MEMORANDUM OF MEETING
November 30, 1995

ATTENDEES:

FDA

Mr. Bill Schultz, Dr. Ilisa Bernstein, Dr. Fred Shank, Dr. Beth Yetley, Dr. Robert Moore, Dr. Linda Kahl, Mr. John Gordon, Ms. Karen Carson, Mr. Robert Guidos, Ms. Vicky Wolfhard

External

Council for Responsible Nutrition: Annette Dickinson
American Herbal Products Association: Carol Dillard, Michael McGuffin
National Nutritional Foods Association: Michael Ford, Tony Young
Nonprescription Drug Manufacturers Association: Patrice Wright
Utah Natural Products Alliance: Loren Israelsen
Botanicals International: Fran Ertl
Nutrilite Products, Inc: Ofelia Barretto
Banner Pharmacaps, Inc: Ira Berry
Pharmavite Corporation: Paul Bolar
Perrigo Company of South Carolina: Marilyn Langley
General Nutrition Products: Ron Thompson

SUBJECT: Good Manufacturing Practices for Dietary Supplements

The meeting was requested by industry representatives to discuss their draft Good Manufacturing Practices (GMP) document, and other dietary supplement issues, with Mr. Schultz and CFSAN staff.

Ms. Dickinson opened the meeting by presenting the agency with a draft GMP document (prepared by a working group composed of industry representatives) submitted as a discussion document on behalf of the Council for Responsible Nutrition (CRN), the Nonprescription Drug Manufacturers Association, the National Nutritional Foods Association, the American Herbal Products Association, the Utah Natural Products Alliance. The proposed GMPs are modeled after existing GMPs for foods. The draft document was supported by all of the industry representatives present.

Ms. Dickinson explained that following today's meeting, the group will further evaluate the document, make amendments as necessary, and then possibly submit the revised document to the agency formally as a citizen petition.

Mr. Bolar, Ms. Barretto, Ms. Langley, and Mr. Thompson reviewed various sections of the draft discussion document highlighting those areas where the food GMPs are being fully incorporated and where there are additional requirements that industry representatives consider as essential to the manufacture of safe and properly labeled dietary supplement products.

Drs. Shank, Yetley, Kahl and Mr. Derfler asked a variety of questions, respectively, concerning the level of detail being proposed, effect on small businesses, requirements for manufacturers of supplement products who also produce drugs, and use of HACCP procedures.

It was agreed that the dialogue on the draft GMPs would continue sometime after the first of the year.

Vicky Wolfhard
FDA Executive Secretariat

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REMARKS

attached are the 4 references for docket # 96N-0417.

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