



0023 7 OCT -2 P2:07

SEP - 4 2007

Mr. Oskar Thorvaldsson  
Source of Health, Inc.  
1055 Bay Boulevard, Suite A  
Chula Vista, California 91911

Dear Mr. Thorvaldsson:

This is in response to your letter of August 22, 2007 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Source of Health, Inc. (dba Self Health Resource Center, Dr. Clark Store, and Dr. Clark Purity Products) is making the following claims, among others, for the following products:

Dr. Clark ParaZap

"Helps create an unfriendly environment for parasites"

"[H]alf of all Americans are infested with unwanted parasitic organisms (worms, larvae, and eggs."

"ParaZap Parasite Cleanse supports your body's own ability to destroy and remove these unwelcome "guests."

Dr. Clark Liver & Gallbladder Cleanse

"Helps remove unwanted gallstones that do not interfere with normal health."

Dr. Clark Kidney Cleanse

"Helps remove unwanted kidney stones that do not interfere with normal health."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases (i.e., gallstones, kidney stones, and parasitic infestations). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If your client intends to make claims of this nature, they should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

19975-0163

LET 963

Page 2 - Mr. Oskar Thorvaldsson

Please contact us if we may be of further assistance.

Sincerely yours,

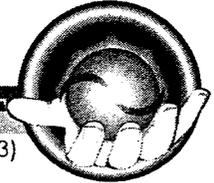


Vasilios H. Frankos, Ph.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutrition, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

**Copies:**

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

# Dr. Clark Purity Products



1055 Bay Boulevard ste A • Chula Vista, CA 91911 • Orders by phone 1-888-DHC-PURE (342-7873)  
E-mail: Service@DrClarkPurity.com • www.DrClarkPurity.com

Wednesday, August 22, 2007  
8/21/07



**Source of Health, Inc.**  
**DBA: Self Health Resource Center**  
**DBA: Dr. Clark Purity Products**  
**DBA: Dr. Clark Store**  
**1055 Bay Blvd, Ste A**  
**Chula Vista, CA 91911**

**Three Page(s)**  
**From: Oskar Thorvaldsson**  
**Fax: 619-409-9501**  
**Tel: 619-409-9500**

**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**

**Regarding:** Notification of Structure and Function Claims, per section 403(r)(6)  
**Enclosed:** An original and two copies of this notification

Hello,  
Please find enclosed the following three labels:

***Dr. Clark ParaZap***  
***Dr. Clark Kidney Cleanse***  
***Dr. Clark Liver & Gallbladder Cleanse***

I talked with Dr. Kenneth Taylor about structure and function claims. Among other things, we discussed the label from Nature's Secret called Parastroy, Para-Rid, and Para-Sweep. I also spoke to Gary Coody, R.Ph., who forwarded me your correct address and regulation 403(r)(6). I have also hired a label consultant. I have used all the advice gathered in the creation of the claims on the labels enclosed.

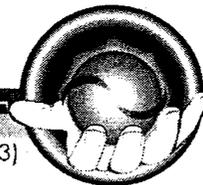
I am eager to follow the rules, therefore, in the case of you sending me corrective orders, please specify the paragraph of the rule that I am not following, this would be of great help for us to follow the rules when designing future labels. I have printed 700 of each label (about 6 months supply).

Dr. Taylor referred me to Mr. Fred Lockwood ([fred.lockwood@fda.hhs.gov](mailto:fred.lockwood@fda.hhs.gov) - tel - 301-827-1491) for advice on if I could enclose a separately packaged Epsom Salt bag in the liver cleanses kits. I contacted Fred on May 30<sup>th</sup> 2007. I talked to him several weeks after first contacting him however he never heard back from the people he asked about this for me. I assumed therefore that it was OK to include it in the kit.

Should you have any comments or have any questions please don't hesitate giving me a call, I am available at 619-409-9500.

1938

# Dr. Clark Purity Products



1055 Bay Boulevard ste A • Chula Vista, CA 91911 • Orders by phone 1-888-DHC-PURE (342-7873)  
E-mail: Service@DrClarkPurity.com • www.DrClarkPurity.com

## **Dr. Clark ParaZap**

Text of the statement: *Helps create an unfriendly environment for parasites. \**

*Numerous studies indicate that over half of all Americans are infested with unwanted parasitic organisms (worms, larva and eggs). In most instances, people are unaware that they have them. ParaZap Parasite Cleanse supports your body's own ability to destroy and remove these unwelcome "guests". ParaZap is a Professional Grade Parasite Cleanse made in accordance with Dr. Clark's published protocols. \**

*ParaZap contains a unique combination of tincture and pure, fresh herbs that provide powerful cleansing support when used as directed. This cleanse supports the body's natural defenses with natural compounds that discourage the proliferation of foreign organisms known to occupy the human body. ParaZap is designed to help support the body's immune system so that foreign organisms are naturally expelled.\*\**

**\*Disclaimer:** These statements have not been evaluated by the U.S. Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Only use this cleanse to help your body to remove parasites that prior to removal did not cause any disease. Please consult with your Health Professional about parasite infestations that cause illness.

Although some of us or our customers may be interested in the research and statements of Dr. Clark, this company, its web site and owner do not adopt any health or disease related claims based on her work or otherwise.

## **Ingredients:**

1. Green Tincture of Black Walnut Hull (1 fl. oz.)  
Black Walnut Hulls (From Green Hulls) – 14955 mg – Tincture Strength Average (hull : grain alcohol) 1:0.68
2. Freshly Ground Cloves (102 capsules)  
Cloves – 1500 mg
3. Power W Blend (77 capsules)  
Wormwood – 1890 mg, Quassia, Male Fern

## **Dr. Clark Kidney Cleanse**

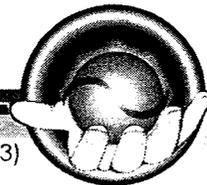
Text of the statement: *Helps remove unwanted kidney stones that do not interfere with normal health. \**

*The Dr. Clark Kidney Cleanse is a Professional Grade Cleanse researched and developed by Dr. Hulda Clark. This cleanse contains pure, fresh herbs and carefully selected supplements that provide powerful cleansing action when used as instructed. \**

*Your kidneys are sophisticated reprocessing machines. Every day, your kidneys process about 200 quarts of blood, filtering out some two quarts of waste products and extra water. If your kidneys did not remove these wastes, toxins would build up in the blood and damage your body. The Dr. Clark Kidney Cleanse may help you maintain cleaner, healthier, more efficient kidneys. The Dr. Clark Kidney Cleanse is designed to help stimulate the body's natural tendency to function smoothly and efficiently. \**

**\*Disclaimer:** These statements have not been evaluated by the U.S. Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

# Dr. Clark Purity Products



1055 Bay Boulevard ste A • Chula Vista, CA 91911 • Orders by phone 1-888-DHC-PURE (342-7873)  
E-mail: Service@DrClarkPurity.com • www.DrClarkPurity.com

Only use this cleanse to help your body to remove kidney stones that prior to removal did not cause any disease. Please consult with your Health Professional about kidney stones that cause illness.

Although some of us or our customers may be interested in the research and statements of Dr. Clark, this company, its web site and owner do not adopt any health or disease related claims based on her work or otherwise.

**Ingredients:** Hydrangea Root, Marshmallow Root, Gravel Root, Ginger Root, Goldenrod Tincture, Uva Ursi, Vitamins B6 and B2, Magnesium Oxide, and Hydrochloric Acid.\*

## Dr. Clark Liver & Gallbladder Cleanse

Text of the statement: *Helps remove unwanted gallstones that do not interfere with normal health.\**

*This is a two-part Liver Cleanse consisting of Liver Support Tea and Liver/Gallbladder Cleanse. After feeding your liver with the phytonutrition packed tea (enough supplies for 48 cups are included) you then help your body to remove unwanted gallstones that do not interfere with normal health from your gallbladder and liver following the cleanse directions enclosed. This box includes enough supplies for 5 separate Liver/Gallbladder Cleanses\*. Caution: Do not use if you know or suspect you have an obstructed bile duct or problematic gallstones.*

**PREPARATIO:** *Always make sure you have completed the ParaZap Parasite Cleanse and stayed on the Parazap Maintenance Program before taking the Liver Cleanse. For best results also complete the Dr. Clark Kidney Cleanse before taking this cleanse. Initially, you may repeat the Liver Cleanse at two-week intervals. After your initial cleanses, a quarterly or semi-annual Liver Cleanse may be enough.\**

**\*Disclaimer:** These statements have not been evaluated by the U.S. Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Only use this cleanse to help your body to remove gallstones that prior to removal did not cause any disease. Please consult with your Health Professional about gallstones that cause illness.

Although some of us or our customers may be interested in the research and statements of Dr. Clark, this company, its web site and owner do not adopt any health or disease related claims based on her work or otherwise.

**Ingredients:** Tanner's Oak Bark, White Oak Bark, Gravel Root, Queen of the Meadow Root, Marshmallow Root, Althea Root, Black Walnut Hull, Mullein Leaf, Milk Thistle Herb, Wild Yam Root, Licorice Root, and Skullcap.

~\*~\*~\*~

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement is truthful and not misleading.

Should you have any questions please don't hesitate calling me.

Thank you,

Oskar Thorvaldsson