

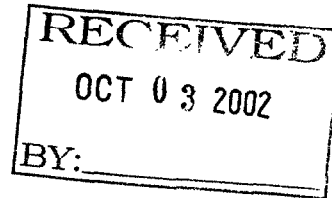


Quality Through Nature

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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

September 27, 2002



Re: CHELIDONIUM CURCUMA COMPOUND

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

1. Weleda, Inc.
175 North Route 9W, Congers, NY 10920
2. Text of Nutritional Support Statement being made: "Liver and Gallbladder Tonic"
3. Name of dietary ingredients: Giant squash (fruit pulp), Turmeric (rhizome), Celandine (rhizome)
4. Brand Name: CHELIDONIUM CURCUMA COMPOUND
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,

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

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Weleda, Inc., 175 North Route 9W, Congers, NY 10920

(800) 241-1030 ■ Fax: (845) 268-8574 ■ e-mail: admin@weleda.com ■ Internet: usa.weleda.com



WELEDA

Chelidonium Curcuma Compound

Liver and gallbladder
Tonic*

Dietary supplement

100 TABLETS

Supplement Facts	
Serving size, 1 tablet (220 mg)	
Amount per serving:	
Giant squash (fruit pulp) 58mg**	
Turmeric (rhizome) 17.6mg**	
Celandine (rhizome) 4.4mg**	
**Daily value not established	

Other ingredients:

Rice starch, Calcium behenate (from rape seed oil)

Directions:

Take 1-2 tablets three times daily with a small glass of water, before meals

Warnings:

Do not use for an extended period. If you take heart medications, consult your doctor before taking this product. If you have kidney problems or loss of appetite, see your doctor before taking this product. If you have liver or gallbladder problems, see your doctor. Discontinue use if you experience stomach problems, and see your doctor.

Keep out of reach of children.
Do not purchase if safety seal around cap and neck is broken or missing.

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

Made in Switzerland
Distributed by Weleda Inc. Congers NY 10920 USA
Lot# Exp