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FDA-2019-N-2012

**VIA ELECTRONIC SUBMISSION**

August 26, 2019

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

Re: Docket No. FDA-2019-N-2012: New Drugs Regulatory Program Modernization: Improving Approval Package Documentation and Communication

Dear Sir or Madam:

The Combination Products Coalition (“CPC”)<sup>1</sup> welcomes the opportunity to offer comments on FDA’s “New Drugs Regulatory Program Modernization: Improving Approval Package Documentation and Communication” and specifically, the proposed new integrated review template.

While the CPC supports the integrated review template and acknowledges the value of implementing a system that effectively communicates the basis for new drug approvals, CPC is concerned that the proposed integrated review template will lack the level of detail currently provided in the discipline-specific review memos. As stated by FDA, the proposed new integrated review template will ‘replace the current documentation where each discipline provides a separate application review document’ with a summary document that provides an ‘overview of the major decisions made during the review process’ and that ‘highlights key issues in an interdisciplinary manner that the review team thinks are pertinent to the decision-making process.’ CPC members regularly reference these publicly available discipline-specific review memos for combination products to better understand the Agency’s current thinking on a variety of combination product submission requirements. For example, DMEPA review memos are referenced for human factors testing, risk documentation, and labeling requirements; CDRH review memos are referenced for device constituent and combination product performance and testing requirements; CDER clinical/cross discipline team review memos are referenced for clinical data and real-life patient

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<sup>1</sup> 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.

handling study requirements; Clinical Pharmacology review memos are referenced for bioequivalence/ bioavailability study requirements; and DMPP review memos are referenced for labeling requirements. Additionally, these review memos may include justification for why a specific request has been made and would typically provide insights regarding the types of responses that FDA finds acceptable for a given request.

As such, CPC strongly requests that, as FDA implements the integrated review document, the discipline-specific review memos remain publicly available to ensure full transparency and understanding of the Agency's current thinking with respect to combination product requirements. The availability of these FDA review memos has been extremely valuable to industry, FDA, and ultimately combination product users as the review memos facilitate more complete filings, which leads to fewer FDA concerns and shorter FDA review and approval timelines, thus reducing time-to-market for combination products designed to positively impact patient experiences and outcomes. CPC would also like to note that this same concern has been echoed by others in industry (e.g., Pink Sheet. US FDA's Integrated Review Document Would Dramatically Downsize Public Information. 29 June 2019.).

Furthermore, although CPC members are most concerned with the combination product-related information listed above, our member companies are interested in continued access to all information currently made publicly available following a drug/biologic approval. This information includes, but is not limited to, pre-submission correspondence, inquiries and responses, review memos, and inspection reports.

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We appreciate the opportunity to provide input on this proposed new regulatory program.

Yours truly,



Bradley Merrill Thompson,  
On behalf of the Combination Products Coalition