WELEDA
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

RECEIVED 2/13/04

January 23, 2004

Re: CORDIODORON TABLETS

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

1. Marketed by: Weleda, Inc., 175 North Route 9W, Congers, NY 10920.
2. Text of Nutritional Support Statement being made: "Supports heart health and circulation."
3. Name of dietary ingredients: Cowslip extract (flower), Scotch thistle extract (flower), Henbane extract (herb).
4. Brand Name: CORDIODORON TABLETS.
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.

Yours truly,

Petra A. Augenstein-Caporale

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

97S 0162 LET 13495

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Weleda, Inc., 175 North Route 9W, Congers, NY 10920
(800) 241-1030 v Fax: (845) 268-8574 v e-mail: admin@weleda.com v Internet: usa.weleda.com

Package Insert on carton inside.

WELEDA

Cordiodoron Tablets

Package Insert on carton inside.

Keep out of reach of children. Do not purchase if safety seal ring in closure is broken or missing.

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

Données sur le supplément

Portions par flacon : 200
Portion : 1 comprimé

Quantité par portion	% valeur quotidienne
Extrait de grémil blanchâtre (fleur) 5 mg	**
Extrait de chardon lancéolé (fleur) 5 mg	**
Extrait de jusquiame noire (herbe) 0,2 mg	**

** valeur quotidienne non établie

WELEDA AG - Schwäbisch Gmünd -Germany
Distributed by/Distribué par
WELEDA INC., NY – USA.
Est.#2430869
Purity Life Health Products Ltd.
Ontario - Canada

Autres ingrédients : lactose, eau, amidon de blé, calcium-béhénate

Mode d'emploi : A partir de 7 ans : 1 comprimé 4 fois par jour. Enfants de 2 à 7 ans : 1/2 comprimé 4 fois par jour.

Précautions : Si vous êtes enceinte ou si vous allaitez, consultez un professionnel de la santé avant d'utiliser ce produit. Ne pas prendre plus de 8 comprimés par période de 24 heures (ou 4 comprimés de 2 à 7 ans) Ne pas utiliser ce produit si vous êtes allergique au grémil blanchâtre ou à l'amidon de blé. Ne pas prendre ce produit si vous souffrez de tachycardie, d'arythmie, d'adénome prostatique, de glaucome par fermeture de l'angle, d'œdème pulmonaire aigu, de sténose du tube digestif ou du mégacôlon. Ne pas prendre ce produit si vous prenez déjà des antidépresseurs tricycliques, de l'amantadine, des antihistaminiques, des phénothiazines, de la procaïnamide ou de la quinidine. Si vous souffrez d'intolérance au lactose, consultez un professionnel de la santé avant d'utiliser ce produit. Garder hors de la portée des enfants. Ne pas acheter si le sceau de sécurité entourant le capuchon est brisé ou manquant.

*** 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

Cordiodoron Tablets

Dietary supplement
Supports heart health & circulation*

Supplément alimentaire
Encourage la santé du coeur et la circulation*

200 tablets /comprimés

Supplement Facts

Servings per container 200
Serving size: 1 tablet

Amount per serving	%Daily value
Cowslip extract (flower) 5 mg	**
Scotch thistle extract (flower) 5 mg	**
Henbane extract (herb) 0,2 mg	**

**Daily value not established

Other Ingredients: Lactose, Water, Wheat starch, Calcium-behenate.

Directions: Age 7 and older: 1 tablet 4 times daily
Age 2 - 7: 1/2 tablet 4 times daily.

Warnings: If you are pregnant or breastfeeding, consult a health professional before use. Do not exceed 8 tablets in 24 hours (or 4 tablets for age 2-7). Do not take if you are allergic to cowslip or wheat starch. Do not take if you suffer from tachycardiac arrhythmias, prostatic adenoma, angle-closure glaucoma, acute pulmonary edema, mechanical stenoses of the gastrointestinal tract or megacolon Do not take together with tricyclic antidepressants, amantadine, antihistamines, phenothiazines, procainamide or quinidine. If you are lactose-intolerant, consult a health professional before use.

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Cordiodoron Tablets

Dietary supplement
Supports heart health and circulation*
Supplément alimentaire
Encourage la santé du coeur et la circulation*

Most of the necessary fresh plants used in WELEDA medicines are grown in WELEDA's own biodynamic gardens. Wild crafted plants are collected directly in their natural habitats. In addition, we purchase some plants from sources that meet our high quality standards.

About the ingredients used in Cordiodoron Tablets:
Cowslip extract (Primula veris) supports the anabolism in the heart through its sulfuric nature and is a mild cardiac stimulant.
Henbane (Hyoscyamus niger) regulates the interaction between Cowslip extract and Scotch thistle and, as such, works on the rhythmic aspect of the heart function.
Scotch thistle (Onopordum) supports the catabolic processes in the heart and stimulates the concurrent formative forces.
Other ingredients:
Calcium Behenate, an excipient for tablet manufacturing.
Lactose: milk sugar.
Wheat Starch: helps disintegrate tablets for better absorption.

Other WELEDA self-medication products
ALOE VERA NASAL SPRAY - *Moisturizing care for nasal passages. Preservative-free.*
SINUS ALLERGY FORMULA - *Relief for sinus and allergy symptoms.*
ECHINADORON - *Immune support**
ARNICA OINTMENT - *For sprains, bruises and muscle pain.*
CALCIODORON AM - *Supports calcium absorption. Taken in the morning.*
CALCIODORON PM - *Supports calcium absorption. Taken in the evening.*
HEPATODORON - *Supports normal liver function.**
BURN-CARE - *For burns, sunburns and insect bites.*
CALENDULA OINTMENT- *For rashes and minor skin irritations.*
WOUND-CARE - *For cuts, skin abrasions and slow healing wounds.*

For more information visit our website www.weleda.com or call (800) 241-1030

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