumbria LA9 6NL
   United Kingdom
   FDA Registration No. 18373050946

6. **Distribution Plan:**
   A distribution plan was provided in the request.

7. **Quantitative Formulation:**
   A full quantitative formulation of the product was provided in the request.

8. **Copy of the Product Label(s):**
   The product label was provided in the request.

9. **Product Packaging Description:**
   A description of the product packaging was provided in the request.

10. **Nutrition Information and Nutrient Test Results:**
    All nutrients required by 21 CFR 107.100 are included on the label for Kendamil Mehadrin, and the label nutrient declarations meet specified minimum and maximum levels. Nutrient test results were provided for Kendamil Mehadrin for 7 nutrients required by 21 CFR 107.100. All results meet minimum and maximum requirements and also support the label declarations.

11. **Summary of Test Results for *Cronobacter* spp. and *Salmonella* spp.**
    Global Kosher Ltd provided microbiological testing results for *Cronobacter* spp. and *Salmonella* spp. Global Kosher Ltd. also provided information on microbiological test methods. Based on the information provided by the firm, the sampling plans for *Cronobacter* spp. is in conformance with those recommended in FDA's Guidance for Industry: Infant Formula Enforcement Discretion Policy (FDA's Guidance).[1] However, the sampling plan for Salmonella does not conform with FDA's guidance, as the certificates of analysis (COAs) indicate that a total of 750g of sample was analyzed rather than 1500g sample.

12. **Good Manufacturing Practices and Controls:**
    Adequate information regarding current good manufacturing practices and controls, along with a process flow diagram and process description, were provided. Additional helpful information (e.g., complete HACCP plan, environmental monitoring plan and results, and supplier control plan) was also supplied.

13. Inspection Data:

Inspection data and UK Food Safety Certification from BRCGS were provided in the request. The facility has not undergone FDA inspection. A summary and complete inspection report from BRCGS, conducted on June 22-24, 2021, were included in the request. No need for major corrective actions was noted in the report.

We have evaluated your request to determine whether Kendamil Mehadrin raises any concerns regarding safety or nutritional adequacy. Based on our review of the information provided, we do not have any questions at this time about the information regarding the safety and nutritional adequacy of the product included in your request.

Based on the information Global Kosher Ltd. has presented to FDA and provided that Global Kosher Ltd. FDA does not intend to object to the import, sale, or distribution of Kendamil Mehadrin Infant milk through November 14, 2022:

The FDA acknowledges the history and surroundings for this particular cargo being rejected by UK Port Health authorities and accepts that no EHC was received for import, nor will an EHC be will be available upon release.

We do not consider the marketing of products under any such temporary exercise of enforcement discretion to alter the status of such products as "new infant formula" under Title 21 of the Code of Federal Regulations, section 106.3 (21 CFR 106.3) for purposes of the applicability of the new infant formula registration and submission requirements under section 412(c) and (d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 United States Code (U.S.C.) 350a(c) and (d)) and 21 CFR 106.110 and 106.120.

FDA reserves the right to suspend this exercise of enforcement discretion, as appropriate, if, for example, we become aware of information that raises a concern about the safety or nutritional adequacy of the product.

Sincerely,

Leslie Kux -S

Digitally signed by Leslie Kux -S
Date: 2022.06.22 12:31:27 -04'00'

Leslie Kux, J.D.

Deputy Director for Nutrition, Regulatory Policy, and Engagement

Center for Food Safety and Applied Nutrition

[1] FDA's Guidance is available at https://www.fda.gov/media/158476/download.

July 26, 2022

Sussy Kraus
U.S. Representative for Global-Group UK
Global Kosher Ltd.
Unit 1, The Quad
Great Marlings
Luton LU2 8DL, United Kingdom
sussy@focusgroup.com

Re: Request Number(s): 001.016

Dear Sussy Kraus:

This letter is to notify you that, effective immediately, FDA is suspending the exercise of enforcement discretion with respect to the import, sale, and distribution of infant formula that was announced in FDA's June 22, 2022, letter to you. See Exhibit A. As set forth in the final paragraph of that letter, FDA reserved the right to suspend our exercise of enforcement discretion, and we now do so.

It has come to our attention that FDA's June 22, 2022, letter announcing an exercise of enforcement discretion with regard to importation of a specific infant formula product, which was based on information that you provided to FDA on behalf of Global Kosher Ltd., appears to have been modified after issuance without FDA authorization. See Exhibit B. The modified version of the letter adds, deletes, and changes the information in FDA's original letter and apparently was submitted to the United Kingdom (UK) regulatory authorities, and from the UK to FDA as well as to the United States Department of State.

The modification of FDA's enforcement discretion letter and its submission to governmental authorities as if it were FDA's original letter causes significant concern about the quality and integrity of the information Global Kosher Ltd. has provided, such that FDA is compelled to immediately suspend our previously announced exercise of enforcement discretion with regard to Global Kosher Ltd. and the importation of infant formula. We note that Global Kosher Ltd. has not, to date, actually shipped any infant formula product to the United States under the terms of the enforcement discretion.

Sincerely,

Leslie Kux -S

Digitally signed by Leslie Kux -S
Date: 2022.07.26 15:19:54 -04'00'

Leslie Kux, J.D.
Deputy Director for Nutrition, Regulatory Policy, and Engagement
Center for Food Safety and Applied Nutrition