

Final

**Dietary Supplements; Premarket Notification for New Dietary Ingredient  
Notifications; Public Meeting  
November 15, 2004**

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Good Afternoon, I would like to begin by thanking the Agency for this opportunity to provide input on this very important subject. My name is John Zenk. I am a licensed and board certified physician and I also have a degree in pharmacy. I am the Chief Medical and Scientific Officer of Humanetics Corporation located in Eden Prairie, Minnesota.

Humanetics is a privately held company that discovers, researches, develops and commercializes new ingredients for the dietary supplement and drug industries. We have made a substantial investment in the research of our new dietary ingredients and our company has more than 20 patents. Our current ingredients include 7-Keto DHEA; a natural metabolite of DHEA, D-Pinitol; a naturally occurring methyl inositol and MicroLactin; a specially processed dairy protein. Our direct investment in research associated with our ingredients is in excess of \$10 million dollars. Much of this investment has gone toward well-designed human clinical trials to establish the safety and efficacy of our products. To date, more than 16 clinical studies have been performed on our ingredients.

When Humanetics made a decision to enter the dietary supplement market, the company looked at the Dietary Supplement Health and Education Act and saw that our 7-Keto DHEA ingredient met the definition of a new dietary ingredient. With our first customer, General Nutrition Corporation, we notified the Agency, as required by law, in May of 1997 prior to commercial sales of this ingredient. We appear to have been the 14th company to do so. Our company has now filed or supported the filing of six New Dietary Ingredient notifications. Two of these were for our patented ingredient, 7-Keto DHEA; another was for D-pinitol for which we presently have three US patents: another was for D-ribose, and two were for a polyphenolic extract of the evening primrose plant. Four of these NDIs were filed by the Agency without objection and the new dietary ingredients were introduced to the market by our company. The company completed two NDI filings for the polyphenolic extract and the Agency concluded that the ingredient was not shown, by the data submitted, to be reasonably expected to be safe for use in dietary supplements. Although we did not completely agree with this assessment, out of respect for the Agency and the provisions of DSHEA, neither Humanetics nor the New Zealand company that developed that ingredient has introduced it for sale as a dietary ingredient in the United States.

DSHEA established the shape and the contour of the playing field for new dietary ingredients. The Agency promulgated implementing regulations in September 1997 and we structured our business model for dietary ingredients around these regulations. As competitors in the marketplace, however, we are at a disadvantage because others ignore this important part of the law and the Agency has only once (in the case of androstenedione) invoked this part of the law in its ten-year history. Although we have followed the NDI provisions of DSHEA, we compete with many who do not. I am sure many of us in this room today are aware of ingredients that would be considered New Dietary Ingredients, for which no pre-market notification was filed. We are also aware of ingredients for which pre-market notifications were filed, subsequently objected to by FDA, and the ingredient is sold in the market today.

This public meeting appears to approach the New Dietary Ingredient provisions of the law as if they were just discovered and need to be explained. These provisions have been in the law since 1994. They became effective upon enactment. We are here today to express our opinion that the Agency should focus its efforts on the enforcement of this most important aspect of DSHEA. We believe that it is a good provision, we support it and we feel it is critical for many reasons, including the most important reason of all, to protect the safety of consumers.

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