Resolution 15A

FDA Warning Letters

2012 US Health Freedom Congress
Schaumberg, IL, June 14, 2012
Submitted by Citizens for Health

WHEREAS the Food and Drug Administration (FDA) has recently begun to issue warning letters to manufacturers of dietary supplements containing DMAA, based on draft guidance that says synthetic copies of botanicals are not dietary ingredients;

WHEREAS guidance documents are not regulations and reflect only the current, non-binding thinking of FDA and are subject to change at any time;

WHEREAS FDA, in its warning letters, made adverse safety claims about DMAA without evidence, using anecdotal incidents that were not properly researched or contextualized;

WHEREAS synthetic copies of botanicals are a modern-day necessity due to rising global consumer demand, the lack of available botanical farmland and the escalating contamination of our biosphere. Many healthful botanicals are absorbers of toxic substances from the air, water and soil. With continued environmental degradation worldwide, sourcing of organic and/or non-contaminated botanical raw materials is getting more difficult, with increasingly expensive and labor-intensive cleansing and purifying practices and processes necessary with every harvest and batch of raw materials. These combined factors are making it increasingly impossible to meet consumer demand - and thereby the actual health needs of billions of humans and animals worldwide - through organic, natural, farmed botanical sourcing of nutrients. Synthetic alternatives and complements are becoming necessary across a wide range of nutritive compounds;

WHEREAS FDA, in its warning letters, told manufacturers of products containing DMAA that "Failure to immediately cease distribution of your products … could result in enforcement action by FDA" despite the lack of final, binding regulation saying synthetic copies of botanicals are not dietary ingredients;

WHEREAS FDA has failed to show any evidence of risk to consumers who use products containing DMAA;

THEREFORE BE IT RESOLVED that we:

1. Urge FDA to end the practice of issuing warning letters to companies who are not in violation of final FDA regulations. This approach of regulating the food and drug

Resolution 15A

industry through warning letters is an act of intimidation that pressures companies to remove products that are not in violation of any law, and requires legal purveyors of these products to engage in the costly process of defending their legality to keep their products on the market.

2. Urge FDA to issue warning letters to companies only upon violations of final FDA regulations, not draft guidelines.

3. Urge FDA should document and verify any alleged adverse health effects it claims in warning letters, rather than citing anecdotal military reports or unverified foreign information.

4. Urge FDA to issue warning letters to companies only upon violations of DSHEA and any final FDA regulations, not draft guidelines.

Be it resolved that the 2012 Health Freedom Congress has considered the following resolutions and hereby adopts the health freedom principles embodied in the resolutions and offers the support of the member organizations to the extent determined by each organization's governing principles. *

*This statement was adopted to apply to the set of resolutions that the 2012 Health Freedom Congress passed June 14, 2012.