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DEC 12 2002

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 submissions to the Food and Drug Administration (FDA), dated November 19, 2002. Your submissions are intended to be the notifications required by 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a).

21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed (emphasis added) by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submissions do not meet this requirement in that the notices do not contain the signature of a responsible individual nor do they certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit notifications in accordance with the requirements in 21 CFR 101.93(a).

Nonetheless, in resubmitting your notification, you should be aware that the labeling of the product "Aller-g-Ease Supplement" that is the subject of your submission bears claims that do not appear to be claims subject to 21 U.S.C. 343(r)(6). The product claims to "provide nutritional and herbal support for children with allergies." Moreover, the name of the product is an implied claim to treat allergies in that it is a fanciful derivation of the name of a disease (i.e., Aller-g).

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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 statements that you are making for this product, including the name of the product, suggest that it is intended to treat, prevent, or mitigate a disease, namely allergies. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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.

Please contact us if we may be of further assistance.

Sincerely yours,



John B. Foret

Director

Division of Compliance and Enforcement

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.

November 19, 2002

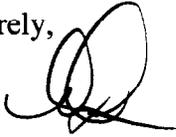
Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park MD 20740

DEC 6 2002

Dear Madam or Sir,

Enclosed, please find ChildLife, Statements of Nutritional Support for your records.

Sincerely,



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

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Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park MD 20740

Statement of Nutritional Support- ALLER-G-EASE

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-g-Ease**:

- 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-g-Ease Supplement is designed to provide nutritional and herbal support for children with allergies."
- 3) Name of dietary ingredient: See attachment.
- 4) Brand Name: **Aller-g-Ease**
- 5) Substantiation information is on file at the company office. The Corporate officer who can certify same is **Murray C. Clarke, President.**

Yours truly,

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

4051 Glencoe Ave , #11
Marina del Rey
California 90292

310 305-4640
800 993-0332
Fax: 310 305-4680

e-mail
mailroom@childlife.net
Web. www.childlife.net

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Aller-g-Ease seasonal

4 Fl. Oz. (118.5 ml)

Contents: each teaspoon provides		
Amla (<i>Emblica Officinalis</i>)	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.

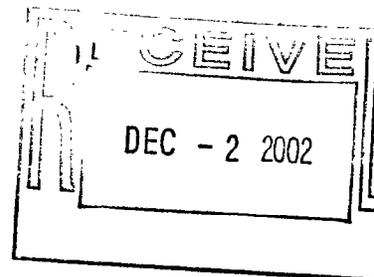
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November 19, 2002

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College Park MD 20740



Statement of Nutritional Support- ESSENTIAL FATTY ACIDS

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 **Essential Fatty Acids**:

- 1) Name and Address of Distributor: **4051 Glencoe Avenue, unit 11. Marina del Rey, California 90292.**
- 2) Text of Nutritional Support Statement being made:
"Essential Fatty Acids Supplement is designed to supply the optimum balance of Omega 3 and 6 fatty acids."
- 3) Name of dietary ingredient: See attachment.
- 4) Brand Name: **Essential Fatty Acids**
- 5) Substantiation information is on file at the company office. The Corporate officer who can certify same is **Murray C. Clarke, President.**

Yours truly,

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

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310 305-4640
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82751

Essential Fatty Acids

8 Fl. Oz. (237 ml)

Average Analysis per teaspoon	
Omega-3 EFAs	1825 mg
Omega-6 EFAs	850 mg
Omega-9 EFAs	1125 mg
Lignans	1.7 mg

Other Ingredients: Unrefined Organic Oils of Flax, Olive, and Pumpkin, Organic Flax Seed Particulate, and Natural Butterscotch Flavoring.

Omegaflo® processed to ensure quality and integrity of EFA contents.

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Nutrition for Kids!

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

November 19, 2002

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College Park MD 20740

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Statement of Nutritional Support- MULTI-VITAMIN & MINERAL

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 **Multi-Vitamin & Mineral**:

- 1) Name and Address of Distributor: **4051 Glencoe Avenue, unit 11. Marina del Rey, California 90292.**
- 2) Text of Nutritional Support Statement being made:
"Multi-Vitamin & Mineral Supplement is designed to support healthy development."
- 3) Name of dietary ingredient: See attachment.
- 4) Brand Name: **Multi-Vitamin & Mineral**
- 5) Substantiation information is on file at the company office. The Corporate officer who can certify same is **Murray C. Clarke, President.**

Yours truly,

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

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4051 Glencoe Ave #11
Marina del Rey
California 90292

310 305-4640
800 993-0332
Fax 310 305-4680

e-mail
mailroom@childlife.net
Web www.childlife.net

Multi-Vitamin & Mineral

8 Fl. Oz. (237 ml)

Contents: Two teaspoons provide:		Children under 4 years % USRDA	Children 4 years and older % USRDA
VITAMINS			
Vit A (Retinol Palmitate)	850 IU	70%	35%
Beta Carotene	850 IU	70%	35%
Vit B 1 (Thiamine HCL)	2 mg	140%	135%
Vit B 2 (Ribo-5-phosphate)	2 mg	140%	135%
Vit B 3 (Niacinamide)	10 mg	100%	50%
Vit B 5 (d-pantothenal)	7 mg	70%	65%
Vit B 6 (Pyridoxine HCL)	2 mg	100%	100%
Vit B 12 (Cyanocobalamin)	6 mcg	200%	100%
Vit C (Ascorbic Acid)	135 mg	170%	165%
Vit D 3 (Cholecalciferol)	275 IU	70%	65%
Vit E (d-alpha-tocopheryl)	20 IU	100%	65%
Vit K (Phytonadione)	15 mcg	15%	15%
Biotin	65 mcg	45%	20%
Folic Acid (Folate)	135 mcg	130%	35%
PABA (para-amino benzoic acid)	1 mg	*	*
Inositol	5 mg	*	*
Choline	20 mg	*	*
MINERALS			
Calcium (lactate)	55 mg	8%	5%
Magnesium (hydroxide)	15 mg	12 %	3%
Potassium (citrate)	14%	*	*
Iodine (potassium iodide)	50 mcg	70%	30%
Chromium (polynicotinate)	7 mcg	25%	5%
Manganese (gluconate)	1.5 mg	100%	70%
Selenium (selenomethionine)	35 mcg	110%	50%
Zinc (gluconate)	5 mg	60%	30%
* No USRDA established			

Other Ingredients: Natural Orange-Mango Flavor, Purified Water, Fructose, Lecithin, Xanthan, Citricidel (grapefruit seed extract), Citric Acid, Potassium Sorbate (as preservative).

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November 19, 2002

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5100 Paint Branch Parkway
College Park MD 20740

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Statement of Nutritional Support- VITAMIN C

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 **Vitamin C**:

- 1) Name and Address of Distributor: **4051 Glencoe Avenue, unit 11. Marina del Rey, California 90292.**
- 2) Text of Nutritional Support Statement being made:
“**Vitamin C Supplement is designed to support healthy immune functions.**”
- 3) Name of dietary ingredient:

Contents: each teaspoon provides		
Vitamin C (ascorbic acid)	250 mg*	USRDA 416%

Other Ingredients: Naturally flavored with Purified Water, Glycerin, Potassium Sorbate, Xanthan Gum, Fructose, and Natural Orange Flavor.

- 4) Brand Name: **Vitamin C**
- 5) Substantiation information is on file at the company office. The Corporate officer who can certify same is **Murray C. Clarke, President.**

Yours truly,

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

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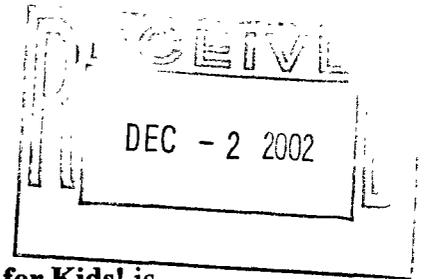
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November 19, 2002

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College Park MD 20740



Statement of Nutritional Support- FIRST DEFENSE

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 **First Defense**:

- 1) Name and Address of Distributor: **4051 Glencoe Avenue, unit 11. Marina del Rey, California 90292.**
- 2) Text of Nutritional Support Statement being made:
"First Defense Supplement is designed to support natural immune responses and defend the body."
- 3) Name of dietary ingredient: See attachment.
- 4) Brand Name: **First Defense**
- 5) Substantiation information is on file at the company office. The Corporate officer who can certify same is **Murray C. Clarke, President.**

Yours truly,

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

4051 Glencoe Ave . #11
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California 90292

310 305-4640
800 993-0332
Fax 310 305-4680

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mailroom@childlife.net
Web: www.childlife.net

82751

First Defense

4 Fl. Oz. (118.5 ml)

Contents: each teaspoon provides		
Olive Leaf Extract	80 mg	
St. John's Wort	20 mg	
Larch Arabinogalactan	15 mg	
Silver	12 ppm	
Zinc Gluconate	3mg	USRDA 40%

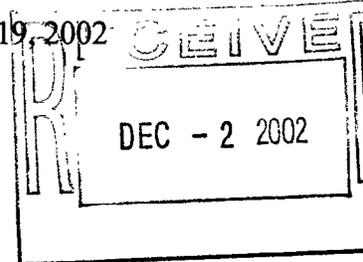
Other Ingredients: Naturally flavored with Glycerin, Citric Acid, Grapefruit Seed Extract, Potassium Sorbate, and Gum Arabic.

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Statement of Nutritional Support- COLOSTRUM WITH PROBIOTICS

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 **Colostrum with Probiotics**:

- 1) Name and Address of Distributor: **4051 Glencoe Avenue, unit 11. Marina del Rey, California 90292.**
- 2) Text of Nutritional Support Statement being made:
"Colostrum with Probiotics Supplement is designed to support immune and digestive strength."
- 3) Name of dietary ingredient: See attachment.
- 4) Brand Name: **Colostrum with Probiotics**
- 5) Substantiation information is on file at the company office. The Corporate officer who can certify same is **Murray C. Clarke, President.**

Yours truly,

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

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Colostrum with Probiotics

50g Powder

Contents: ¼ tsp (1 g) provides	
Colostrum	625 mg*
Rice Tocotrienols	200 mg
F.O.S. (Fructo-Oligo-Saccharides)	100 mg*
Probiotic Bacteria	75 mg*
Providing	
Bifidobacterium Bifidum	0.5 billion*
Bifidobacterium Infantis	0.5 billion*
Lactobaccillus Acidophilus	0.5 billion*
<i>*Daily value not established.</i>	

Other Ingredients: All Natural Citrus Flavor, Energy Smart®.

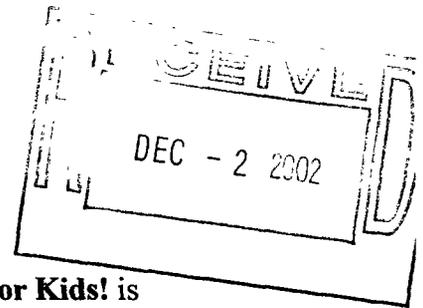
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College Park MD 20740



Statement of Nutritional Support- ECHINACEA

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 **Echinacea**:

- 1) Name and Address of Distributor: **4051 Glencoe Avenue, unit 11. Marina del Rey, California 90292.**
- 2) Text of Nutritional Support Statement being made:
"Echinacea Supplement is designed to support natural immune responses and defends the body."
- 3) Name of dietary ingredient:

Contents: 10 drops (0.5 ml) provides	
Echinacea augustifolia	15.00 mg
Echinacea purpurea	15.00 mg

Other Ingredients: Naturally flavored with Vegetable Glycerin, Distilled Water, and Natural Orange Flavor.

- 4) Brand Name: **Echinacea**
- 5) Substantiation information is on file at the company office. The Corporate officer who can certify same is **Murray C. Clarke, President.**

Yours truly,

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

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