

Shimakawa, Tomoko

From: Valerie & Richard James [divulge@xtra.co.nz]
Sent: Friday, February 25, 2005 4:39 AM
To: Shimakawa, Tomoko
Subject: Re: Your February 14, 2005 email message to Shellee Anderson

Dear Dr Shimakawa. Thank you for your letter below. We at www.soyonlineservice.co.nz have a number of concerns at the way this petition has been, and is being, dealt with.

First, as we have already stated, it has the appearance of a fait accompli when the petitioner is permitted to present options for claims, and for labelling, before the petition has been finally dealt with

Second, there have been cogent opposing views to the whole petition submitted to FDA. Why have those opposing not been allowed to meet with your officials? Soy Information Service filed such a document. Yet we have not had the opportunity to enlarge on it after the petitioner altered its petition. In fact we were not informed of that event, nor that the time for a determination had been extended.

Third. It is clear from a literature search in Medline (PubMed) that there is a substantial research resource demonstrating that soy and/or the bioflavonoids (isoflavones) it contains can cause breast cancer cells to multiply.....and as we have already pointed out in our submission last April, these findings were by Federal laboratories. In fact, the finding that soy isoflavones are a potential carcinogen in thyroid tissue was by your own laboratory, the NCTR. See "Anti-thyroid Isoflavones from Soybean" by R Divi et al, which we already have drawn to your attention. It seems to us that basic consumer law dictates that if a vendor of product wishes to claim benefits then they should be equally assiduous in revealing risks. See the U K Food Standards Agency website www.food.gov.uk/news/newsarchive/phyto-report0403news "The Group concluded it is possible that phytoestrogens could adversely affect people with hypothyroidism and considered that, despite many claims that phytoestrogens have a beneficial impact on health, the evidence does not convincingly support this view."

Fourth Our webmaster, Dr M G Fitzpatrick, is a well published and internationally acknowledged expert on the toxicity of the soybean and its derivative products His comments are in www.soyonlineservice.co.nz "Phytoestrogens...Cancer" Here is what he writes "In reality there can be no blanket approach to cancer prevention and an agent that may reduce the risk of cancer in one person may increase the risk of cancer in another. If you're still confused there are several other things that we'd like to make crystal clear: It is completely irresponsible for the soy industry or isoflavone supplement manufacturers to promote (or even suggest) that their products are cancer preventing without: any reference to individual case history; any real idea of what constitutes a safe dose; or any mention of the fact that soy may increase the risk of cancer. Those soy food or isoflavone supplement manufacturers that proclaim the anti-cancer properties of their products are guilty of giving false hope to millions; but worse they may be placing consumers at greater risk of contracting the same horrendous diseases they are trying to avoid.

Soy Online Service conclude that those on the 'soy prevents cancer' bandwagon are the lowest form of life on the planet".

Fifth This petition has the potential to affect the health of millions, yet those petitioning you are so woefully inept that they tell you there are no bioflavonoids in soy. How can you make a decision on their favor when they display such incompetence?

Sincerely, For Soy Information Service, Richard F James .

----- Original Message -----

From: Shimakawa, Tomoko
To: 'divulge@xtra.co.nz'
Cc: Anderson, Shellee
Sent: Wednesday, February 23, 2005 4:59 AM
Subject: Your February 14, 2005 email message to Shellee Anderson

Dear Valerie & Richard James:

I would like to respond to your February 14, 2005 email message to Shellee Anderson.

On November 5, 2004, FDA met with the Solae Company at the company's request. Please see the attachment for the information regarding the meeting. The meeting with the Solae Company was not

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out of the ordinary because the agency can meet with petitioners when a meeting is requested by them. However, the agency does not discuss the outcome of a petition with anyone, including the petitioner, until final action is taken on the petition.

FDA has not made any final decisions regarding the Solae Company's petition. The agency considers all pertinent information in deciding how to respond to petitions.

I hope this is helpful.

<<Meeting with Solae 11-5-2004.wpd>>

Tomoko Shimakawa, Sc.D.
Division of Nutrition Programs and Labeling
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway, HFS-830
College Park, MD 20740-3835

Tel: (301) 436-1461
tshimaka@cfsan.fda.gov

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