

KING & SPALDING

1730 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, D.C. 20006-4706
TELEPHONE: 202/737-0500
FACSIMILE: 202/626-3737

DIRECT DIAL:

EMB: 202-626-2903
AW: 202-626-5615

ebasile@kslaw.com
awhitesides@kslaw.com

November 7, 2000

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

3413 00 NOV -7 P1:33

**RE: Docket Number 00N-1380
Human Bone Allograft: Manipulation and Homologous Use in Spine and Other
Orthopedic Reconstruction Repair (FDA Public Meeting August 2, 2000)
NOTICE OF THE COMMENT PERIOD EXTENSION**

Dear Sir or Madam:

The purpose of this letter is to voice our concern over the Food and Drug Administration's (FDA) failure to publish the requisite notice of the extension period for comments submitted regarding the above-referenced meeting.

After the August 2, 2000 public meeting, numerous interested parties (including King & Spalding) requested that FDA extend the period of time for parties to comment on the various issues presented by the meeting from the September 1, 2000 deadline to October 31, 2000. The purpose of an extension was to allow *all* interested parties adequate time to review the hearing transcript, and develop and submit proposals to the numerous questions presented by FDA at the public meeting.

On August 30, 2000, King & Spalding contacted FDA to determine if the extension was granted and both Kathy Eberhart and Marty Wells confirmed that FDA extended the comment period for 60 days. FDA, however, never publicly announced the extension of the comment period in the Federal Register nor did it informally notify the public on the FDA website.

FDA's failure to publish the extension defeats the purpose of granting it in the first place---allowing interested parties enough time to submit thoughtful comments on this very important issue. By not publishing the notice of the extension, FDA failed to provide the public the opportunity to participate meaningfully in the extension of the notice and comment rulemaking process, as required by the Administrative Procedure Act. See 5 U.S.C. § 553(b).

00N-1380

191 PEACHTREE STREET
ATLANTA, GA 30303-1763
TELEPHONE: 404/572-4600
FACSIMILE: 404/572-5100

1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-4003
TELEPHONE: 212/556-2100
FACSIMILE: 212/556-2222

1100 LOUISIANA STREET, SUITE 3300
HOUSTON, TX 77002-5219
TELEPHONE: 713/751-3200
FACSIMILE: 713/751-3290

LET 2

Notice of the extension was imperative in this case. FDA convened the public meeting for the *specific purpose* of soliciting public comment on the important issues surrounding human bone allograft, their uses, and FDA's regulation of these products.

FDA should remedy this error by immediately issuing a notice of the extension in the Federal Register. The notice should also provide for an additional extension of 60 days from the date of the notice to allow interested parties who were not notified of the extension the same opportunity to file comments with FDA.

Sincerely,

Edward M. Basile /EB/AW
Edward M. Basile

Ashley Whitesides
Ashley Whitesides

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

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.
SAMIA N. RODRIGUEZ
ALAN M. KIRSCHENBAUM
DOUGLAS B. FAROUHAR
JOHN A. GILBERT, JR.
JOHN R. FLEDER
ROBERT T. ANGAROLA
(1945-1998)

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D. C. 20005-5929
(202) 737-5600
FACSIMILE
(202) 737-9329
2603 MAIN STREET
SUITE 650
IRVINE, CALIFORNIA 92614-4260
(949) 553-7400
FACSIMILE
(949) 553-7433
www.hpm.com

MARY KATE WHALEN
OF COUNSEL

JENNIFER B. DAVIS
FRANCES K. WU
DAVID B. CLISSOLD
KATE DUFFY MAZAN
HOLLY M. BAYNE
CASSANDRA A. SOLTIS
JOSEPHINE M. TORRENTE
MICHELLE L. BUTLER
PATRICIA A.A. VANSTORY
THOMAS R. GIBSON
PAUL L. FERRARI

FACSIMILE TRANSMITTAL SHEET

The pages in this facsimile transmission are for the sole use of the individual and entity to whom they are addressed. They may contain information that is privileged, confidential and exempt from disclosure under applicable law. If you are not the intended recipient or the employee or agent responsible for delivering this transmission to the intended recipient, be aware that any disclosure, duplication, distribution, review or use of the contents of this transmission is strictly prohibited. If you have received this transmission in error, please notify this firm immediately by collect call so we may arrange to retrieve this transmission at no cost to you.

Tel. No.: (202) 737-5600

Fax No.: (202) 737-9329

FROM: Jennifer Davis **DATE:** November 6, 2000

TO: Dockets Management Branch **FAX NO.:** 301-827-6870
FDA

NO. OF PAGES (including this page): 3

27 08 '00 NOV -7 A7:56