DUVAL & ASSOCIATES

MARK E. DUVAL

DuVal & Associates, PA
3902 IDS Center
80 South 8th Street
Minneapolis, MN 55402

612-338-7170 *Main*
612-843-2398 *Fax*

First Class Mail

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

Re: **Request for Extension of Comment Period**
Docket No. 2006N-0362
General and Plastic Surgery Devices; Reclassification of Absorbable Hemostatic Device 21 CFR Part 878 (the "Proposed Rule")

Dear Sir or Madam:

On behalf of my client Ferrosan A/S, Sydmarken 5, DK-2860 Soeborg, I am writing to respectfully request an extension of the comment period for the above-referenced Proposed Rule. We request an extension of ninety (90) days, to April 27, 2007, to file comments with the Agency. I have only just met with my client in Denmark to begin the time consuming, expensive and complex process of reviewing these documents and finding appropriate experts, both within and outside of the company, to assist in developing the company's comments.

Ferrosan is a Danish company that develops and manufactures innovative products for the medical device industry, specifically the hemostatic device marketplace. Its current product, Surgifoam™ Absorbable Gelatin Sponge, U.S.P. PMA #990004 (owned by Ferrosan) and Surgifoam™ Absorbable Gelatin Powder, U.S.P. both of which are distributed in the United States by Ethicon, a Division of Johnson & Johnson. Ferrosan is developing future generation products for sale in the United States and has a significant stake in the regulatory regime that nurtures or retards investment in this arena. Surgifoam™ is a product approved by FDA through a PMA after extensive investment in vitro, in vivo, animal and human clinical testing as well as other controls that make this class of products safe and effective. Ferrosan respectfully requests the opportunity to comment upon the reclassification and the special controls document that is part of the reclassification effort.

2006N-0362 EXT 1

Ferrosan requests, pursuant to 21 CFR Section 10.40(b)(3), a ninety (90) day extension of the comment period for the Proposed Rule. The medical and scientific issues involved with the proposed reclassification also involves the examination of the FDA's recent published and proposed draft guidance entitled "Class II Special Controls Guidance Document: Absorbable Hemostatic Device," issued on October 31, 2006 ("Special Controls"). This Special Controls document was requested by FDA's General and Plastic Surgery Device Panel of Medical Devices Advisory Committee at its meeting on July 8, 2002 and an outline of a special controls document was shared with the panel one year later on July 24, 2003. The proposed Special Controls document is FDA's attempt at putting an actual document into public consideration. The timing of this Proposed Rule and the Special Controls document is coincident with the holidays and deprives the respondents such as my client the opportunity to meaningfully analyze and comment upon these documents. This situation is exacerbated for a Danish company whose primary language is not English and who must rely upon scheduling United States experts to assist the company in the analysis and any resulting submission.

The FDA's own Advisory Panel originally stated it would not support reclassification of these devices until special controls were actually developed and shared with the Advisory Panel and industry. When the special controls were shared one year later, they were in outline form only and not specific to hemostatic devices, rather they were generic and the FDA listed categorically what types of issues should be considered by special controls. We now have for the first time a Special Controls document specific to absorbable hemostatic devices. The analysis of this document that will take time as will the comments that will be developed.

Ferrosan has a history of complying with FDA regulatory requirements, but these kinds of changes and the process FDA follows are new to Ferrosan and I've had to background their management and the team assigned this project on how to meaningfully participate. They are unfamiliar with this process and the formality of the interactions. They've asked me to convey to the Agency that it has been difficult for them to gear up quickly to respond and we are just now doing so, but we are running into the holidays.

Because the industry now has a document with sufficient specificity upon which it can base its comments, we can meaningfully comment. The Advisory Panel repeatedly expressed concern over whether the industry would have an opportunity to meaningfully comment upon these complex and interwoven medical, scientific, testing and manufacturing issues.

We are assembling experts in toxicology, pharmacokinetics, pharmacodynamics, biocompatibility, biologics, manufacturing, veterinary pedigree issues and clinical trial design to examine FDA's proposed requirements. These experts need time to review, absorb and meaningfully respond to FDA's Proposed Rule and the corresponding Special Controls. We respectfully request approval of its request for a ninety (90) day extension.

Should you have any questions or need additional information, do not hesitate to contact me.

Sincerely,

Mark E. DuVal
Counsel to Ferrosan

Cc: David Krause, FDA, CDRH