



IASC Member Update

Report From FDA's "Nutrition Roundtable" Meeting

December 18, 2008 – The International Aloe Science Council (IASC) attended the Food & Drug Administration's (FDA) inaugural "Nutrition Roundtable" on Friday, Dec. 12. Topics covered during the meeting included functional foods and section 912 of the Food & Drug Administration Amendments Act (FDAAA), which was effective immediately upon the passage of the Act on Sept. 27, 2007.

FDAAA section 912, entitled "Prohibition Against Foods to Which Drugs or Biologics Are Added," creates new section 301(l) of the Federal Food, Drug, and Cosmetic Act (FFDCA). It prohibits interstate commerce in foods to which an approved drug or a licensed biological product has been added, and also prohibits the addition to foods of any drug or biological product that has been the subject of publicly-disclosed substantial clinical investigations.

There are exceptions to these prohibitions, most importantly for any ingredient that was marketed in a food before it is approved as a new drug or licensed as a biological product, or before it becomes the subject of substantial clinical investigations. Similar prohibitions, with the attendant exceptions, have been in place for dietary supplements since the adoption of the Dietary Supplement Health and Education Act (DSHEA) in 1994.

FDA is currently reviewing comments from industry and other interested parties on the implementation of section 912. Agency representatives at the roundtable indicated that the issuance of guidance for industry on section 912 was "under discussion".

"IASC is closely monitoring the implementation of section 912 on behalf of its members and the aloe industry," said Executive Director Devon Powell. "The association is committed to keeping members abreast of any developments and will provide guidance as needed."

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