



Global Research & Development

January 29, 2007

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

Dear Dockets Management:

Re: **Draft Guidance for Industry and Food and Drug Administration Staff;
Class II Special Controls Guidance Document: Absorbable Hemostatic
Device**

[Docket No. 2006D-0363, 71 *Federal Register*, 63774, October 31, 2006]

Pfizer submits these attached comments to the Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Absorbable Hemostatic Device, 71 *Federal Register*, 63774, October 31, 2006.

Pfizer appreciates the opportunity to provide comments on this Draft Guidance and would invite direct dialog with the Agency if you would consider the opportunity valuable.

Sincerely,

Mary Boylan-Bost /plp

Mary Boylan-Bost
Associate Director
Worldwide Regulatory Affairs
Pfizer Global Research and Development

- 1. We agree with the Agency's position on reclassification of absorbable hemostatic devices; however, it should be noted that this will have an enormous impact on the market.**

Currently, MDUFMA fees of approximately \$281,600 are associated with filing of a PMA, \$20,275 to 60,544 for a PMA Supplement; and \$4,158 for a Premarket Notification [510(k)]. Reclassification would open barriers to entry and enable competitors to jump quickly into the market. Due to the reclassification of these devices, Pfizer is concerned with the huge impact on Agency resources based on the potential influx of 510K applications.

- 2. We request clarification from the Agency on whether submission of a 510K is required for absorbable hemostatic devices that are currently approved under a PMA.**

We believe that if submission of a 510(k) is the intent then the additional burden that will be placed on the Sponsor and the Agency does not support the least burdensome approach.

We strongly recommend that the agency take a status-quo approach to existing applications and not require submission of a 510(k). We would ask that the Agency carefully consider the resources (i.e. man-hours) that would be required for Sponsors to submit an additional regulatory filing [i.e. 510(k)].

- 3. We recommend that for a safe, well-established hemostatic agent that is currently on the market for an extensive period of time (> 60 years) and currently approved under a PMA that the Agency do not require additional product characterization requirements as this will not necessarily provide additional benefit to patient safety.**
- 4. We strongly recommend that shelf-life (i.e. labeled expiration date) be a requirement.**
- 5. We request clarification from the Agency on their recommendation of the use of the LAL test as a pyrogen test as this test is not a measure of sterility, but rather a test for the presence of endotoxins.**
- 7. We request clarification from the Agency with respect to the proposed guidance which states that "Your animal study should include a comparison with a legally marketed predicate device of similar component and manufacturer."**

We believe that for a well established device that is currently on the market for an extensive period of time (> 60 years) and currently approved under a PMA, that the additional animal study requirement would not necessarily further substantiate safety and effectiveness of the device.