Combination Products Coalition

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VIA ELECTRONIC SUBMISSION
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. 2015-01410: Request for a 30-Day Extension to Comment Period

To Whom It May Concern,

On January 27, 2015, FDA released the Draft Guidance on Current Good Manufacturing Practice Requirements for Combination Products ("Draft Guidance") and opened a docket to which stakeholders could submit comments until March 30, 2015.

The Combination Products Coalition ("CPC") is glad to see the release of this long-awaited Draft Guidance and is appreciative of FDA's apparent sense of urgency in finalizing it, as evidenced by the limited 60-day comment period. However, the CPC is not only interested in ensuring this guidance is finalized with due haste, we are also interested in ensuring it addresses the needs of all stakeholders. Therefore, the CPC is requesting that FDA extend the comment period for an additional 30 days and allow stakeholders to submit comments to the docket until April 29, 2015.

We recognize that this extension could delay publication of the final guidance. However, members of the CPC are more than willing to delay its publication for 30 days in order to have sufficient time to provide reasoned, well supported and hopefully valuable feedback. This additional time will give our members the time they need to digest and work through the broad range of complex issues addressed in this guidance.

One of the more complicated issues is the application of design controls to combination products that include a device constituent part and are manufactured under a Part 210/211 compliant GMP system. This issue not only involves understanding how to apply design controls to the product development process moving forward, but also how to apply design controls to products that are already marketed, but might not have been developed under a design control compliant process ("legacy products"). This issue, as well as others addressed in the 46-page Draft Guidance, touch on many different aspects of our members' operations and will require input from a broad array of stakeholders. As FDA may appreciate, compiling and distilling this input into specific, actionable comments, agreeable to many stakeholders, is a time consuming process.

We also note that the CPC is currently working with the Regulatory Affairs Professional Society ("RAPS") and individuals from FDA to organize and host a workshop where stakeholders will work through case studies to help them apply and better understand the concepts addressed in the Draft Guidance. Our goal is to hold this workshop during the comment period so that we can incorporate the issues raised at this workshop into our comments. Because of the

effort needed to plan the workshop, a 30-day extension would allow us sufficient time to organize the workshop and incorporate the findings into our comments.

The CPC membership greatly appreciates the two-year effort that has gone into developing the Draft Guidance and looks forward to collaborating with FDA in its efforts to finalize it as quickly as possible. We want to reiterate our commitment in providing feedback to help finalize the guidance as quickly as possible but, again, would not want to sacrifice the quality of the input. We want to thank FDA in advance for considering our request to extend the comment period until April 29, 2015, which we believe will ensure that the value of the final guidance is commensurate with the effort that went into its development.

Kindest regards,

Daniel G. Gottlieb,
On behalf of the Combination Products Coalition

Cc: FDA Office of Combination Products via e-mail to combination@fda.gov