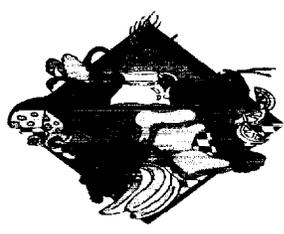
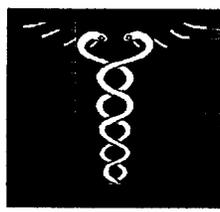


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Preventive Medicine of Tempe
8857 South Myrtle Avenue
Tempe, Arizona 85284
Tel./ Fax. : (480) 456 0475



Special Nutritional (HFS-450),
Food and Drug Administration,
200 C Street SW, Washington,
DC 20204
Tel: 202-205-4168
Fax 202-205-5295,

Tempe, April 12, 2000

To: Sharon Ross

My name is Martina Skujins, Director of Preventive Medicine of Tempe. Our company was founded in 1997 under the name Preventive and Alternative Medicine and changed in 1999 to Preventive Medicine of Tempe. Our mission is to educate the people in our community about the correct use of nutritional supplements, herbs and homeopathic remedies and warn them about potential hazard supplements that are out in the market. We totally agree with the process mention in the FDA Guidance Document of February 22, 2000.

Before significant scientific agreement can be assessed, a number of sequential threshold questions are addressed In the review of the scientific evidence:

- Have studies appropriately specified and measured the substance that is the subject of the claim?
- Have studies appropriately specified and measured the disease that is the subject of the claim?
- Are any and all conclusions about the substance/disease relationship based on the totality of publicly available scientific evidence?

The assessment of significant scientific agreement then derives from the conclusion that there is a sufficient body of sound, relevant scientific evidence that shows consistency across different studies and among different researchers and permits the key determination of whether a change in the dietary intake of the substance will result in a change in a disease endpoint.

The specific topics addressed in this guidance document are: identifying data for review, performing reliable measurements, evaluating individual studies, evaluating the totality of the evidence, and assessing significant scientific agreement.

However there are some products at the moment in the national market that are significant potential hazards to the human health. One good example is Prologix TM, a liquid mineral, which contains mercury and lead and is sold mostly to elderly people or people that have GI difficulties. So far, they got away with the claim note: that it has not been FDA approved. I personally started my own battle explaining people and retailers about the potential hazard of mercury and lead. But is there any way that products like these can be taken out of the market sooner?

We want to contribute in the process of selecting safer nutritional supplements and can be reached at the address above or via e-mail at: preventivehealth@usa.net

Sincerely

Martina Skujins, Director
Preventive Medicine of Tempe

PEOPLE HELPING PEOPLE

99D-5424

C11

Memo

11 8 3 '00 APR 28 P2 :20

To: Dockets Management Branch (HFA-305)
From: Sharon Ross, Nutritionist (HFS-832)
Date: April 28, 2000
Subject: RE: Comment to Docket Number 99D-5424

Attached please find a comment on the document 'Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements' for submission to Docket Number 99D-5424.

Thank you.

A handwritten signature in black ink, appearing to be 'Sharon Ross', written in a cursive style.