DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

SAMPLE DOCKETS TRANSMITTAL MEMO

Date: JAN 23 2003

From: Consumer Safety Officer, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-821

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification:	Yamoa ™ Powder (tree bark of *Funtumia Elastica*)
Firm:	The Remedy Company, Inc.
Date Received by FDA:	March 18, 2002
90-Day Date:	June 6, 2002

04 06 '03 JAN 27 P1:59

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Victoria Lutwak
HFS-821
Tel. 301-436-1775

Attachments

95S-0316

RPT 124

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD

MAY 31 2002

Paul G. Cowan
President
The Remedy Company, Inc.
800 del Lago Circle, #202
Palm Beach Gardens, Florida 33410

Dear Mr. Cowan:

This is in response to your correspondence, dated February 13, 2002, to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 350b(a)(2). On March 18, 2002, FDA received and filed your notification that asserts that Yamoa™ Powder, that is the bark of *Funtumia Elastica* of the *Apocynaceae* family, a gum tree indigenous to Ghana, West Africa, is a new dietary ingredient. We cited species name for this botanical ingredient in lower case letters to conform to the internationally accepted rules of botanical nomenclature.

21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor of a dietary supplement that contains a new dietary ingredient submit certain information to FDA at least 75 days before the dietary ingredient is introduced or delivered for introduction into commerce. This information must include the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the new dietary ingredient is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B), because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness and injury.

Your notification is incomplete and does not meet the minimum requirements in 21 CFR § 190.6. Without the complete required information, we cannot review the basis for your determination regarding the safety of your ingredient. For your convenience, we have attached a copy of the section of the CFR that addresses these requirements. There is also a website address http://www.cfsan.fda.gov/~dms/ds-ingrd.html that may further assist you in submitting the required information.

The notification you sent us concerning Yamoa™ Powder does not comply with the requirements of 21 CFR § 190.6 because it fails to:

- sufficiently describe Yamoa™ Powder, (e.g., identify the genus, species, and the author and any other known relevant properties of the ingredient);

- your suggested labeling indicates mixing instructions but does not provide enough information to clarify the level of use recommended/suggested by the mixing instructions. Section 402(f)(1)(A) references conditions of use recommended or suggested in labeling. Therefore, please specify the level of Yamoa™ Powder that would be the level of use per serving, i.e, what amount of Yamoa™ Powder is contained in a 5 mL dose (1 teaspoonful) of the honey and Yamoa™ Powder mixture. Information on recommended number of servings per day is not specified. Moreover, while your suggested label states that the recommended course is for one month, it is not clear whether it is recommended that use cease after one month or whether intermittent use for long-term or chronic use is anticipated; and
- provide a history of use or other evidence of safety indicating that Yamoa™ Powder when used as indicated in the suggested labeling or under ordinary conditions of use is reasonably expected to be safe (e.g., citations to published articles must be accompanied by photostatic copies or reprints of the published articles in English) (See 21 CFR § 190.6). The information you sent does not clarify whether the herbal preparation tested was identical to the Yamoa™ Powder you wish to market as a dietary supplement. Without further details, it is not possible for FDA to determine how the data relates to your Yamoa™ Powder product at the recommend intake level.

For the reasons discussed above, the information in your notification does not provide an adequate basis to conclude that the use of Yamoa™ Powder in a dietary supplement is reasonably expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 321(g)(1)(B) as a dietary supplement that contains Yamoa™ Powder for which there is inadequate information to provide reasonable assurance that it does not present a significant or unreasonable risk of illness or injury. Introduction of such products into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

We note that your conditions of use suggest that the use of Yamoa™ Powder is "not to be taken by pregnant or breastfeeding women" and that "if symptoms persist or worsen consult your doctor." However, you did not provide or describe the symptoms. Further, your reference to "symptoms" suggests that Yamoa™ Powder is used to cure, mitigate, or treat disease. Under 21 U.S.C. 321(g)(1)(B), an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals is defined as a drug. Therefore, Yamoa™ Powder may be subject to regulation as a drug under 21 U.S.C. 321(g)(1)(B) and may not be a dietary supplement. If you want Yamoa™ Powder to be evaluated for its use in the treatment of a disease, you should contact FDA's Center for Drug Evaluation and Research, Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Your notification will be kept confidential for 90 days from the date of its receipt. After, June 16, 2002, your notification will be placed on public display at FDA's Dockets Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notification will not be disclosed to the public. You may wish

to identify what information you believe is proprietary. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notification should be redacted before it is posted at Dockets.

Sincerely yours,

Felicia B. Satchell

Felicia B. Satchell
Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

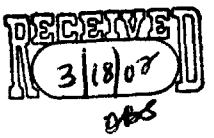
Enclosures

02.13.02

TO: Office of Special Nutritionals (HFS-450)

FROM: The Remedy Company, Inc.

RE: New Dietary Ingredient Notification.



Dear Sir/Madam,

Please find listed the requirements for pre-market notification of a new dietary supplement as listed in Sec 190.6 in 21 CFR Part 190.

1. The name and address of the manufacturer of the supplement is:

   Mr. Jerry Yamoa
   NHC Ltd
   13 Lyon Road
   Hersham Industrial Estate
   Walton-on-Thames
   Surrey
   KT12 4YH
   United Kingdom

2. The name of the new dietary supplement is ***Yamoa™ Powder***. The dietary ingredient is the bark of *Funtumia Elastica* of the *Apocynaceae* family, a gum-tree indigenous to Ghana, West Africa.

3. (i) The dietary supplement contains no other ingredients or additives, it is 100% the new dietary ingredient, the powdered bark of Funtumia Elastica.

   (ii) As suggested on the labelling, the conditions for use are:

   Mix the entire contents thoroughly with a 454g jar of honey. Stir the mixture each time before use. Recommended course: 1 month.
   Adults: One 5ml spoon twice a day.
   Children under 12 years: Half a 5ml spoon twice a day.
   Keep out of reach of children.
   Not to be taken by pregnant or breastfeeding women.
   If symptoms persist of worsen consult your doctor.

The Remedy Company, Inc., 800 del Lago Circle #202, Palm Beach Gardens, FL 33410
Tel: 561-624-4463 Email: remcompany@hotmail.com

4. Scientific studies have been performed upon the new dietary ingredient to prove it is safe for human consumption. The results of these studies are shown in:

   (i) **Document 1** — Centre for Scientific Research into Plant Medicine (Ministry of Health – Ghana)- "Acute Toxicity Study and Phytochemical studies on 'Yamoa Herbal Preparation", dated 19th Nov 1996, conducted by Prof. A.N. Tackie, Acting Director.

   (ii) **Document 2** — Centre for Scientific Research into Plant Medicine (Ministry of Health – Ghana)- "Yamoa Herbal Preparation", dated 9th Feb 1998, conducted by S. Osafio Mensah Msc., (Research Officer) Pharmacology & Toxicology Dept.

   (iii) **Document 3** — University of Central Lancashire (United Kingdom). "Microbiological Analysis of Yamoa Powder", dated 17th Dec. 2001, conducted by Dr. E.L. Prince, Consultancy Manager.

   Also included is an article published by Dr David Williams, for Alternative magazine. I have hundreds of testimonials of people who have tried the new dietary ingredient, but as I understand only scientific evidence will be considered. However if this, or any other information will be of use to you, please do not hesitate to contact me.

   Sincerely,

02/13/02

Paul G. Cowan
President

The Remedy Company, Inc., 800 del Lago Circle #202, Palm Beach Gardens, FL 33410
Tel: 561-624-4463 Email: remcompany@hotmail.com

Centre for Scientfic Research Into Plant Medicine

(MINISTRY OF HEALTH)

In case of reply the number and date of this letter should be quoted.

My Ref. No.....

Your Ref. No.....

Tel. 41

REPUBLIC OF GHANA

P. O. Box 73
Mampong - Akwapim
Ghana

19th November, 1996

Dear Sir,

ACUTE TOXICITY STUDY AND PHYTOCHEMICAL STUDIES ON 'YAMOA.' HERBAL PREPARATION

I attach hereto a report on the toxicity study and phytochemical studies which you requested the Centre to conduct on your 'Yamoa ' herbal preparation.

Yours faithfully,

Prof. A.N. Tackie
(Acting Director).

'Yamoa.' (Natural Asthma Product)
c/o P.O. Box C1020,
Accra.

encl.

I certify that this a true copy of the original

CLEMENT A COLLISON
B.A.(Hons.) SOLICITOR

COLLISONS & CO SOLICITORS
Nationwide Building
1st, 2nd & 3rd Floors
1-3 Hildreth Street Balham, London
SW12 9RQ
Tel 0181 673 9242 Fax 0181 673 732

Acute toxicity and Phytochemical studies on "Yamoa " Herbal Preparation

Abstract

The "Yamoa " herbal preparation was investigated for its acute toxicity in albino rats and phytochemical screening. The acute toxicity concentration of the herbal preparation which killed 50% (LD_{50}) of albino rats within 24 h was 528 mg/kg body weight. The phytochemical screening revealed the presence of alkaloids, saponins and gallic tannins.

Introduction

"Yamoa " is a herbal preparation claimed to be used for the treatment of asthma. It was submitted to the Centre for safety assessment. This work sought to investigate into the acute toxicity using albino rats and to conduct phytochemical screening.

Materials and Method

Preparation of extract

The "Yamoa " herbal preparation weighing 30g was boiled with water for 30 minutes to give an aqueous extract of 90ml. This was freeze-dried and the final product (9.7g) was re-dissolved in physiological saline and this solution (.107g/ml) was used in this experiment.

Acute toxicity

Five groups (n=6) of male albino rats weighing between 150-200g were injected intraperitoneally with increasing amounts of the herbal mixture: 300, 405, 548, 740, 1000 mg/kg body weight. The rats were observed continuously for 10 h and the percentage mortality over 24 h period was recorded. The changes in various autonomic and behavioural responses were noted. The LD_{50} was calculated by probit analysis.

Results and Discussion

In the acute toxicity study, "Yamoa "-treated animals exhibited no signs of toxicity and no mortality observed up to 300 mg/kg dose level. Death was recorded 8 h after the injection of 1000 mg/kg i.p. of the herbal preparation, a dose that caused 100 percent death. Most of the rats showed nervous signs and crawling gait before death.

Their muscles contracted followed by severe depression and death in ventral recumbency with the hind limbs stretched backwards. The acute toxicity concentration of the herbal mixture which killed 50% (LD_{50}) of rats within 24 h was 528 mg/kg body weight.

The manufacturer's dosage of 1 teaspoonful twice daily (2.54g) worked out to be 820mg. Considering the LD_{50} (528 mg/kg) and an average human body weight to be 65kg, the manufacturer's dosage is within acceptable range of 0.02% of the LD_{50}.

The phytochemical screening results indicated the presence of alkaloids, saponins and gallic tannins as the major constituents. Detected in trace amounts were polyamides, triterpen glycoside and enodels.

Organoleptics:

Colour - Dirty brown

Taste - Tasteless immediately after taken, followed by bitterness in the throat

Odour - Odourless

Conclusion

The acute toxicity investigation has shown that it may be safe for human use since the manufacturer's dosage is within acceptable range of 0.02% of the LD_{50}.

Reference

Finney, D.S. (1971) Probit Analysis. Cambridge.

18/ul96

S. Osafo-Mensah MSc.
(Research Officer)
Pharmacology & Toxicology Dept.

Centre for Scientfic Research Into Plant Medicine

(MINISTRY OF HEALTH)

In case of reply the number and date of this letter should be quoted.

My Ref. No.....

Your Ref. No.....

Tel. 41

REPUBLIC OF GHANA

P. O. Box 73
Mampong - Akwapim
Ghana

9th FEBRUARY 19 98

Yamoa Herbal Preparation: A totally natural product that brings a healthy alternative to drugs.

The Yamoa herbal preparation was investigated for its acute toxicity and phytochemical screening in November 1996. Between January 1997 and January 1998 further work was done to arrive at the therapeutic safety of Yamoa.
Several clinical trials have been conducted to ascertain the true healing properties of the product.
In the acute toxicity study, "Yamoa"- treated animals exhibited no signs of toxicity, and no mortality observed up to 300mg/kg dose level.
The manufacturer's dosage of 1 teaspoon, twice daily (2.54kg) worked out to be 820mg. Considering the Ldso (528mg/kg) an average human body weight to be 65kg, the manufacturer's dosage is within an acceptable range of 0.02% of the Ldso.

The phytochemical screening results indicated the presence of alkaloids, saponins and gallic tannins as their major constituents.
Detected in trace amounts were polyamides, triterpen glucoside and enodels.
Yamoa is a totally natural product that is made from the ground bark of a tree, there are no additives or chemicals, it is a simple and effective alternative to conventional drugs.
The first patient that tried this product were amazed at how quickly it brought relief, and soon able to stop using their conventional medicine to control symptoms.
Asthmatics are normally prescribed preventative corticosteroids that are slow to reduce inflammation, along with brochodilators, such as ventolin, that open the airways and bring instant relief during attacks. Patients that are diagnosed as severe asthmatics, may also be prescribed steroid tablets.
There are also patients classified as latent asthmatics. Those people who have never had asthma before, but find themselves becoming increasingly breathless in their middle 40's due to environmental factors, very often have relentless attacks of coughing.

Since the product has been used, patients have been able to breathe better and symptoms have become minimal. Most never have to use any reliever medication.
Yamoa is simple, yet effective. It does not need commitment to the daily routine of conventional medicines or breathing exercises to control asthma attacks. After a few days attacks are reduced, and if the remedy is taken continuously for a month, patients can become free from symptoms.

I certify that this is a true copy of the original

COLLISONS & CO SOLICITORS
Nationwide Building

CLEMENT A COLLISON

Organoleptics:

Colour- Dirty brown.

Taste- Tasteless immediately after taken, followed by bitterness in the throat.

Odour- Odourless.

The investigation and clinical trials conducted have shown that Yamoa is safe for human use, since the manufacturer's dosage is within the acceptable range of 0.02% of the Ldso, and when the bark is dried, it can be safely stored for up to 6yrs before being ground for use.

The remedy has no known side effect, and has been used as a natural herbal medicine for many generations.

S. Osafo Mensah Msc.
(Research officer)
Pharmacology & Toxicology Dept.

UNIVERSITY
OF CENTRAL
LANCASHIRE

Microlan
Consultancy Services
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Preston PR1 2HE
Tel 0772 893503
Fax 0772 892903
Telex 677409 (UCLAN G)
Consultancy Manager
Dr Eddie Prince
BSc PhD

Paul Cowan
800 Del Lago Circle
202 Palm Gardens
Florida 33410
USA

17th. December 2001

Microbiological Analysis of Yamoa Powder

Samples received

Six individual sealed containers each containing 30 g of Yamoa Powder

Methods

According to your instructions, the above samples were pooled and subjected to a variety of microbiological analyses, with the following results;

Results

Faecal coliforms	none detected
Faecal streptococci	none detected
E.coli	none detected
Salmonella	none detected
Yeasts and Moulds	less than 100/g

Conclusion

The analyses undertaken provided no evidence of the presence of pathogenic bacteria on any of the samples examined.

Yours sincerely

Dr. E.L. Prince
Consultancy Manager