



Thomas
Jefferson
University

Jefferson
University
Physicians

Cataldo Doria, MD, PhD

Associate Professor of Surgery
Interim Director, Division of Transplantation

1949 7 JAN 26 P3:12

Founded 1824

Jefferson Medical
College

January 22, 2007

Jefferson College of
Graduate Studies

Jefferson College of
Health Professions

Jefferson University
Physicians

Division of Dockets Management (HFA-305)
Food and Drug Administration
Fax: 301-827-6870

Ref: Docket number 2006N-0362

To whom it may concern:

It has come to my attention that the FDA is going to reclassify hemostatic devices from Class III to Class II and that reclassification means new hemostatic products will not be required to meet mandatory clinical evaluation and pre-market approval to ensure that they are safe and effective. I am a transplantation surgeon and topical absorbable hemostatic agents are vital to my procedures and I am concerned that FDA is willingly to allow any product to enter the operating room without first undergoing stringent clinical evaluations.

Transplantation surgery already has a number of concerns to include organ rejection, recurrent hepatitis, compromised physiology, and concurrent drug therapies. I routinely leave topical hemostatic inside the abdominal cavity and I am concerned that new agents not screened adequately for infection could cause lethal events in my transplant patient population.

I urge the committee to reconsider reclassification. I am concerned that reclassification will open the door to products that may affect the safety and effectiveness of absorbable hemostats. Without pre market clinical trials there is no way for me to distinguish between those product that are clinical effective and those that are danger to my patients. Keeping topical absorbable hemostats as Class III ensures that all hemostatic agents will undergo pre market clinical trials. This is a serious issue with many facets and I appreciate the committee's consideration of my concerns.

Sincerely,

Cataldo Doria MD, PhD

2006N-0362

C 1