Combination Products Coalition

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FDA-2018-D-1339

VIA ELECTRONIC SUBMISSION

June 25, 2018

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

Re: Docket No. FDA-2018-D-1339: Multiple Function Device Products; Draft Guidance for Industry and Food and Drug Administration Staff

Dear Sir or Madam:

The Combination Products Coalition ("CPC")[1] welcomes the opportunity to offer comments on FDA's "Multiple Function Device Products; Draft Guidance for Industry and Food and Drug Administration Staff" ("Draft Guidance") dated April 27, 2018. The CPC applauds the Agency's efforts to provide guidance on Section 520(o)(2) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") (21 U.S.C. § 360j(o)(2)) and the specific provisions around products that contain at least one software function that is not a device. However, we would like to offer three suggestions related to the Draft Guidance, as detailed below.

I. Clarification Regarding Drug/Biologic-Led Combination Products

The preface of the Draft Guidance only lists CDRH and CBER as the Agency centers that have endorsed the content of the document. However, the Draft Guidance notes that the document applies to FDA's review of the device constituent of a combination product (line 210). As the Agency is aware, combination products as defined in 21 CFR part 3 may have software medical device constituent parts that receive premarket approval under drug or biologic marketing applications. Yet, CDER is not listed as an endorsing center. Further, we note that the 21st Century Cures Act altered the definition of a medical device to exclude regulation of specific software functions that do not meet the definition of a medical device. Therefore, software functions that are part of a combination product, but do not meet the definition of a medical device, should also not be regulated by the Agency.

[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 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.

CPC respectfully requests that the Agency centers collaborate more closely on the final version of the Draft Guidance to provide: (i) meaningful information regarding the applicability of the Draft Guidance to sponsors of combination products with a drug or biologic primary mode of action, and (ii) additional drug or biologic regulatory requirements that would apply if a non-regulated software function is present within a combination product.

II. Implementation of Multiple Function Exclusion

The Draft Guidance provides extensive information on how the new multiple function exclusion to the definition of a medical device will be practically implemented within premarket review of medical devices. However, the document provides almost no practical information on how the Agency intends to interpret the multiple function provision within other aspects of device regulation, such as manufacturer audit, adverse event reporting, or reports of correction and removal. Appendix 1 of the document contains a single sentence regarding the Postmarket Oversight of non-device functions, which concludes that "FDA requirements [are] not applicable." Additional specificity should be provided in this regard. For example, we ask that the Agency clarify whether it intends to intentionally preclude non-device functions from inspectional review or other compliance and postmarket safety investigations.

III. Identification of New Risks

The Draft Guidance mentions the assessment of increased risk and/or an adverse effect on performance due to the combination of the other function with the device function. While risk assessment associated with increased risk is important, any potential new risks should be identified, evaluated, and mitigated as needed to ensure acceptable residual risks of the device function. This approach aligns with FDA-recognized standards such as ISO/AAMI 14971. CPC requests that the Agency incorporate this comment in the final guidance.

We are thankful for the opportunity to provide input on the Draft Guidance and are happy to meet with the Agency to clarify or discuss any of our suggestions.

Very truly yours,

Bradley Merrill Thompson
On behalf of the Combination Products Coalition