CPC COMBINATION PRODUCT COALITION

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June 11, 2009

VIA OVERNIGHT DELIVERY

Margaret Hamburg, M.D.
U.S. Food and Drug Administration
Office of the Commissioner
10903 New Hampshire Ave., Bldg 1
Silver Spring, MD 20993

Re: Combination Products; Meeting Request

Dear Dr. Hamburg:

The Combination Products Coalition ("CPC") would like to commend the Agency, and in particular the Office of Combination Products ("OCP"), on its continuing attention to issues affecting combination products and how best to serve patient needs with respect to such products. The OCP has been engaged on these issues in a very patient-focused manner. In this regard, the CPC would like to offer its thoughts on the Agency's activities in the area of combination products, as described more fully in the attached White Paper, *Increasing Focus on Combination Products.*

By way of background, the CPC is a group of leading drug, biological product, and medical device manufacturers with substantial experience and interest in the combination products arena. One of the principal goals of our organization is to work collaboratively with the Agency on issues affecting combination products, in order to advance our common missions of providing the best possible health care for patients. Because of our diverse, cross-industry membership, we think the CPC brings a broad and unique perspective to issues affecting combination products.

As the attached paper describes, combination products – products that involve the convergence of two or more different types of FDA-regulated articles (drugs, medical devices, and biological products) – represent promising advances in patient care. Patients suffering from numerous types of serious diseases and conditions have already benefited from combination products, and many more innovative and beneficial combination products are currently being researched and developed. Industry estimates reflect this growth and development.

The OCP has participated in public dialogue on combination product issues, and has done so in a transparent, fair, and balanced manner. However, as Agency data demonstrate, increases in the development and marketing of combination products have significantly impacted the OCP's workload, while the resources FDA has been able to devote to combination products have remained nearly static. As a consequence, the OCP understandably has had to focus primarily on its regulatory responsibilities, which the Office has executed timely and efficiently. However, policy making has had to take a back seat. In addition, structural dedication and prioritization throughout the Agency is equally important in ensuring combination products receive a high enough priority to accomplish needed policy-making goals.

To give patients access to innovative products, manufacturers need clarity and regulatory predictability on these important policy development issues. Further, because of the rapid pace of technology, combination product manufacturers need early, real-time access to FDA personnel to inform development and manufacturing issues for the most cutting-edge products.

The CPC recommends that the Agency review the Agency's prioritization of and resources allocated for combination product issues and consider ways in which the Agency could support the advancement of combination product policy development. In particular, and as discussed in more detail in the attached White Paper, we believe the following three areas represent the most pressing policy issues facing combination products today:

1. Good Manufacturing Practices (GMPs) applicable to combination products
2. Clinical trials on combination products
3. Post-approval product modification issues

In our view, these issues are at the heart of combination products regulation, and efforts to move policy development forward in these areas would help provide the clarity and regulatory predictability that is needed to provide patients with safer and more effective health care.

We would like to schedule a meeting with you to discuss these important issues impacting combination products. To arrange a time when we could meet, please contact me at: bthompson@ebglaw.com or (317) 514-5008.

Respectfully submitted,

Bradley Merrill Thompson,
On behalf of the Combination Products Coalition

Enclosure

cc:

Thinh X. Nguyen
Director, Office of Combination Products

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner, FDA

Jesse Goodman, M.D., MPH
Deputy Commissioner; Chief Scientist