

Docket No. 00P-1355

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BEFORE

THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON THE

CITIZEN PETITION OF THE CONSUMER HEALTHCARE PRODUCTS ASSOCIATION REGARDING
STRUCTURE/FUNCTION CLAIMS FOR CONDITIONS ASSOCIATED WITH PREGNANCY OR NURSING

March 5, 2000

00P-1355

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The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as importers, growers, processors, manufacturers, marketers, and distributors of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs and that are used to enhance health and quality of life.

On March 11, 2000 the Consumer Healthcare Products Association (CHPA) submitted a petition to have the Commissioner of Food and Drugs establish a requirement that many dietary supplements bear certain cautions with respect to their use in pregnancy or while nursing a baby. At the same time, CHPA proposes that other dietary supplements be exempted from any such requirement. AHPA disagrees with the CHPA petition and, with this comment, suggests that the Food and Drug Administration reject the petition and the positions set forth in the petition.

AHPA'S POSITION REGARDING PREGNANCY LABELING FOR HERBAL SUPPLEMENTS

In July of 1998, AHPA's Board of Trustees adopted a trade recommendation for its members with respect to herbs that have been identified as not for use in pregnancy or when nursing an infant. In 1997, AHPA published the *Botanical Safety Handbook*. This book was authored by various herbalists and AHPA's current president Michael McGuffin. The authors utilized the rich history of use and reporting of information regarding the safe use of herbs to present a conservative and cautionary view to the use of herbs in dietary supplements. In this book, herbs classified in Class 2b or 2c are defined as not for use in pregnancy or nursing, respectively, unless otherwise directed by a qualified expert. AHPA's trade recommendation is that products containing any Class 2b or 2c herbs be labeled in accordance with this recommendation.

AHPA is opposed to the CHPA petition because it disregards current existing data and information regarding the use of botanicals while pregnant or nursing. Moreover, AHPA is concerned that the general statement that CHPA proposes to be included on the labels of most dietary supplements presents a message that is so common as to be ignored. AHPA's view is that more thought and attention must be given to the message delivered to pregnant women and mothers and its form and substance.

At the Spring 2000 hearing convened by the Administration to discuss this subject, AHPA made its views known and contributed substantially to the debate on this issue. AHPA encourages the Administration carefully to consider the views expressed at that hearing by AHPA and those AHPA members who provided testimony.

Respectfully submitted,



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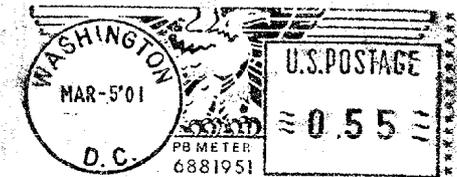
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