DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of Combination Products
15800 Crabbs Branch Way (HFG-3)
Suite 200
Rockville, MD 20855

Food and Drug Administration
Rockville MD 20857

December 3, 2009

Shepard Bentley, RAC
Aubrey Inc.
5930 Sea Lion Place
Suite 100
Carlsbad, CA 92010

Re: Request for Designation
AWBAT Plus Wound Dressing
Our file: RFD090048
Dated: n/a
Received: October 2, 2009
Filed: October 8, 2009

Dear Mr. Bentley:

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) for the AWBAT Plus Wound Dressing that was submitted on behalf of Aubrey Inc. As explained below, we conclude that the AWBAT Plus Wound Dressing is a combination product that will be reviewed and regulated by the Center for Devices and Radiological Health (CDRH) under the device provisions of the Federal Food, Drug, and Cosmetic Act (Act).

Description of the Product

According to the RFD, the AWBAT Plus Wound Dressings are intended to close the wound so healing can occur, and to allow the body to heal the wound in a moist environment. The AWBAT Plus Wound Dressing has three slightly varying configurations, each indicated for a different intended use. AWBAT-S Plus is to be used on clean superficial wounds; AWBAT-D Plus is to be used on donor sites after hemostasis has been established; and AWBAT-M Plus is to be used as a protective covering for meshed autografts. Each of the three Plus products contains the AWBAT Wound Dressing, comprised of nylon, silicon, and collagen peptides, which has previously received premarket clearance from CDRH.[1] The composition of the AWBAT Plus products are as follows: nylon,[2] silicon, collagen peptides [redacted], chondroitin-4-sulfate, chondroitin-6-sulfate [redacted], immuno-10 [redacted] vitamin E oil [redacted], vitamin C crystals [redacted], and polysorbsate 20 [redacted]. The distal side of the nylon is bonded to a thin, porous silicone membrane. The proximal side of the nylon is coated with the mixture of the remaining components. The nylon and silicon provides a protective barrier for the wound; the silicon surface contains precision pores to allow exudate to flow through the pores into an outer sterile wrap (not

[1] The premarket notification number for AWBAT Wound Dressing is K082869.
[2] AWBAT-S Plus and AWBAT-D Plus contain multiple filament nylon and AWBAT-M Plus contains single filament nylon. The other ingredients, as well as the percentages of these ingredients, are identical in each of the three configurations.

included as part of the AWBAT Plus Dressing). The RFD likens this structure to a "scaffold" that provides a 3-dimensional structure within which clotting immediately occurs. You explain that the additional components of the AWBAT Plus Dressings are intended to increase the product's hydrophilicity, which would promote a moist wound healing environment after the initial clotting occurs. [redacted].

You recommend that the AWBAT Plus Dressings be assigned to CDRH because you believe the PMOA of the combination product is provided by the device components' action to close the wound, while the additional components provide a secondary role in maintaining a moist wound-healing environment.

Product Classification: Combination Product

We have considered the information in the RFD and discussed the issues with staff from CDRH, the Center for Drug Evaluation and Research (CDER), and the Office of General Counsel (OGC).

Under the Act, the term "drug" means articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals.[3]

Under the Act, the term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.[4]

The classification of the nylon and silicon components of your product as devices is not in question; also, collagen to promote hemostasis is regulated as a device[5]. With regard to the additional ingredients, we note that the RFD contains no data to support that these ingredients increase the hydrophilic properties of the dressing through a means other than chemical action. Consequently, we have determined that the additional components of your product each meets the definition of a drug in the Act but does not meet the definition of a device. These components are drugs within the meaning of section 201(g) of the Act because each is an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man; and/or an article intended to affect the structure or any function of the body.

Therefore, we have determined that because the AWBAT Plus Wound Dressings are composed of components regulated as devices (nylon, silicon, as well as collagen peptides to promote hemostasis), as well as drugs (chondroitin-4 and chondroitin-6 sulfates, immuno-10, vitamins C and E), it is a combination product within the meaning of section 503(g) of the

[3] Section 201(g) of the Act, 21 U.S.C. § 321(g)
[4] Section 201(h) of the Act, 21 U.S.C. § 321(h).
[5] See 21 CFR 878.4490; 42 FR 63,472 (Dec. 8, 1977) (transferring absorbable hemostatic agents and dressings, including collagen products such as this one for this use, to CDRH from CDER).

Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(g)), and 21 CFR 3.2(e)(1). In accordance with section 503(g)(1) of the Act and 21 CFR section 3.4, assignment of a lead Center to conduct the review of a combination product is based on the Agency's determination of the product's PMOA.

Assignment of Lead Center: CDRH

We have considered the information in the RFD, and discussed the issues with staff in CDRH and the Center for Drug Evaluation and Research (CDER).This product has two modes of action. One action of the product is that of the device components to provide a physical barrier for and to promote clotting of the wound, while the drug components have a secondary role in providing a moist wound-healing environment. We have determined that the PMOA of the combination product is attributable to the device components' action to provide a physical barrier for and to promote clotting of the wound.

Accordingly, we are assigning the product to CDRH.[6,7] For further information regarding regulation of combination products, please refer to the webpage for the Office of Combination Products (http://www.fda.gov/CombinationProducts/default.htm). We encourage you to discuss with CDRH these and other regulatory requirements applicable to your combination product.

CDRH's Plastic and Reconstructive Surgery Devices Branch (PRSB) will be responsible for the combination product's premarket review and regulation. For further information about review requirements and how to proceed with submitting an application to CDRH, please contact Dr. David Krause, Chief, PRSB, at 301-796-6442. Please include a copy of this letter with your initial submission to CDRH.

If you have any other questions about this letter, please contact me at (301) 427-1934. Finally, the Office of Combination Products is available to you as a resource for questions or issues that may arise throughout the development of your product. You may reach us at the above address or by email at combination@fda.gov.

Sincerely,

Leigh Hayes

Leigh Hayes
Product Assignment Officer

cc: Dr. David Krause

[6] A different jurisdictional determination may be appropriate if there is a change in intended use, or constituent parts, or if the agency becomes aware of additional information that reveals that there are different modes of action than those originally described in the RFD.

[7] We note that this classification and assignment is consistent with other wound dressings that are comprised of both device and drug components, with the PMOA attributable to the action of the device components.