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MAR 12 2003

Murray C. Clarke, D.Hom., L.Ac.
Biozeal
dba ChildLife Nutrition for Kids!
4051 Glencoe Avenue, #11
Marina del Rey, California 90292

Dear Dr. Clarke:

This is in response to your submission to the Food and Drug Administration (FDA), dated February 5, 2003. Your submission responds to our letter dated December 12, 2002 in which we stated, among other things, that the claims being made for the product "Aller-g-Ease Supplement" appeared to be claims that caused the product to be a drug under the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR 101.93(a).

Your current letter states that you have changed the name of the product "Aller-g-Ease Supplement" to "Aller-Care." Your letter also states that you have changed the claim cited in our earlier letter to "...provide nutritional and herbal support for children during allergy season." We have considered the change you propose for the claim for this product and are not persuaded that the change that you have made causes the claim to fall within the scope of claims permitted to be made in the labeling of a dietary supplement pursuant to 21 U.S.C. 343(r)(6). Rather, the claimed effect of the product (namely, that it is intended for "children during allergy season") remains squarely within the realm of a disease claim (see 21 CFR 101.93(g)(1)) because it implies that the product is intended for use by children with allergies, a disease for which specific nutritional consequences are not recognized to exist during different times of the year.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease, namely allergies. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a stylized flourish at the end.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

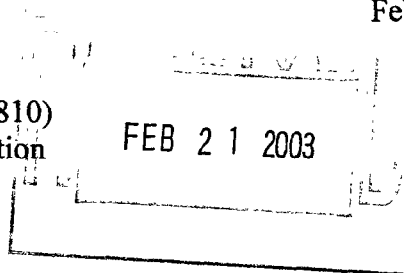
CHILD LIFE^{ESSENTIALS}™

Nutrition for Kids!

Formulated by Dr. Murray C. Clarke, D. Hom., L.Ac

February 5, 2003

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park MD 20740



Statement of Nutritional Support- ALLER-CARE 4 KIDS

Pursuant to 21 CFR Part 101.93, Biozeal LLC, dba **ChildLife Nutrition for Kids!** is filing the following Statement of Nutritional Support for the Dietary/Herbal Supplement marketed as **Aller-Care**:

- 1) Name and Address of Distributor: **4051 Glencoe Avenue, unit 11. Marina del Rey, California 90292.**
- 2) Text of Nutritional Support Statement being made:
"Aller-Care 4 Kids Supplement is designed to provide nutritional and herbal support for children during allergy season."
- 3) Name of dietary ingredient: See attachment.
- 4) Brand Name: **Aller-Care 4 Kids**
- 5) Substantiation information is on file at the company office. The Corporate officer who can certify same is Murray C. Clarke, President, for Research and Development.

Yours truly,

Dr. Murray C. Clarke, D.Hom., L.Ac.
ChildLife Nutrition for Kids!

CHILD LIFE^{ESSENTIALS}™

Nutrition for Kids!

Formulated by Dr. Murray C. Clarke, D. Hom., L.Ac.

Aller Care 4 Kids

4 Fl. Oz. (118.5 ml)

Contents: each teaspoon provides		
Amla (Emblica Officinalis)	50 mg	<1%
Bromelain	50 mg	
MSM (Methyl Sulfonyl Methane)	25 mg	
Vitamin C (Ascorbic Acid)	50 mg	
Gingko Biloba	12 mg	
Elderberry Concentrate	250 mg	
Zinc Gluconate	1 mg	

Other Ingredients: Purified Water, Citric Acid, Potassium Sorbate, and Grapefruit Seed Extract.