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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
HFS-830

Docket #2004Q-0151 Solae Company Health Claim on Cancer

Dear Dr. Shimakawa:

The Israeli Health Ministry has issued a health advisory which strongly recommended that consumption of soy foods be limited for young children and adults and that soy formula be avoided altogether by infants. This was published in the *British Medical Journal* on July 30, 2005 and the citation is: Siegel-Itzkovich, Judy. Health committee warns of potential dangers of soya. *BMJ* 2005; 331: 254-a. We are writing to request that you consider this health advisory as you evaluate the Solae Company's proposed health claim for soy-protein-containing products and a reduced risk of certain cancers.

The Israeli Health Ministry's action clearly refutes Solae's contention that there is a "scientific agreement among experts qualified by scientific training and experience" that soy products are not only safe but prevent cancer. The Israeli Ministry based its health advisory warning upon conclusions reached by a 13-member committee of nutritionists, oncologists, pediatricians and other specialists who spent more than a year examining the evidence on soy and disease. The committee concluded that the phytoestrogens found in soy protein products can cause adverse effects on the human body, including cancer promotion and reproductive problems. They strongly urged that consumption of soy foods be minimized until absolute safety has been proven, especially for babies and children.

The Israeli Health Ministry plans to distribute information about the dangers of soy foods and soy infant formula to pediatricians, health care workers and the public. It firmly recommends that babies that cannot be breast-fed receive cow's milk formula and be given soy infant formula only as a last resort. Day care centers and schools are being told to limit soyfoods to no more than one serving per day and no more than three times per week. Finally, the Health Ministry advised doctors to closely monitor the blood thyroxine levels of babies and toddlers suffering from hypothyroidism who are on soy

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infant formula and/or eating soy foods because of the well-known adverse effects of soy on the thyroid.

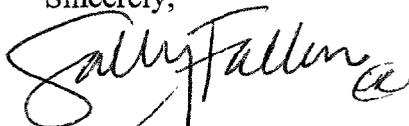
The Israeli Health Ministry's recommendations are in accord with those made by the United Kingdom's Chief Medical Officer and the British Dietetic Association, both of which have alerted pediatricians and parents to use soy infant formula only in unusual circumstances. In New Zealand, the health ministry has suggested that doctors carefully monitor the thyroids of infants on soy formula. However, no country has come close to Israel's warning against soy foods for children up to age 18. This sets an important precedent.

Although the Israeli Health Ministry stopped short of making recommendations on soy consumptions for adults, it found that the evidence on soy foods alleviating menopausal symptoms is inconsistent, that soy phytoestrogens can increase breast cancer risk and that they can reduce male fertility. The ministry determined that soy has been shown to reduce blood cholesterol but stated that there is no clear proof that it reduces the risk of heart disease.

The bottom line is that the Israeli Health Ministry looked long and hard at the evidence and reached the appropriate conclusion that we should eat soy only occasionally and in moderation because possible benefits are far outweighed by proven risks. The Ministry also noted that there are longstanding concerns in the scientific community about soy's possible role in carcinogenesis that need to be addressed.

In the interests of public safety, we again request that the Solae petition be declined and the health claim be denied.

Sincerely,



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