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Attorneys at Law

September 10, 2013

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Supplement to the Citizens Petition Docket ID: FDA-2012-P-0617 Filed by the Combination Products Coalition

Dear Sir or Madam:

On June 8, 2012, the Combination Products Coalition submitted a Citizens Petition[1] pursuant to 21 C.F.R. § 10.20 ("Petition") requesting that the Commissioner of Food and Drugs ("Commissioner") take specific steps to improve the transparency of combination product regulation. In that Petition, we outlined the following four steps that are essential to fostering the development of innovative combination products.

1. The Commissioner should improve transparency with regard to combination products by streamlining the internal FDA process for developing combination product guidance and rules and producing more guidance on combination products.

2. The Commissioner should ensure that more FDA records with regard to combination products regulation are released on the Agency's website (e.g., requests for designation, Form FDA-483s, new drug approvals).

3. We recommended a number of ways to improve the FDA's processes and procedures for guidance document development.

4. We provided recommendations in support of transparency in both broad decision-making and also individual adjudication.

Today, we submit a supplement to the original Citizens Petition that outlines additional ways FDA can give guidance to industry. In this supplement, we recommend that FDA look outside the Agency for best practices in managing the sharing of information on complex topics by large enterprises. In this regard, we strongly support the use of new technologies by FDA as communication tools, including the use of social media and electronic knowledge databases.

[1] Citizens Petition Docket ID: FDA-2012-P-0617

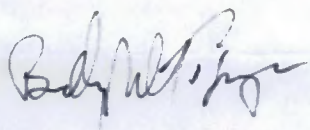
Industry needs answers to questions on a timelier basis. By analogy, when policymakers wanted to figure out a way to allow new products to reach the market faster, they analyzed whether they could lessen the premarket obligations and instead strengthen the post-market obligations. We think policymakers should examine the same opportunities when it comes to releasing FDA information: lighten up on the pre-release review and create better mechanisms for ensuring post-release review. To that end, we recommend the Agency push down responsibility for addressing narrow questions and streamline the process to eliminate extensive review and approval by FDA management, but balance that with more robust post-release quality review by the agency and appeal procedures.

Finally, to supplement existing guidance processes, we also suggest FDA consider a process by which the Agency will issue "micro guidance", or guidance on a narrow topic, as well as recognize industry-developed guidance similar to how FDA accepts industry-developed standards.

We file this supplement on behalf of the Combination Products Coalition, but also another coalition we represent called the mHealth Regulatory Coalition (or "MRC"). The MRC believes that the guidance problems are not limited to combination products, and wants to see these reforms adopted more broadly. The MRC is a diverse group of mobile healthcare technology stakeholders focused on promoting the development of an honest, realistic, and thoughtful regulatory policy perspective on mobile health technologies. MRC members include medical device manufacturers, smartphone healthcare application developers, cellular handset manufacturers, network operators, and back end software services and data storage providers, as well as representatives of provider organizations, clinicians, healthcare researchers, and other industry and trade associations. Its members share the common goal of promoting a balanced approach between regulatory policies, and the need for innovation and getting new products to the market for patient's best interests.

If you would like any further information on any of these topics, we would be pleased to help in any way we can.

Respectfully submitted,



Bradley Merrill Thompson
On behalf of the Combination Products Coalition and mHealth Regulatory Coalition

Enclosure: Good Guidance Practices 2.0: supplement to Citizens Petition Docket ID: FDA-2012-P-0617 filed by the Combination Products Coalition

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