



January 26, 2007

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane
Rockville, Maryland 20852

RE: Docket Number 2006D-0363
Class II Special Controls Draft Guidance Document:
Absorbable Hemostatic Devices

To Whom It May Concern:

Vascular Solutions, Inc., a leading manufacturer of state-of-the-art medical products including a variety of hemostatic devices comprised of collagen and/or gelatin in combination with a licensed biologic, bovine-derived thrombin, hereby submits comments regarding the above referenced draft guidance document.

We appreciate the opportunity to comment on the proposed special controls published by the Centers for the Food and Drug Administration (FDA) on October 31, 2006, which provide guidance regarding the nature and content of pre-market notifications (510(k)) for absorbable hemostatic devices. See Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Absorbable Hemostatic Device; Availability, 71 Fed. Reg. 63774 (October 31, 2006) and General and Plastic Surgery Devices; Reclassification of the Absorbable Hemostatic Device, 71 Fed. Reg. 63278 (October 31, 2006).

Vascular Solutions is supportive of FDA's proposal that advocates reclassification of certain absorbable hemostats from Class III into Class II and generally believes that the special controls identified in the draft guidance document will provide reasonable assurances of the safety and effectiveness of absorbable hemostatic devices. However, Vascular Solutions believes that certain sections of the draft guidance would benefit from further clarification and we therefore submit the following specific comments for FDA's consideration.

Page 1, Section 1 (Introduction):

In general, FDA's specific mention that "the devices may include a licensed thrombin" suggests an intent to treat hemostatic devices containing thrombin as Class II medical devices suitable for review under 510(k), but to exclude combination products that contain other molecular entities from a Class II designation. If this is FDA's true intent, we ask that FDA provide a clear statement

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regarding treatment of hemostatic devices that contain an entity other than licensed thrombin. This could be accomplished by modifying the following sentence on page 2 of the document:

Thus, combinations of licensed thrombin and an absorbable hemostatic device would be reviewed under 510(k), while other combinations of a biologic or drug component with an absorbable hemostatic device that are assigned to CDRH may require a PMA.

to read:

Thus, combinations of licensed thrombin and an absorbable hemostatic device would be reviewed under 510(k), while combinations of other licensed biologics or drug...may require a PMA.

We believe the modified sentence more clearly reflects biologics other than thrombin are excluded from reclassification **and** that the drug or biologic must be licensed or approved by CBER or CDRH prior to incorporation into a combination device.

We believe that this reference to licensed thrombin should be further defined to include thrombin that is licensed “for further manufacture” to allow incorporate of thrombin that has been approved as an active pharmaceutical ingredient (API).

Page 6, Section 4 (Scope):

This section seems to suggest that specific indications that include blood vessel anastomosis sites will excluded from the reclassification and require a PMA. We believe FDA’s true intent was to exclude the polymerizing sealant device category from reclassification rather than excluding the specific indication for blood vessel anastomosis sites since this specific use has been extensively studies in the clinical trials supporting the approval of currently marketed absorbable hemostats. We therefore suggest that the first sentence in this paragraph be reworded as follows:

The device type does not include devices intended to control bleeding at femoral artery puncture sites (vascular hemostasis device, product code MGB) or polymerizing sealants (product code NBE).

Page 8, Section 6, Part A (Material Specifications-Collagen or Animal-Derived Materials):

We understand and respect FDA’s efforts to control the risks associated with the use of bovine-derived materials; however, certain recommendations listed in this section, and specifically “certification that an animal is from a country free of bovine spongiform encephalopathy”, are inconsistent with the language of FDA’s proposed rule “Use of Materials Derived from Cattle in Medical Product Intended for Use in Humans and Drugs for Use in Ruminants” which was published in the January 12, 2007 Federal Register. We urge FDA to consider language that is consistent with the proposed rule. In addition, we urge FDA to include reference to the existing international standard EN12442 “Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices” since this document provides clear direction pertaining to the management and control of risk associated with the use of materials of animal origin.

Page 9, Section 7 (Animal Testing):

We urge consideration of the potential confounding results that will arise with the use of comparative controls in the recommended animal studies. Use of both the investigational and control materials in the same animal will be necessary to evaluate the suggested endpoints (time to

hemostasis, time to resorption and tissue response); however, such a study design will not allow a conclusion to be drawn in the event that a coagulopathy develops.

Page 10, Section 8 (Clinical Studies)

We agree that clinical studies should not be necessary in most cases that are consistent with the scope of the reclassification proposal; however, we urge FDA to consider further clarification of the examples under which FDA may require clinical data. FDA has suggested that clinical data may be required for dissimilar designs or for new technologies. We believe these terms may benefit from further clarification since current FDA device guidance documents discussing design and technology changes are not amenable to the combination products included in this guidance document. We believe that the following examples will assist FDA in the development of appropriate language in this section.

We do not believe that a clinical study would be required if the presentation of the licensed biologic or drug included in the device was different than the presentation approved by CBER or CDER as long as the device manufacturer provided data to support the quantity, purity and stability of the biologic or drug. An example of this would be incorporation of a drug or biologic approved for packaging in a vial or syringe into a user-friendly device format that physically combines the device element, e.g. collagen or gelatin, with the biologic/drug.

In addition, we do not believe that a clinical study would be required if the production of the combination product subjected the licensed biologic to an additional or different sterilization method than specified in the CBER or CDER approval documents as long as the device manufacturer provided data to support the quantity, purity and stability of the drug or biologic.

Vascular Solutions appreciates the opportunity to comment on this draft guidance document and we are eager to provide FDA with any additional information that would enable the agency to complete the reclassification of the affected devices. If FDA staff would like to discuss these issues in detail, please do not hesitate to contact Deborah Neymark at (763) 656-4349.

Sincerely,



Deborah L. Neymark
Vice President, Regulatory Affairs, Clinical Research and Quality Systems