

LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

700 THIRTEENTH STREET, N.W.

SUITE 1200

WASHINGTON, D. C. 20005-5929

(202) 737-5600

FACSIMILE

(202) 737-9329

www.hpm.com

JAMES R. PHELPS
PAUL M. HYMAN
ROBERT A. DORMER
STEPHEN H. MCNAMARA
ROGER C. THIES
THOMAS SCARLETT
JEFFREY N. GIBBS
BRIAN J. DONATO
FRANK J. SASINOWSKI
DIANE B. McCOLL
A. WES SIEGNER, JR.
ALAN M. KIRSCHENBAUM
DOUGLAS B. FARQUHAR
JOHN A. GILBERT, JR.
JOHN R. FLEDER
MARC H. SHAPIRO
JEFFREY N. WASSERSTEIN
DAVID B. CLISSOLD
JOSEPHINE M. TORRENTE

ROBERT T. ANGAROLA
(1945-1996)

JENNIFER B. DAVIS
KIRK L. DOBBINS
OF COUNSEL

CASSANDRA A. SOLTIS
MICHELLE L. BUTLER
ANNE MARIE MURPHY
PAUL L. FERRARI
LARRY K. HOUCK
DARA S. KATCHER*
KURT R. KARST
CHRISTINE P. BUMP
BRIAN J. WESOLOSKI
NOELLE C. SITHIKUL
RIËTTE VAN LAACK
CARMELINA G. ALLIS*
BRYON F. POWELL*
*NOT ADMITTED IN DC

CHERYL F. GRAHAM, MD, FCP
REGULATORY SCIENTIST

December 21, 2006

BY FACSIMILE/CONFIRMATION COPY BY MAIL

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1062
Rockville, MD 20852

Re: Request for Extension of Comment Periods for Dockets 2006N-0362 (71 Fed. Reg. 63728 (Oct. 31, 2006)) and 2006D-0363 (71 Fed. Reg. 63744 (Oct. 31, 2006))

Dear Sir/Madam:

We are writing on behalf of our client, Ethicon, Inc., the manufacturer of three FDA-approved absorbable hemostatic devices (Surgicel (N12159); Surgifoam (P990004); and Instat (P830079)). Ethicon requests a ninety (90)-day extension of the comment periods for the above-referenced dockets, until April 30, 2006. Given the sparse and outdated record that FDA has supplied for these dockets, a ninety-day extension is warranted to permit interested parties an adequate opportunity to identify and address the information which the agency has omitted from the record, and for FDA to place into the docket the necessary information and documents. We also request the extension because of the importance of FDA's proposal to patient care and the need to address fully the issues raised by the proposal, a task made more difficult by the gaps in the docket.

2006N-0362

EXT 2

2603 MAIN STREET
SUITE 760
IRVINE, CALIFORNIA 92614
(949) 553-7400
FAX: (949) 553-7433

4819 EMPEROR BOULEVARD
SUITE 400
DURHAM, NORTH CAROLINA 27703
(919) 313-4750
FAX: (919) 313-4751

In the proposed reclassification notice (71 Fed. Reg. 63732), FDA cited only two references – the now 4- and 3-year-old 2002 and 2003 transcripts of the General and Plastic Surgery Devices Panel meetings. FDA did not identify or place in the docket any of the materials provided to the Panel in preparation for these meetings, or prepared by FDA in connection with the meetings. Nor did FDA identify or place in the docket an evaluation of any of the new information that has developed since the Panel meeting. These omissions are particularly significant in that the materials provided to the 2003 Panel contain a listing of proposed special controls on which the Panel purported to base its recommendation. The special controls discussed with the Panel differ in some notable ways from the special controls FDA is now proposing, such as the indications for use. The 2003 Panel transcript shows that FDA told the Panel that the agency would impose restriction on indications for use in urologic, ophthalmologic and neurologic procedures unless specific data were provided to remove these exclusions. However, the Draft Guidance does not mention these exclusions. FDA has not provided any documentation explaining the deviations in the proposals from the special control elements that were presented to the Panel.

The proposed reclassification notice (71 Fed. Reg. 63730) states that FDA determined the risks to health presented by absorbable hemostatic devices “[a]fter considering the information in the Panel’s recommendation, as well as the published literature and Medical Device Reports.” The agency has not, however, adequately identified the published literature or Medical Device Reports on which it relied. If the agency prepared a report evaluating this information, that report is not in the docket. Moreover, it is unclear from the Federal Register notice whether the agency reviewed or considered any of the new published literature or MDR data on absorbable hemostats since the 2003 Panel meeting over three years ago. For example, a Baxter Floseal adverse event report dated August 24, 2005, MAUDE Database Catalog #4095894 reports life-threatening bleeding and proposes to educate customers that the product cannot prevent post-operative bleeding. Tomizawa authored a publication entitled: “Clinical benefits and risk analysis of topical hemostats: a review in the Journal of Artificial Organs, 2005; 8(3):137-142. Indeed, it is impossible to tell from the docket when FDA last evaluated the literature or MDRs, or what literature or MDRs were reviewed in connection with the Panel presentation.

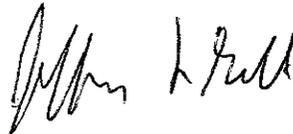
There have been two additional PMA approvals for absorbable hemostatic devices since the 2003 Panel meeting, one composed of an entirely new material than the products considered in 2003. There is nothing in the docket or the proposed regulation reflecting this information. These PMA’s present safety and effectiveness data for new and previously marketed products that may have informed FDA’s judgment in the reclassification process and are relevant to the reclassification of the category of products.

On November 23, 2005, Ethicon submitted a letter to FDA providing supplemental information about the types of risks that concern surgeon-users – risks which were not raised or discussed during the 2002 and 2003 Panel meetings. The letter further expressed concern about the narrow composition of the Panel. Several important surgical specialties, where different risks are encountered, such as neuro- and cardiovascular surgery, were not represented on the Panel. We would note that FDA has not addressed these issues raised in the letter. A copy of this letter is attached.

The Administrative Procedure Act (APA) requires with regard to notice-and-comment rulemaking that the “[a]gency notice . . . be sufficient to fairly apprise interested parties of the issues involved, so that they may present responsive data or argument relating thereto.” S. Doc. No. 248, 79th Cong. 2d Sess. 200 (1946). This requirement is not met, for example, when there is a key literature review which was cited to the Panel but is not publicly available, let alone in the administrative docket. FDA has therefore failed to comply with the requirements of the APA.

FDA needs to promptly correct the above deficiencies in its notices proposing reclassification of, and special controls, for absorbable hemostats. In addition, the agency should extend the comment period by ninety days to allow interested parties sufficient time to collect and review the data and information – which FDA has not placed into the docket – needed to prepare a fully informed response. We look forward to a prompt and favorable decision.

Respectfully submitted,



Jeffrey N. Gibbs

JNG/JBD/rd
Attachment

cc: Donna-Bea Tillman, Ph.D.
Sheldon Bradshaw, Esq.