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October 14, 2016

VIA ELECTRONIC SUBMISSION

Janice M. Soreth, M.D.
Acting Associate Commissioner,
Office of Special Medical Programs
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2016-N-2147: Request for a 30-Day Extension to Comment Period; General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee (“Panel”) Meeting

Dear Dr. Soreth:

The Combination Products Coalition¹ asks that FDA extend the comment period for the above-referenced docket by 30 days. This extension will provide stakeholders the ability to (1) fully assess information that was released by FDA shortly in advance of the Panel Meeting, (2) give further consideration to the comments made at the Panel Meeting, and (3) prepare and submit fulsome comments. Given the importance of the issues raised at the meeting – which go beyond wound care products to fundamental matters regarding regulation of combination products – we believe an extension is warranted so that FDA receives the best information and ideas to aid in its decision-making.

We appreciate your consideration of this request and look forward to continuing work with FDA on this and other combination product matters going forward.

Very truly yours,

A handwritten signature in black ink, appearing to read "James A. Boiani".

James A. Boiani, MS, JD
Deputy General Counsel
Combination Products Coalition

¹ The “CPC” is a diverse group of combination product manufacturers that involve all types of constituent parts – drugs, biological products, and medical devices. Our members are innovative manufacturers that range in both size and focus, and it is this diverse, cross-industry membership which allows the CPC to bring a unique perspective to the various policy issues affecting combination products.