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Office of Nutritional Products Labeling and Dietary Supplements (HFS-810) Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Pkwy COLLEGE PARK MD 20740

July 19, 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)
- 4. Brand Name: Echinadoron
- 5. Substantiation information on file at the company office. The corporate officer who can certify same is Erk Schuchhardt, President of Weleda, Inc.

Yours truly,

Pelm a. aiguile -

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

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Dietary supplement **50 TABLETS**

Echinadoron Immune Support* WELEDA ÷.,

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

Ingredients: Lactose, Sucrose, extract of Echinacea angustifolia (whole plant), extract of Calendia (herb) extract of Charnomie (flower), Tragacanth Calcium behenate Eucalyptus oil

(nower), tragacanin Calcium benenate Eucalyptus oil 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 diabetic, 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 before 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

Made in Switzerland Distributed by Weleda Inc Congers NY 10920 USA