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July 2, 2007

SENT VIA US MAIL

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Rm 1061
Rockville, MD 20852

Re: Citizen Petition and Petition for Stay of Action Under 21 CFR Sections 10.30 and 10.35

Dear Sir or Madam:

Please accept for immediate filing the above-referenced document filed by the law firm of DuVal & Associates on behalf of its client Ferrosan A/S, Sydmarken 5, DK-2860 Soeborg ("Ferrosan").

Respectfully submitted,



Mark E. DuVal
Counsel to Ferrosan
On behalf of Ferrosan

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Department of Health and Human Services
5630 Fishers Lane
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Re: Citizen Petition and Petition for Stay of Action Under 21 CFR Sections 10.30 and 10.35

Dear Sir or Madam:

INTRODUCTION

We respectfully submit this Citizen Petition and Petition for Stay of Action under 21 CFR Sections 10.30 and 10.35 on behalf of our client Ferrosan A/S, Sydmarken 5, DK-2860 Soeborg ("Ferrosan"). Specifically, we request that the Commissioner refrain from and stay the FDA from finalizing and promulgating the proposed regulation entitled "General and Plastic Surgery Devices; Reclassification of Absorbable Hemostatic Device," 71 Fed. Reg. 63,728, Docket No. 2006D-0362 (the "Proposed Reclassification"), and the accompanying draft Special Controls Guidance document entitled "Draft Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Absorbable Hemostatic Devices," Docket No. 2006D-0363. ("Draft Special Controls"). We also respectfully request that the Commissioner reopen the rulemaking for the Proposed Reclassification and Draft Special Controls and convene a new Advisory Panel. This Citizen Petition and Petition for Stay of Action is supported by the comments submitted by Petitioner on January 25, 2007 and June 5, 2007, as well as the comments submitted by other interested parties. Copies of these comments are incorporated by reference here.

A. Action Requested

We respectfully request that the Commissioner:

- 1) refrain from finalizing and promulgating a final regulation for the Proposed Reclassification and the final Draft Special Controls guidance unless and until an updated and complete administrative record is made available to the public;

2) reopen the rulemaking for the Proposed Reclassification to allow submission of comments based on the administrative record;

3) convene another, appropriately comprised, Advisory Panel to review FDA's Proposed Reclassification regulation and Draft Special Controls along the lines discussed below; and

4) stay further administrative action on the Proposed Reclassification and Draft Special Controls until 1) through 3) above are accomplished.

B. Statement of Grounds/Analysis

1. The Administrative Record is Incomplete and Deficient

Both Ferrosan and Ethicon submitted comments during the initial and reopened comment periods for the Proposed Reclassification and Draft Special Controls explaining how the administrative record was incomplete. Both parties had requested an extension to the initial comment period based, in part, upon the fact that the full administrative record was not made available to the public. In response to those comments, the Agency did reopen the comment period for one month for additional comments on May 8, 2007, but FDA failed to update and complete the administrative record. Interested parties cannot comment fully and effectively without the complete administrative record being available. Today, the administrative record only contains the two transcripts of the 2002 and 2003 Advisory Panel meetings and the comments submitted to date. Among the omissions from the administrative record are:

- Briefing materials provided to the General and Plastic Surgery Devices Panels for the 2002 and 2003 meetings and the materials prepared by FDA in connection with such meetings.
- FDA's explanation for the proposed Draft Special Controls guidance document deviating materially from the recommendations made by the 2002 and 2003 Advisory Panels.
- The description or last of the published literature considered which FDA stated at the Advisory Panel supported FDA's Proposed Reclassification and Draft Special Controls, and any analysis of the literature and MDR data conducted by FDA.
- An explanation of the relevance of the two absorbable hemostatic agents granted PMAs since 2003, at least one of which contains new materials not included in any of the products considered by the 2002 or 2003 Advisory Panels.

- Any discussion or analysis of FDA's warning notice issued on April 2, 2004, entitled "FDA Public Health Notification: Paralysis From Absorbable Hemostatic Agent." This warning addressed adverse events in "bony or neural spaces."
- The letter submitted by Ethicon on November 25, 2005 discussing new information about the types of risks with which surgeon-users of absorbable hemostatic devices are concerned.

These are significant omissions. It is fundamental to the administrative rulemaking process that the public know the basis upon which the Agency's decisions are made. To meaningfully participate in the rulemaking process, the public needs to be able to review and evaluate the information considered by the Agency.

We respectfully request that the Agency refrain from finalizing and promulgating a final rule and final Special Controls unless and until a complete administrative record is made available to the public.

2. The Proposed Reclassification and Draft Special Controls Guidance are Not What Was Discussed by or Promised to FDA's Advisory Panel

As a corollary to the request made above, Petitioner also respectfully requests that the rulemaking for the Proposed Reclassification be reopened and a new Advisory Panel convened. Because the administrative record is incomplete and because the Draft Special Controls has changed so markedly from the comments and requests made by the 2002 and 2003 Advisory Panels when discussing special controls, the Agency should reopen the rulemaking process and convene a new Advisory Panel. A new Advisory Panel should be presented with FDA's actual Proposed Reclassification and Draft Special Controls (whether the present version or one updated following the comments received) and the Panel requested to provide their advice in a public forum.

The Draft Special Controls does not address many of the concerns expressed by the 2002 or 2003 Advisory Panel members. The document FDA shared with the 2003 Advisory Panel was not the draft Special Controls we are commenting upon today. Rather, it was an outline of what was expected to be included in a special controls guidance for absorbable hemostatic agents. The Agency used the proposed special controls for sutures entitled "Class II Special Controls Guidance Document: Surgical Sutures; Draft Guidance for Industry and FDA" as a model. The document was not specific to absorbable hemostatic agents. Indeed, Dr. Krause called it a "kind of a guide" and parts of it "boilerplate" (see **2003 Advisory Panel Transcript at 42 and 43, 46, 47.**), suggesting it was to show the panel categorically, not specifically, what would be found in a future special controls guidance document for absorbable hemostatic agents. The actual content of the Draft Special Controls document differs in material respects from what was described by FDA to the Panel and recommended by Panel members to FDA.

In addition, the FDA must consider the composition of the Advisory Panel to ensure that it is representative of those who use these products extensively, particularly in some

very critical uses. For example, the use of these products can be found in the fields of trauma, vascular, transplant, cardiac, urology, neurosurgery and pathology, none of which are covered by the labeling for the product. To exclude these experts from the Advisory Panel was a fundamental flaw and inconsistent with applicable legal requirements. FDA's own regulations require "technical advisory committee[s]" to have "experience in the subject matter with which the committee is concerned and have diverse professional education, training, and experience to handle the problems that come before it." See 21 C.F.R. Section 14.80(b)(1)(i).

Indeed, the May 7, 2007 comments submitted by the law firm of Hyman, Phelps & McNamara, P.C. on behalf of its client Ethicon cites the following statistics:

Publicly available literature and Ethicon's own research, for example, indicates that absorbable hemostatic devices are used in more than 90 percent of the approximately 800,000 laminectomy, craniotomy and spinal/cervical fusion procedures performed annually in the US; more than half of the approximately 350,000 coronary artery bypass graft and valve procedures; and approximately 80% of the approximately 250,000 vascular procedures including carotid endarterectomies, abdominal aortic aneurism graft, and femoral-popliteal arterial graft surgeries.

There are wide and disparate uses to which these products are put and they can account for serious differences of opinion on the performance characteristics of these products in critical applications. The 2003 Advisory Panel had one general surgeon, two oncology surgeons and a professor of plastic surgery and a thoracic surgeon. The 2002 Advisory Panel had three professors of plastic surgery, one dermatologist and one specialist in obstetrics and gynecology. These specialties do not have the experience in dealing with the use of hemostats in these clinically critical applications. The FDA also cannot ignore the reality that new products cleared under a 510(k) will be used more expansively than their indicated uses. We know that these products will be used off-label and yet none will have clinical information supporting the cleared use, much less these expanded uses. The two Advisory Panels lacked the expertise to address these issues.

For these reasons Petitioner respectfully requests that the Agency reopen the rulemaking for the Proposed Reclassification and Draft Special Controls and convene a new Advisory Panel, which includes representatives of these other specialties who use hemostats in patient critical applications.

3. Stay Further Action to Promulgate the Final Regulation for the Proposed Reclassification

In addition to refraining from further action, Petitioner, for the reasons discussed above, also requests that the Commissioner stay further action to promulgate the final regulation on the Proposed Reclassification and Draft Special Controls by finding it is in the public interest. Petitioner further requests that the stay be in effect unless and until

the Agency updates and corrects the administrative record and reopens the rulemaking process by convening a new Advisory Panel to consider FDA's actual Proposed Reclassification and Special Controls guidance document.

C. Environmental Impact

According to 21 CFR Section 25.30(h), this Petition qualifies for a categorical exclusion from the requirement for the submission of an environmental assessment.

D. Economic Impact

According to 21 CFR Section 10.30(b), information on economic impact is to be submitted only when requested by the Commissioner following review of this Petition.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

Respectfully submitted,



Mark E. DuVal
Counsel to Ferrosan
On behalf of Ferrosan