WELEDA
Quality Through Nature

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

February 5, 2004

Re: NURSING TEA

Pursuant to 21 CFR Part 101.93, Weleda, Inc. is filing a Statement of Nutritional Support for the Dietary Supplement marketed as NURSING TEA. Please note that the formula has been changed as stated below; the product with the previous formulation is not marketed any more.

1. Marketed by: Weleda, Inc., 175 North Route 9W, Congers, NY 10920.
2. Text of Nutritional Support Statement being made: "Supports Healthy Lactation."
3. Name of dietary ingredients: Fenugreek seed, Anise seed, Fennel seed, Caraway seed and Lemon verbena leaves.
4. Brand Name: NURSING TEA.
5. Substantiation information on file at the company office. The corporate officer who can certify same is Erk Schuchhardt, President of Weleda, Inc.

A copy of the labeling is attached (box).

Yours truly,

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

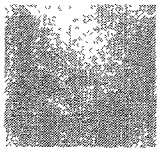
97S 0162 LET 13808

WELEDA

Nursing Tea

Dietary supplement

Supports Healthy Lactation*



Mode d'emploi : Placer un sachet de tisane dans une tasse d'eau bouillante. Couvrir et laisser infuser pendant 5 minutes. Boire jusqu'à 3 tasses par jour. Etant donné qu'il est essentiel d'utiliser de l'eau de qualité pour obtenir une bonne tisane, nous recommandons de l'eau de source ou de l'eau filtrée afin d'optimiser les résultats.
Ingrédients : Fenugrec (graines), anis (graines), fenouil (graines), carvi (graines), verveine citronnelle (feuilles).
Tous les ingrédients qui composent notre tisane d'allaitement sont cultivés et récoltés selon les normes de qualité de WELEDA, et sont certifiés biologiques par BCS ÖKO-GARANTIE GMBH, Allemagne
Aucun arôme, agent conservateur ou édulcorant n'a été ajouté à ce produit.
Précautions : Ne pas utiliser si vous êtes allergique à l'anis, à l'anéthole ou à tout autre ingrédient contenu dans cette infusion. Si vous souffrez d'allergie au céleri ou êtes sous traitement contre le diabète, veuillez consulter un professionnel de la santé avant d'utiliser ce produit. Les personnes atteintes de maladies du rein ou du coeur doivent utiliser ce produit avec précaution. Si une éruption cutanée survient, cesser l'emploi et consulter un médecin.
Grossesse: Ce produit est recommandé pour les femmes qui allaitent. Il ne devrait pas être utilisé durant une grossesse sans avoir consulté un médecin traitant.

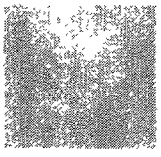
***Cette allégation n'a pas été évaluée par la FDA. Ce produit n'est pas destiné à diagnostiquer, traiter, guérir ou prévenir des maladies**

WELEDA

Nursing Tea

Dietary supplement

Supports Healthy Lactation*



20 TEA BAGS 14 OZ (40g)

WELEDA Natural Medicines for Mothers and Children

Calciodoron AM & Calciodoron PM
Supports calcium absorption, relieves painful and slow teething; helps inadequate lactation. These lactose-based remedies are taken internally:
- In the morning: Calciodoron-AM; active ingredient: Apatite 5X
- In the evening. Calciodoron-PM, active ingredient: Calcarea carbonica 1X

Calendula Ointment
This effective ointment helps to treat minor skin irritations and rashes. Ideal for even the most sensitive areas, particularly sore and cracked nipples in nursing mothers
Active ingredient: Calendula officinalis Tincture (M)

Sedative Pilules
Weleda's Sedative Pilules represent Avena sativa Compound in convenient pellet form, used for the temporary relief of sleeplessness, nervousness and agitation. Active ingredients: Avena sativa Tincture (M), Valeriana Tincture (N), Passiflora incarnata Tincture (N), Coffea tosta Decoction , Humulus lupulus Tincture (N).

Wound-Care
Apply this essential balsam for the care of cuts, skin abrasions and slow-healing wounds. Active ingredients Mercurialis perennis Tincture (M), Calendula officinalis Tincture (M)

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Apply this essential balsam for the care of cuts, skin abrasions and slow-healing wounds. Active ingredients. Mercurialis perennis Tincture (M), Calendula officinalis Tincture (M)

Arnica Ointment
Use WELEDA's Arnica Ointment for bruises, sprains, sore and aching muscles, black and blue marks. Active ingredient Arnica montana Tincture (N).

Burn-Care
A soothing, cooling gel, WELEDA's Burn-Care offers treatment of minor household's burns, sunburns and insect bites. Active ingredients: Urtica urens 1X, Arnica montana 1X

Venadoron Leg Toner
Revitalizes and tones tired legs. With copper and various plant extracts, this gel helps ease the feeling of discomfort and heaviness in tired feet and legs. Useful during pregnancy, as well as for people who are on their feet a lot.

Foot Balm
Weleda's Foot Balm contains myrrh and calendula in a citrus base; it cools, softens calluses and revitalizes the skin. It does not contain menthol, which could be irritating.

WELEDA NURSING TEA – Certified organic, rich in vitamins and minerals

Mother's Milk is a complete and perfect nourishment. Generally, breast-fed babies develop harmoniously, partly due to the close bond formed between mother and child. Breast-feeding provides a basis for good health throughout life. Even the best substitutes cannot impart the resistance to illnesses that mother's milk provides.

'digestible and rich in vitamins and minerals. WELEDA's
thy lactation*, but it also has a soothing effect on the
)A's Nursing Tea has been sold to thousands of satisfied

v.weleda.com or call (800) 241-1030

he FDA. This product is not intended to diagnose,

Directions: Add one tea bag to a cup of boiling water. Cover and let stand for 5 minutes. Drink up to 3 cups daily. Because good water is essential to brewing a great cup of tea, we recommend using spring or filtered water to ensure the best result.
Ingredients: Fenugreek seed, Anise seed, Fennel seed, Caraway seed and Lemon verbena leaves.
All the ingredients in our Nursing Tea are grown and harvested according to WELEDA quality standards and are certified organic by BCS ÖKO-GARANTIE GMBH Germany.
No flavorings, preservatives or sweeteners are added to this product.
Warnings: Do not use if you are allergic to anise, anethole, or any of the ingredients of this tea. If you have a celery allergy or are being treated for diabetes, consult a health professional before use. Use with caution in individuals with kidney and heart disease. If you experience a skin rash, discontinue use and consult your doctor.
This product is intended for lactating women, and should not be used during pregnancy without consulting with your health care provider.

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

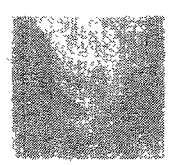
Made in Germany / Fabriqué en Allemagne
Distributed by / Distribué par: WELEDA INC., NY – USA /
Purity Life Health Products Ltd. Ontario – Canada
www.weleda.com

WELEDA

Tisane d'allaitement

Supplément alimentaire

Favorise une lactation saine*



20 SACHETS 1.4 OZ (40g)

0 95508 81601 7

Nutrition Facts

Serving size: 1 Tea Bag (0.07 oz)
Servings per container: 20

Amount per serving	
Calories: 0	Calories from fat: 0
	%Daily value**
Total fat 0g	less than 2%
Sodium 0g	less than 2%
Total carbohydrates 0g	less than 2%
Sugars 0g	
Protein 0g	less than 2%

**Percent values are based on a 2000 calories diet

Valeur nutritive

Quantité par portion : 1 sachet (2g)
Portions par boîte : 20

Quantité par portion	
Calories: 0	Calories provenant des matières grasses: 0
	% valeur quotidienne**
Total lipides 0g	moins de 2%
Sodium 0g	moins de 2%
Total glucides 0g	moins de 2%
Sucres 0g	
Protéines 0g	moins de 2%

** Valeurs fondées sur un régime de 2000 calories