Public Meeting: Responsible Innovation in Dietary Supplements

Thursday, May 16, 2019: 8:00 am – 4:30 pm

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Wiley Auditorium
5001 Campus Drive
College Park, MD 20740

Docket No. FDA-2019-N-1388

AGENDA

8:00 AM Registration

8:30 AM Welcome & Housekeeping/Logistics

8:35 AM Opening Remarks

Norman E Sharpless, *Acting Commissioner of Food and Drugs, FDA*

Steve Tave, *Director, Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, FDA*

9:00 AM Session 1: The scope of dietary ingredients under DSHEA

This panel will discuss topics relating to the scope of permissible dietary ingredients under section 201(ff) of the Federal Food, Drug and Cosmetic Act (FD&C Act), including issues such as synthetic copies of botanical constituents and the phrase "dietary substance for use by man to supplement the diet by increasing the total dietary intake."

Moderator: Cara Welch, *Acting Special Assistant to the Deputy Commissioner for Policy, Legislation, and International Affairs, Office of the Commissioner, FDA*

Panelists:
Scott Bass, *Head, Global Life Sciences Team, Sidley Austin LLP*
Pieter Cohen, *Associate Professor, Harvard Medical School and Internist, Cambridge Health Alliance*
Loren Israelsen, *President, United Natural Products Alliance*
George Paraskevakos, *Executive Director, International Probiotics Association (also presenting on behalf of the International Food Additives Council)*

10:00 AM Session 1: Q&A

10:15 AM Break

10:30 AM Session 2: Understanding exceptions to the NDIN requirement

This panel will discuss issues related to when an NDI notification is not required for new dietary ingredients and whether evolution in the dietary supplement marketplace has altered the impact of this provision.

Moderator: Cara Welch, *Acting Special Assistant to the Deputy Commissioner for Policy, Legislation, and International Affairs, Office of the Commissioner, FDA*

Panelists:
Laura MacCleery, *Policy Director, Center for Science in the Public Interest*
Michael McGuffin, *President, American Herbal Products Association*
Ashish Talati, *Partner, Amin Talati & Upadhye*

11:15 AM Session 2: Q&A

11:30 AM Lunch

1:00 PM Session 3: Comparative perspectives from other regulatory systems

Moderator: Steve Tave, *Director, Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, FDA*

Panelists: TBA

1:30 PM Session 4: Promoting compliance with the NDI notification requirement

This panel will discuss some of the challenges and opportunities associated with promoting overall compliance with the NDI notification requirement through avenues such as marketing advantages and enforcement.

Moderator: Steve Tave, *Director, Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, FDA*

Panelists:
Sandra Eskin, *Project Director, Food and Dietary Supplement Safety, The Pew Charitable Trusts*

Daniel Fabricant, *President and CEO, Natural Products Association*
Andrew Shao, *Interim Senior Vice President of Scientific & Regulatory Affairs, Council for Responsible Nutrition*
Wes Siegner, *Senior Counsel, Hyman Phelps & McNamara, P.C.*
Jay Sirois, *Senior Director of Regulatory & Scientific Affairs, Consumer Healthcare Products Association*

2:30 PM Session 4: Q&A

2:45 PM Break

3:00 PM Session 5: Open public comment

Moderator: Steve Tave, *Director, Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, FDA*

4:30 PM Adjourn