



August 18, 2015

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201
Via email: Sylvia.Burwell@hhs.gov

The Honorable Stephen Ostroff, M.D
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Via email: Stephen.Ostroff@fda.hhs.gov

RE: Elevating the Division of Dietary Supplement Programs to an “Office” within CFSAN

Dear Secretary Burwell and Commissioner Ostroff:

On behalf of the trade associations representing the dietary supplement industry—the Consumer Healthcare Products Association (CHPA), Council for Responsible Nutrition (CRN), Natural Products Association (NPA) and United Natural Products Alliance (UNPA)—we write to express collectively our interest in and support for the elevation of the Division of Dietary Supplement Programs (DDSP) to an “Office” status within the Food and Drug Administration’s (FDA) Center for Food Safety and Applied Nutrition (CFSAN).

Since DDSP was established within FDA, shortly after the passage of the Dietary Supplement Health and Education Act of 1994, the dietary supplement industry has grown from around \$6 billion in annual sales to more than \$35¹ billion in sales in 2014. This robust growth of the industry reflects not only increased interest among consumers in these products, but also significant advancements in the science of nutrition and wellness and new regulatory challenges to appropriately monitor this marketplace. We believe that the elevation of DDSP to an “Office” would provide appropriate regulatory attention to the growing industry and increase FDA’s enforcement activities and priorities. In addition, we believe such a reorganization would enhance the effectiveness of dietary supplement regulation by allowing this new Office to better compete for resources and attention within the Agency, along with other products under

¹ 2015 Nutrition Business Journal

CFSAN's jurisdiction (e.g., cosmetics, medical foods). Such a move would aid in accomplishing FDA's current and long-range goals related to dietary supplements.

Moreover, the industry is deeply concerned about entities—both individuals and companies—who engage in blatant criminal activity by manufacturing and marketing products that masquerade as “dietary supplements” but contain anabolic steroids, active pharmaceutical ingredients (APIs), or analogues of APIs. As you know, our associations have consistently urged FDA to engage in stronger enforcement activities to address bad actors that illegally manufacture and sell misbranded drug products falsely labeled as dietary supplements. We believe that elevating DDSP's status to an Office could help increase FDA's abilities to take more aggressive enforcement action; better utilize CFSAN's compliance and enforcement resources than it currently does as a “Division” where it competes with other divisions for enforcement priorities within the Office of Nutrition, Labeling, and Dietary Supplements (ONLDS).

Please let anyone of us know if you have questions related to this request and we look forward to your reply.

Best regards,



Scott Melville
President & CEO
Consumer Healthcare Products Association



Steve Mister
President & CEO
Council for Responsible Nutrition



Daniel Fabricant, Ph.D.
Executive Director & CEO
Natural Products Association



Loren Israelsen
President
United Natural Products Alliance

cc: Mike Taylor, Deputy Commissioner for Food
Ted Elkin, Deputy Director, CFSAN
Robert Durkin, Acting Director, Division of Dietary Supplement Programs
Cara Welch, Acting Deputy Director, Division of Dietary Supplement Programs
The Honorable Orrin Hatch of Utah
The Honorable Martin Heinrich of New Mexico