

**VIA EMAIL ([www.fda.gov/dockets/comments](http://www.fda.gov/dockets/comments))**

October 17, 2007

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

Re: **Comment to Docket No. 2007D-0201**  
**Guidance on Premarket Notification Submissions for Medical Devices that**  
**Include Antimicrobial Agents**

Dear Sir or Madam:

Covidien is submitting these comments in response to the FDA's notice requesting comments on the draft guidance, "Premarket Notification Submissions for Medical Devices that Include Antimicrobial Agents" (Docket No. 2007D-0201). 72 Fed. Reg. 39630 (July 19, 2007).

Our comments on the draft guidance are as follows:

1. The draft guidance, page 2, lines 6-7 states, "In certain instances when antimicrobial agents are included on a device, they will be considered drugs and the resulting device...will be considered a combination product." We believe the full significance of this is not clear and could be clarified. Specifically, will it be clearly indicated by the FDA in 510(k)s that are cleared that the device is considered a device or drug/device combination product?
2. Aside from footnote number 2 on page 2 of the draft guidance citing the definition of "drug" from the Federal Food, Drug, and Cosmetic Act and the examples in line 9 on page 2, the draft guidance does not clearly explain how the Agency will determine if the antimicrobial agent is to be considered a drug in the first place. We believe that the final guidance would be strengthened by including additional discussion of practical factors considered by the Agency in determining whether an antimicrobial agent used with a device is a drug. Likewise, additional examples of both types of products, i.e., combination products where the antimicrobial agent is a drug and devices where the antimicrobial agent is not a drug, would also be useful to clarify the scope of the guidance.
3. Please address the affect of the guidance on the status of a currently, legally-marketed device (predicate device) that, under this guidance, may be considered a combination product,

which uses an antimicrobial substance that is not subject to a New Drug Application or an OTC monograph.

4. On page 11 of the Draft Guidance, lines 21-25, the document discusses the need for stability testing to support a shelf life, but the guidance does not clearly indicate if accelerated age testing is appropriate or not. ASTM F1980:2002, Standard Guide for Accelerated Aging of Sterile Medical Device Packages is a consensus standard recognized by the FDA that specifically relates to sterility and has routinely been accepted by the FDA for evaluating device stability as well. However, in the course of reviewing recent 510(k) submissions, FDA has indicated that only real-time stability data is acceptable for a device incorporating an antimicrobial agent. Accordingly, we believe it would be extremely useful for the guidance to clearly state the FDA's position on the use of accelerated age testing to meet stability requirements.

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We appreciate the opportunity to comment on the draft guidance document. Please contact the undersigned with any questions on this matter.

Sincerely,

A handwritten signature in cursive script that reads "Tracy Palmer Berns". The signature is written in black ink and is positioned above the printed name and title.

Tracy Palmer Berns  
Associate General Counsel