DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Food and Drug Administration
Rockville MD 20857

May 17, 2004

Ms. Kristi Kistner
President
Pacific OtterWorks, Inc.
975 Veronica Springs Road
Santa Barbara, CA 93105

Re: Request for Designation
COLLOSS E – Bone Void Filler
Our file: RFD 2004.016
Dated: March 23, 2004
Received and Filed: March 24, 2004

Dear Ms. Kistner:

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) for COLLOSS E – Bone Void Filler you submitted on behalf of OSSACUR AG, Oberstenfeld, Germany. The RFD is dated March 23, 2004; the Office of Combination Products received and filed the RFD on March 24, 2004. On April 27, 2004, representatives of the Office of Combination Products held a follow up telephone conversation with you, three representatives of OSSACUR, Arne Briest, Ingo Mucke, and Josef Friedrich. We have determined that the product is a device that will be reviewed and regulated by FDA's Center for Devices and Radiological Health (CDRH) under the device provisions of the Federal Food, Drug, and Cosmetic Act (the act). A full discussion follows.

Description of the Product

The RFD states that COLLOSS E is a bone void filler intended for use in filling bony voids or gaps in the skeletal system that are not intrinsic to the stability of the bony structure; for example, surgically created defects or defects resulting from traumatic injury.

According to the RFD, COLLOSS E consists of a natural extract from the extracellular matrix of cortical diaphyseal equine bone and is mainly Type I collagen. The product is lyophilized and has a cotton-like appearance.

According to the RFD, COLLOSS E is [redacted]. The RFD states that in larger bone defects, [redacted]. According to the RFD, COLLOSS E is gradually resorbed during the healing process.

The RFD recommends that COLLOSS E be classified as a device to be regulated by CDRH under the device provisions of the act. According to the RFD, COLLOSS E does not achieve any of its primary intended purposes through chemical action within or on the body and is not dependent upon being metabolized for the achievement of its primary intended purposes.

Product Classification: Device

We have considered the information in the RFD, discussed the issues with staff in CDRH, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research, and consulted with the Office of Chief Counsel.

We conclude that the primary intended purpose of COLLOSS E is to fill the void in a bone defect site [redacted]. In fulfilling this purpose, COLLOSS E meets the statutory definition of a device in that it affects the structure or function of the body of man through other than chemical action and is not dependent upon being metabolized for the achievement of its primary intended purpose.[1] Therefore, for this indication, we conclude that COLLOSS E is appropriately regulated by CDRH under the device provisions of the act. We note that classification of COLLOSS E as a device, and its review and regulation by CDRH, are consistent with the review and regulation of other collagen products as well as bone void filler products containing demineralized bone plus other components.

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[1] Section 201(h) of the act; 21 U.S.C.§ 321(h). This decision is based on the understanding that the product is not intended to mediate osteoinductive activity to generate new bone growth. However, if the intended use for this product changes so that it is not consistent with this premise, (if the product is intended for use as an osteoinductive agent) this classification would not apply to that intended use. A separate determination of the product's classification as a drug, device, or biologic would be required for that intended use.

CDRH's Division of General, Restorative, and Neurological Devices will be responsible for the premarket review and regulation of COLLOSS E. CDRH will review COLLOSS E under the device provisions of the act. For further information about review requirements and how to proceed with submitting an application to CDRH, please contact Mr. Theodore Stevens, Chief, Restorative Devices Branch, at 301-594-1296. Please include a copy of this letter in your initial submission to CDRH.

You may request reconsideration of the classification of your product within 15 days of receipt of this letter. If you wish to request reconsideration, or if you have any questions about this letter, please contact me at 301-827-9229.

Sincerely,

Suzanne O'Shea
Product Classification Officer

cc: Mr. Theodore Stevens