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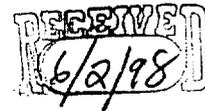


**EM INDUSTRIES, INC.**

7 Skyline Drive  
Hawthorne, New York 10532  
Phone: (914) 592-4660  
Fax: (914) 592-9469

June 1, 1998

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, D.C. 20204



**RE: Notification Pursuant to 21 CFR  
§ 101.93 on Dietary Supplements  
for Galacto-oligosacharides.**

Dear Sir or Madam:

I am writing on behalf of EM Industries, Inc. located at 7 Skyline Drive, Hawthorne, New York 10532 ("EM"). Pursuant to 21 CFR § 101.93, we are providing notice of certain statements or claims which EM may use on labels for the new dietary supplement galacto-oligosacharides. EM Industries provided notification that a new galacto-oligosacharide supplement will be marketed by EM. The 75 day notice was received by the FDA Office of Special Nutritionals on March 19, 1998. I have attached a copy of the receipt confirmation letter for the galacto-oligosacharides supplement notice.

In accordance with 21 CFR § 101.93 we provided the following:

- (I) Notice is Provided by:  
EM Industries, Inc.  
7 Skyline Drive  
Hawthorne, New York 10532
- (II) The following statements, in whole or in part, may be made on labels or other documents, with respect to the new dietary ingredient galacto-oligosacharides:
  - (A) "contains galacto-oligosacharides which are soluble fibers which may reduce or relieve constipation"

97S - 0162

An Associate of Merck KGaA, Darmstadt, Germany

LET 1697  
For (A) and (C),  
also see docket  
97S-0163



Office of Special Nutritionals (HFS-450)  
EM Industries, Inc.  
Galacto-oligosaccharides Label Claims  
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- (B) "promotes intestinal health by increasing growth of beneficial bifidobacteria and Lactobacilli"
  - (C) "low-calorie, low cariogenic carbohydrate"
  - (D) "May promote absorption of mineral nutrients including magnesium, calcium, iron, and zinc."
- (III) EM Industries, Inc. will market this product under the brand name Elix' or. Since EM Industries, Inc. will market this product to retail product manufacturers, additional notice from those manufacturers or retailer may be required.

I certify that the information contained in this notice is complete and accurate, and that EM Industries has documents substantiating that the above statements are truthful and not misleading.

The following statement will be displayed as required in conjunction with any, or all, of the above claims:

"This statement has not been evaluated by the Food and Drug Administration.  
This product is not intended to diagnose, treat, cure, or prevent any disease."

Thank you in advance for your attention to this matter. Please call if you have any questions or comments.

Sincerely yours,

A handwritten signature in cursive script that reads "Anne Gochman".

Anne Gochman  
Director, Regulatory Affairs  
and Quality Assurance

cc: Glenn C. Merritt, Esq.