



4

MEMORANDUM OF MEETING

Date: June 3, 2011

Place: Center for Food Safety and Applied Nutrition, FDA, College Park, MD

Participants:

Industry

Diane Edquist Dorman - Vice President Public Policy, National Organization for Rare Disorders (NORD)

FDA

Michael Landa, Acting Center Director, Center for Food Safety and Applied Nutrition (CFSAN)

Jill Warner, Acting Associate Commissioner for Special Medical Programs, Office of Special Medical Programs

Mary Posa, Deputy Director, Office of Nutrition, Labeling, and Dietary Supplements (ONLDS), CFSAN

Benson Silverman - Director, ONLDS/Infant Formula and Medical Foods Staff, CFSAN

Sue Ann Anderson - ONLDS/Infant Formula and Medical Foods Staff, CFSAN

Shawne Suggs-Anderson, ONLDS/Infant Formula and Medical Foods Staff, CFSAN

Debra Lewis - Acting Director, Office of Orphan Products Development, OC/FDA

James Bona - Office of Orphan Products Development, OC/FDA

Christine Mueller, M.D., Office of Orphan Products Development, OC/FDA

Sanchali Kasbekar, Office of Orphan Products Development, OC/FDA

Carol Fedorchak, Office of the Center Director, CFSAN

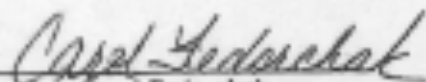
Subject: Issues Related to Access to Medical Foods for Inborn Errors of Metabolism and Other Rare Conditions

Diane Edquist Dorman, Vice President Public Policy, National Organization for Rare Disorders (NORD), requested a meeting with CFSAN to discuss the development of and access to medical foods treating inborn errors of metabolism and other rare conditions. Ms. Dorman noted that the Advance Notice of Proposed Rulemaking regarding the regulation of medical foods issued by FDA on November 29, 1996, was later withdrawn by the Agency. NORD is concerned that there is not a consistent definition of medical foods which may allow for the misinterpretation or abuse of the existing statutory definition.

Page - 2 Memorandum of Meeting - National Organization for Rare Disorders

Actions FDA could take to address NORD's concerns were discussed. Michael Landa told Ms. Doerman that FDA would conduct an internal meeting to discuss the possibilities and that he would follow up with her.

The meeting ended cordially.


Carol Fedorchak

Enclosures