

Ten Year-old Dietary Supplement Law Keeps Potentially Unsafe Ingredients from Market

Austin, Texas claims a new study concludes the Food and Drug Administration(FDA) has rejected about 70 percent of the herbs submitted to the agency for safety acceptance. The report suggests that some of the “new” herbal ingredients proposed to FDA may be unsafe and that the FDA is fulfilling its role to protect the public from unsafe dietary supplements. The report also concludes that with many of the submissions, sellers did not provide the required basic information for FDA to be able to review the herb’s safety. Further, it states that the FDA has not provided adequate guidance to the industry on how to properly submit safety data on these ingredients.

The Dietary Supplement Health and Education Act of 1994 (DSHEA), passed by Congress ten years ago this week, grants the government the authority to protect the American public from potentially unsafe dietary supplement ingredients that have not been sold previously in the United States. The law regulates vitamins, minerals herbs and other dietary supplements.

DSHEA contains a little-known provision that requires that safety data on all new dietary ingredients (NDIs) be accepted by the FDA before the ingredient can be sold in a supplement in the United States. An NDI is defined as a dietary ingredient that was not sold in the U.S. prior to October 15, 1994, the date that Congress passed DSHEA.

According to the law, a seller must first notify FDA at least 75 days before the seller attempts to market a new ingredient. The notification must contain adequate proof of the ingredient’s safety. The agency can accept the safety submission, reject it, or request additional safety information.

The FDA web site (www.fda.gov, www.fda.gov lists all the NDIs for all substances (including non-herbal materials) submitted through June 30, 2003. Of these, 59 percent were rejected and 38 percent were accepted. The rate for botanicals was higher, 70 percent, often due to inadequate data submitted or improper filing procedure.

Mark Blumenthal, founder and executive director of ABC, and editor of Herbal Gram, said, This issue has been ignored in the media, thereby giving the public an erroneous perception of the legal safeguards for herb safety. He continued, The rate of rejection by FDA does not truly reflect the safety of the ingredients. Instead, the rejections often result from inadequate safety data being submitted to FDA by the sellers. Although FDA has done much work on dietary supplements in the past decade, it hasn't issued precise guidance to industry on NDI notifications. If more clarity were available, some of the rejected but safe herbs might be available and the public could benefit from new, low-cost herbal supplements.?

The Herbal Gram report reviewed the NDI process and its importance to consumers, the government and the industry. Chris Noonan and W. Patrick Noonan, the authors, state that if a company is successful in obtaining FDA agreement on the safety of its ingredient, there is no seal of approval from the FDA that can be used on a product’s label. If accepted, the agency takes the position that because all research on the ingredient has not been reviewed, FDA will make no statement regarding the ingredient’s safety.? Thus, the public is usually unaware that the safety of the ingredient or product has been accepted by the FDA.

Sources: *Ten Year-old Dietary Supplement Law Keeps Potentially Unsafe Ingredients from Market*, Healthy News Service, Oct. 20, 2004 www.healthy.net/index.asp.

Herbal Gram (number 63),The American Botanical Council, Austin, Texas (www.herbalgram.org)