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**VIA ELECTRONIC
SUBMISSION**

November 14, 2022

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

Cc: Office of Combination Products

Re: Docket No. FDA-2022-N-2335: Prescription Drug User Fee Act VII; Independent Assessment of Communication Through Product Quality Information Requests During Application Review; Statement of Work; Request for Comments

Dear Sir or Madam:

The Combination Products Coalition (“CPC”)¹ welcomes the opportunity to provide comments on FDA’s statement of work for the independent assessment of communication through product quality information requests during application reviews that will be conducted in PDUFA 7. We understand that an independent assessment of information requests between FDA and sponsors will be conducted to identify best practices and areas of improvement. We request that this assessment or another similar assessment include information requests related to drug and/or biologic-led combination products.

We recognize there are challenges in communications between sponsors and FDA review staff during application reviews. These challenges are further complicated in information requests related to the device constituent part of a combination product. In this scenario, information requests from CDRH’s consult review or DMEPA’s human factors review are shared through the lead center’s (CDER or CBER) project manager to the sponsor. We acknowledge the prior assessment completed in PDUFA 6. However, based on the progress of the inter-center consult review (ICCR) process and the evolving nature of CDRH and DMEPA information requests, we believe an additional assessment focused on combination product information requests (i.e., in IND/NDA/BLAs) could be beneficial.

The CPC has previously expressed interest in collaborating with the FDA to enable more

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 and digital 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.

interactive and iterative communication pathways for combination products. In July 2020, CPC submitted a letter to OCP which detailed the disparity of available interaction mechanisms and provided interactive communication proposals (which is provided as an attachment to this letter). A portion of the recommendations in the July 2020 letter are focused on information requests, while others focus on meeting interactions.

Furthermore, combination product sponsors request more information be communicated at the time of the information request regarding the item (4) of the four-part harmony described in the federal register notice (e.g., “why it is needed”). The CPC outlined in a letter to Office of Combination Products (OCP) on September 3rd, 2021, that recent information requests related to two evolving topics, sequential preconditioning and reliability, have not provided enough background information for the sponsors to take the appropriate action and have not been in alignment current effective regulations or consensus standards. Therefore, we request an emphasis on “why it is needed” for requests that originate from CDRH for combination product reviews.

CPC appreciates the opportunity to comment on recommendations for how industry can solicit interactive and iterative FDA feedback for combination products and kindly requests that drug and/or biologic-led combination products be in scope of the PDUFA 7 independent assessment of communication through product quality information requests.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Bradley Merrill Thompson', with a stylized flourish at the end.

Bradley Merrill Thompson,
On behalf of the Combination Products Coalition