Combination Products Coalition

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FDA-2018-N-3017

December 3, 2018

VIA ELECTRONIC SUBMISSION

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

Re: Docket No. FDA-2018-N-3017: Request for a 30-Day Extension to Comment Period

To Whom It May Concern:

On November 20, 2018, FDA announced the establishment of a docket to solicit public comment on a proposed framework for regulating software for use with prescription drugs (the "Notice"). For the reasons discussed below, the Combination Products Coalition ("CPC") requests that FDA extend the comment period for this docket to provide stakeholders an additional 30 days to submit comments.

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. Notably, CPC member companies comprise ten of the top fifteen pharmaceutical companies in the world (based on 2017 revenue). As such, many of our members are intently focused on how FDA will address the issue of software developed for use with drugs. In fact, we have a specific CPC working group dedicated to digital health issues, and have previously reached out to the Agency regarding coordination of FDA Center positions on the regulatory requirements that apply to software used in conjunction with pharmaceutical products.[1]

This requested 30-day extension, which will allow stakeholders to more effectively digest and work though the issues addressed and questions presented in the Notice, is particularly important for the following reasons:

1. **Timing of Comment Period:** The 60-day time period for public comment began running the week of Thanksgiving and covers the week of Christmas and other end-of-year holidays and vacations. This is a very challenging time to find alignment in CPC members' schedules, which is necessary to arrange meetings and allow the type of fruitful

[1] *See* CPC letter to Drs. Peter Marks, Jeffrey E. Shuren, & Janet Woodcock Re: Coordination of FDA Policy Positions on Software Used with Pharmaceutical Products (Sept. 25, 2017).

collaboration that will result in a thoughtful and comprehensive responsive to FDA's request for comments.

2. **Length and Complexity of the Notice's Contents:** The Notice, which is nine pages long, presents a broad range of complex legal and policy issues. It also solicits input on ten specific questions, which raise important and complicated issues for stakeholder consideration. Allowing additional time for comment will help ensure that the CPC can consult the various experts within our member companies on these issues to gather as many perspectives and obtain as much input as possible.

3. **Very Limited Window for Potential Discussion with FDA:** After fully reviewing and digesting the issues addressed in the Notice, it is likely that the CPC will request a meeting with the Agency to discuss the Notice before submitting its comments. With the comment period closing on January 22, 2019, and the holiday season on the horizon, there is very limited time to schedule such a meeting. We note that this type of meeting could provide an important opportunity for the CPC to better understand the Agency's position on the issues discussed in the Notice, which would ultimately help us offer more valuable and meaningful feedback.

4. **Extension Unlikely to Result in Harm to Interested Parties:** The Notice does not appear to articulate any specific sense of FDA urgency with respect to collecting public comment on the covered issues, which we note have been on both the Agency's and industry's radar for quite some time. In fact, the Notice specifically states that it is "meant to seek *early* input from groups and individuals outside the Agency prior to development of a draft guidance [on the topic]" (emphasis added). As such, allowing an extra 30 days for comment should not frustrate Agency objectives or otherwise result in harm to stakeholders.

We want to thank FDA in advance for considering our request to extend the comment period by 30 days (until February 21, 2019).

Very truly yours,

Bradley Merrill Thompson
On behalf of the Combination Products Coalition

cc: Thinh Nguyen, Director, Office of Combination Products
John (Barr) Weiner, J.D., Associate Director for Policy and Product Classification Officer, Office of Combination Products