Combination Products Coalition

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

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VIA ELECTRONIC SUBMISSION

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

Re: Docket No. FDA-2013-D-0743: Draft Guidance for Industry and Food and Drug Administration Staff: Medical Device Reporting for Manufacturers

Dear Sir or Madam:

The Combination Products Coalition ("CPC") is pleased to offer its comments on the Draft Guidance for Industry and Food and Drug Administration Staff: Medical Device Reporting for Manufacturers ("Draft Guidance").

By way of background, the CPC is a diverse group of drug, biological product, and medical device manufacturers with substantial experience in the combination products area. Our members range in size from small start-ups to multi-billion dollar manufacturers. These companies all share an intense interest in policy issues affecting combination products. Because of our diverse, cross-industry membership, the CPC brings a broad and unique perspective to issues affecting combination products.

One of our principal goals is to work with FDA on such issues in order to advance our common mission of providing the best possible health care for patients. In this regard, the CPC has had frequent dialogue with the Office of Combination Products on regulations, guidance documents, and other policy issues that affect combination products and how best to serve patient needs with respect to such products. For example, we have submitted dozens of written comments, policy documents, proposed guidance documents, and other materials to the agency on these issues for nearly a decade. Several of these submissions can be found on our website: http://www.combinationproducts.com/.

Below we offer our comments on the Draft Guidance. Although the CPC's primary focus is to address issues specific to combination products and this guidance does not appear to address combination products directly, we would like to use this opportunity to:

1. Reiterate the importance that FDA issue a final rule that specifically governs the postmarketing safety reporting for combination products; and

2. Identify a limited number of areas in which this the Draft Guidance appears to contradict the Postmarketing Safety Reporting for Combination Products draft rule published in October of 2009.[1]

I. FDA Should Issue a Final Rule Specifically Governing the Postmarketing Safety Reporting for Combination Products as Soon as Possible

FDA's issuance of final regulations that specifically address postmarketing safety reporting requirements for combination products is long overdue. It has been over eight years since the Office of Combination Products ("OCP") published the concept paper, Postmarket Safety Reporting for Combination Products. This 2005 concept paper was designed to stimulate stakeholder input on potential approaches to adverse event reporting for combination products. In response, the CPC submitted six possible approaches that FDA could adopt to address postmarketing safety reporting for combination products. These six options included approaches that would involve short, intermediate, and long-term changes in the regulatory framework applicable to postmarketing safety reporting of combination products specifically and all regulated products more generally. These options were designed to permit FDA to ultimately develop a unified regulatory framework for postmarketing safety reporting for all regulated products.[2] Although the CPC still believes it is important for FDA to develop this unified regulatory framework, prompt publication of final regulations specifically applicable to the postmarketing safety reporting of combination products would be a step in the right direction.

Although the CPC did not support the Postmarketing Safety Reporting for Combination Products proposed rule in its entirety, we urge FDA to publish the final rule as soon as possible. The CPC continues to believe that the framework set out in the proposed rule should be considered an interim solution only, but as noted in our 2006 response to OCP's concept paper, we understand that an iterative process may be the best pathway to the implementation of a unified regulatory framework.

II. FDA Should Align the Reporting Requirements Set Forth in the Draft Guidance with Those Included in the Postmarketing Safety Reporting of Combination Products Proposed Rule

Because FDA has not issued regulations on postmarketing safety reporting specifically for combination products, FDA and manufacturers have generally applied provisions from the applicable postmarketing safety reporting regulations associated with the type of marketing application used to approve or clear the product. Understanding that this type of regulatory

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[1] 74 Fed. Reg. 50744 (October 1, 2009).

[2] A unified reporting process would result in just one type of report that asks for all relevant information for a regulated article, whether it is comprised of a device, biological or drug, or a stand-alone article. There would also be one integrated set of time periods for reporting.

The benefits of such an approach seem significant both for FDA and for industry. A detailed discussion of these benefits and other aspects regarding the implementation of a unified system may be found in the comments the CPC filed in response to the Agency's adverse event concept paper.These comments are available at: http://combinationproducts.com/images/CPCAEConceptPaperFiled3.23.06.pdf (see in particular pages 6-8).

scheme may limit the ability of FDA to evaluate product safety and therefore jeopardize the public health, FDA proposed a more streamlined approach to postmarketing safety reporting for combination products that would ensure appropriate pathways for reporting adverse events associated with each constituent part, while reducing the overall burden on manufacturers.

Specifically, the combination product proposed rule would allow a manufacturer of a constituent part that did not hold a marketing authorization for the constituent part of the combination product, to either report information about adverse events to FDA or to the other reporter within five calendar days of receiving the information. However, it appears that FDA has decided to change course in the Draft Guidance, as it requires "all manufacturers of medical devices approved or cleared for marketing in the US" to submit the required reports. This duplication of the reporting requirements includes a requirement that both the authorization holder and the contract manufacturer submit the required reports. This duplication is unnecessary, and will increase the cost of compliance without any incremental benefit to the public health, as evidenced by FDA's prior willingness to limit the need for duplicative reporting under the combination product proposed rules.

Therefore, the CPC recommends that FDA align the reporting obligations set forth in Section 2.2 and 2.17 of the Draft Guidance with the reporting obligations under 21 C.F.R. Part 4. This can be accomplished by adding the text in ***bold italics*** to the sections 2.2 and 2.17.

> ***Device manufacturers (contract or otherwise) that manufacture constituent parts of a combination product and are not the marketing authorization holder of the combination product or the constituent part, are exempt from reporting if they comply with 21 CFR Part 4. No request for exemption is required.***

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Again, the CPC thanks FDA for the opportunity to reiterate our interest in FDA issuing regulations specific to postmarketing safety reporting of combination products. We hope that prior to the release of these regulations, FDA will attempt to align any guidance and/or regulations with the combination product proposed rule, to streamline the reporting obligations, and to eliminate all unnecessary and duplicative reporting obligations.

Kindest regards,

Bradley Merrill Thompson,
On behalf of the Combination Products Coalition