Combination Products Coalition

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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-0236: Medical Device De Novo Classification Process

Dear Sir or Madam:

The Combination Products Coalition ("CPC")[1] welcomes the opportunity to provide comments on the proposed rule for the Medical Device De Novo Classification Process published in the Federal Register on December 7, 2018, particularly related to the issue noted in Section V.J.: the application of the De Novo process for combination products.

The CPC concurs with and supports the applicability of the De Novo process to the device constituent of what are commonly referred to as "cross-labeled" combination products (per 21 C.F.R. § 3.2(e)(3)-(4)). Given that the respective constituent parts retain their regulatory identities (see Section III of the draft guidance *Principles of Premarket Pathways for Combination Products*[2]), the least burdensome provisions of the Food, Drug, and Cosmetic Act ("FD&C Act") (ref. 21 U.S.C. § 360c(a)(3)(D)) would still apply to the device constituent (which is acknowledged in Section III of the guidance *The Least Burdensome Provisions: Concept and Principles*[3]).

Additionally, the CPC asks that FDA consider including "co-packaged" combination products (per 21 C.F.R. § 3.2(e)(2)) that are designated as device mode of action in the De Novo process, as such products would also benefit from the application of least burdensome provisions and potentially classification as Class II devices. Such products would also seemingly be well-suited for this process given that predicate devices are unlikely to exist.

[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.

[2] https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM630458.pdf

[3] https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm085999.pdf

We would like to ensure that all means of obtaining market authorization, including the De Novo Classification Process, remain open for such cross-labeled and co-packaged combination products.

Note that we reserve comment on the remainder of the proposed rule as it does not fall within the scope of our organization's interests.

Overall, we strongly support the least burdensome means of bringing the device constituent of combination products to market, and believe that including cross-labeled combination products within the scope of this rule would help accomplish this goal.

We appreciate the opportunity to provide input on the proposed rule and look forward to further dialogue with the Agency to clarify or discuss any of our suggestions.

Very truly yours,

Bradley Merrill Thompson,
On behalf of the Combination Products Coalition