Combination Products Coalition

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VIA ELECTRONIC SUBMISSION

July 19, 2021

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2021-D-0166: ICH Q12: Implementation Considerations for FDA-Regulated Products; Draft Guidance for Industry

To Whom It May Concern:

The Combination Products Coalition ("CPC")[1] welcomes the opportunity to provide comments on FDA's "ICH Q12: Implementation Considerations for FDA-Regulated Products Draft Guidance for Industry" dated May 2021 (the "Draft Guidance"). We greatly appreciate FDA's efforts to incorporate many of the CPC's suggestions regarding the application of ICH Q12 to combination products into this Draft Guidance and believe that the Draft Guidance represents a significant step forward toward enabling the combination product industry to implement ICH Q12 tools.

The CPC has carefully evaluated the Draft Guidance and requests that the Agency clarify what is meant by materials of construction in "indirect" contact with the drug product and patient (Appendix A, line 390).

We appreciate the opportunity to provide input on the Draft Guidance and ask that the Agency consider this feedback as it finalizes the document. We look forward to further dialogue if any clarification is required.

Yours truly,

Suzette Roan
CPC Submissions Working Group Chair
On behalf of the Combination Products Coalition

[1] 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.