



1227 25th St. NW #700
Washington, DC 20037
combinationproducts.com
202.861.1881



February 6, 2013

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

Re: Medical Device User Fee and Modernization Act: Web Site
Location of Fiscal Year 2013 Proposed Guidance Development;
Docket No. FDA-2012-N-1021

Dear Sir or Madam:

On behalf of the Combination Products Coalition (“CPC”), we welcome the opportunity to offer comments on the Proposed Guidance Development Agenda for the 2013 Fiscal Year published by the Center for Devices and Radiological Health (“CDRH”). The CPC wholeheartedly supports this transparency into the Center’s guidance development prioritization.

By way of background, the CPC is a group of leading drug, biological product, and medical device manufacturers with substantial experience and interest in the combination products arena. One of the principal goals of our organization is to work collaboratively with the Agency on issues affecting combination products, in order to advance our common missions of providing the best possible health care for patients. Because of our diverse, cross-industry membership, we think the CPC brings a special, broad, and unique perspective to the prioritization of guidance development.

I. IMPORTANCE OF TRANSPARENCY INTO AGENCY’S PRIORITIES

For an agency like FDA, two basic administrative functions should be transparent: (1) rule and policy-making and (2) individual decision-making and adjudication. As we examine how the Agency should ensure appropriate transparency in policy-making, much of our thinking centers upon guidance issued by the Agency – both the process used for issuing guidance, as well as the ultimate guidance document. Really this isn’t surprising, as guidance is the Agency’s primary

vehicle for communicating regulatory process and substantive expectations to the public and industry. Quite simply, good guidance creates transparency. Through the implementation of Good Guidance Practices (“GGPs”) more than ten years ago, the Agency made vast improvements in both guidance content and process.

An important aspect of the GGPs is the requirement that “[o]nce a year, FDA will publish, both in the Federal Register and on the Internet, a list of possible topics for future guidance document development and revision during the next year.”¹ This publication is important to the CPC and its members because it helps us understand the Agency’s priorities and gives us the opportunity to engage with the various centers to ensure priorities are in alignment. This publication also helps the CPC develop its annual work plan to ensure the needs of our members are considered during the guidance development process.

We commend the commitment of CDRH to consistently publish these topics each year, even though the other centers and the Agency as a whole have not done the same.² However, publishing these topics and requesting input from industry is only helpful if the Center a) dedicates the resources to ensure these guidance documents are drafted and b) appropriately adjusts its priorities based on industry feedback.

II. PROPOSED CHANGES TO DEVELOPMENT AGENDA

As a whole, the CPC does not believe significant changes need to be made to the Proposed Guidance Development Agenda. However, we believe that finalizing certain existing draft guidance documents should be moved from the “B-list” to the “A-List.” In particular, we ask that CDRH finalize the “Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design” that was published on June 22, 2011. This document, when finalized, is designed to supersede the “Medical Device Use - Safety: Incorporating Human Factors Engineering into Risk Management” guidance that was issued on July 18, 2000.

The existence of both documents and uncertainty as to when the draft guidance will be finalized and supersede the July 2000 guidance, makes it difficult for our members to design adequate human factors studies and incorporate adequate human factors controls in their device designs. This uncertainty results in increased interactions between industry and the Agency that tie up Agency and industry resources that could be put to better use. Finalizing this guidance in a timely manner and incorporating industry comments, including those submitted by the CPC, will result in freeing up both Agency and industry resources.

¹ 21 C.F.R. § 10.115(f)(5).

² The last time the Agency appears to have published a complete Annual Guidance Agenda was for Fiscal Year 2011. See FDA Notice: *Annual Guidance Agenda*, 75 Fed. Reg. 76,011 (Dec. 7, 2010).

Additionally, we believe that the “Total Product Life Cycle: Infusion Pump – Premarket Notification [510(k)] Submissions” Draft Guidance should be moved to the “A-List.” As we noted in our July 2010 comments,³ we believe there are several statements included in this guidance document that could be misinterpreted as applying to drug-device and biological-device combination products. However, as has been the long-standing regulatory position of the Agency and industry, the concomitant use of drugs and devices and the infusion pumps that dispense them are not considered combination products under the definition in 21 C.F.R. § 3.2(e). It is our hope that by moving this to the “A-List” this potential ambiguity could be eliminated.

We hope that our comments are helpful to the Agency as it prioritizes guidance development. If the CPC can help in any way, please do not hesitate to contact us.

Kindest regards,

A handwritten signature in black ink, appearing to read "Bradley Merrill Thompson". The signature is fluid and cursive, with the first name being the most prominent.

Bradley Merrill Thompson,
On behalf of the Combination Products Coalition

³ <http://combinationproducts.com/images/CPC-Infusion-pump-guidance-comments-FINAL-23Jul10.pdf>.