CHPA

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July 12, 2013

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

Re: Docket No. FDA-2013-N-0430

Dear Sir or Madam,

Enclosed herein are comments on "510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device: Public Meeting; Request for Comments". This submission references **Federal Register** volume 78, Number 89, Pages 26786-26790, Wednesday, May 8, 2013. The Consumer Healthcare Products Association (CHPA) is the national trade association representing the leading manufacturers and distributors of OTC medicines and dietary supplements in the United States. Many CHPA member companies also market medical devices and support FDA's efforts to develop updated guidance for industry on this important topic.

Historically, FDA has relied on the manufacturer as best qualified to make the decision regarding premarket notification for a change to a 510(k)-cleared device. Compliance with GMPs and robust quality systems, including procedures for change control, are important to ensure safety and effectiveness of a device and should also provide reasonable assurance of safety and effectiveness of modified devices. FDA has access to these systems via inspections. Only changes that could significantly affect safety or effectiveness should require a new 510(k).

Policy Option: Risk Based Stratification of Medical Devices for 510(k) Modifications Purposes

Question 1: How should FDA delineate higher versus lower risk devices?

CHPA proposes that devices that have cleared 510(k)s and meet the following criteria should be considered lower risk devices:

1. Devices that are non-invasive, non-implantable and non-life sustaining/supporting
2. Devices that are available for retail sale without health care professionals' involvement
3. Devices that have transit contact with body tissue or fluid
4. Any combination product where the primary mode of action is a device that meets the above criteria should also be considered as a lower risk device

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Question 2: Should FDA require some other measure, such as periodic reports, for modified lower risk devices in lieu of 501(k) submissions?
CHPA does not support such reporting, which increases the compliance burden for manufacturers and for FDA. FDA has access to information on modifications to lower risk devices via inspections. Devices that are defined as lower risk based upon a risk-based stratification should be exempt from such reporting. Any combination product where the primary mode of action is a device that is delineated lower-risk should also be exempt from periodic reporting. Should FDA ultimately require reporting of device modifications, CHPA supports a frequency of not more than once per year.

CHPA appreciates the opportunity to provide comments to FDA. We are happy to discuss further and look forward to FDA's forthcoming report on this topic.

Respectfully submitted,

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