



1227 25th St. NW #700
Washington, DC 20037
combinationproducts.com
202.861.1881



VIA EMAIL AND FIRST CLASS MAIL

April 20, 2016

Rachel Sherman, M.D., M.P.H.
Associate Deputy Commissioner, Office of Medical Products and Tobacco
Food and Drug Administration
10903 New Hampshire Avenue
WO1-2307
Silver Spring, MD 20993

Re: Combination Products Policy Council

Dear Dr. Sherman:

The Combination Products Coalition (“CPC”) would like to congratulate the Food and Drug Administration (“FDA”) on the creation of the Combination Products Policy Council (the “Council”). By way of background, the CPC is a group of leading drug, biological product and medical device manufacturers with substantial experience and interest in combination product issues. One of our top priorities is to work collaboratively with FDA on issues affecting combination products to advance our common mission: providing the best possible health care to patients. Our diverse, cross-industry membership permits the CPC to bring a special, broad and unique perspective to these issues.

Our members view the Council, as well as FDA’s recently launched lean process mapping initiative, as positive and exciting developments in the combination products space. The CPC applauds the FDA for advancing these efforts, which we are hopeful will improve inter-center coordination and communication during combination product reviews, and add transparency and consistency to the process. As a Coalition, we greatly appreciate that FDA has prioritized improving the combination product review process, and we very much look forward to working closely with the Council on policy issues. We also look forward to learning more about the Council and lean mapping initiative as they are implemented, as well as FDA’s continuing efforts to improve the combination product review process.

Yours truly,

A handwritten signature in black ink, appearing to read "Bradley Merrill Thompson".

Bradley Merrill Thompson
On Behalf of the Combination Products Coalition

April 20, 2016

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cc: Robert Califf, M.D., Commissioner of Food and Drugs
Jill Hartzler Warner, J.D., Associate Commissioner for Special Medical Programs
Thinh Nyugen, Director, Office of Combination Products
John (Barr) Weiner, J.D., Associate Director for Policy and Product Classification
Officer, Office of Combination Products
Nina Hunter, Ph.D., Associate Director for Science Policy, Office of Medical Products
and Tobacco