

JUL V 3 2002

Office of Nutritional Products, Labeling and Dietary Supplements Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW, WASHINGTON DC 20204

June 24, 2002

Re: ECHINADORON

Pursuant to 21 CFR Part 101.93, Weleda, Inc. is filing the following Statement of Nutritional Support for the Dietary/Herbal Supplement marketed as ECHINADORON:

- 1 Weleda, Inc. 175 North Route 9W, Congers, NY 10920
- 2. Text of Nutritional Support Statement being made: "Immune Support"
- 3. Name of dietary ingredients: Extract of Echinacea angustifolia (whole plant), extract of Calendula (herb), extract of Chamomile (flower)
- Brand Name: Echinadoron
- 5. Substantiation information on file at the company office. The corporate officer who can certify same is Erk Schuchhardt, Vice President of Weleda, Inc.

Yours truly,

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Petra Augenstein-Caporale, RPh Chief Pharmacist Weleda, Inc.

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Echinadoron

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Supplement Facts
Serving size 1 tablet
Amount per serving

Calories 3 85Kcal Echinacea angustifolia (whole plant) 75mg** Calendula (herb) 100mg** Chamomile (flower) 10mg**

**Daily value not established Lot# Exp Directions: Let tablet disolve in mouth Adults 1-2 tablets 3-4 times

Dietary supplement **50 TABLETS**

daily Children (4-12) 1 tablet 3-4 times daily

lagretients: Lactose, Sucrose, extract of Echinacea angustifolia (whole plant), extract of Calendula (herb), extract of Chamomie (flower), Tragacanth Calcium behenale, Eucalyptus oil

(flower), tragacanth. Calcum behenaie, Eucalyptus bit Warnings: When used occasionally discontinue use after 10 days When used regularly, discontinue use in 3 week cycles Not recommended for immune-compromised individuals. If you have kidney disease or are dabetic, consult your healthcare provider before using this product. Use with caution if you have ragweed allergy If pregnant or breast-feeding, ask a health professional hefore use

before use Keep out of reach of children

*This statement has not been evaluated by the FDA This product is not intended to diagnose, treat, cure or prevent any disease.

Do not purchase if safety seal is broken or missing

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