DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

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FACSIMILE & UPS EXPRESS MAIL

Mr. Gabriel R. Hyams, President and Executive Director
Pinnacle Transplant Technologies, LLC
1125 W Pinnacle Peak Road
Building 2
Phoenix, AZ 85027-1401

Dear Mr. Hyams:

During a Current Good Tissue Practice (CGTP) inspection of your firm, Pinnacle Transplant Technologics, LLC, located at 1125 W. Pinnacle Peak Road, Phoenix, AZ 85027, from July 8-16, 2014, investigators from the Food and Drug Administration (FDA) collected information on the manufacture of a number of amniotic-membrane based products. This information was provided to the FDA's Center for Biologics Evaluation and Research (CBER) for review.

You are currently registered with the FDA to test, screen, package, process, store, label and distribute these products. During the inspection, FDA investigators noted that you manufacture (b)(4) . All of these products are intended for use, among other things, in treatment of soft tissue injuries and inflammation, to cover and protect wounds or localized inflammation, and facilitate the migration and proliferation of the patient's cells to the site of injury. The Office of Compliance and Biologics Quality in CBER, FDA, has recently reviewed your internet website, http://pinnacletransplant.com. Your website makes clear that your firm continues to manufacture and distribute product.

These morselized amniotic-membrane based products are human cells, tissues, and cellular and tissue-based products (HCT/Ps) as defined in 21 CFR 1271.3(d). However, the products are HCT/Ps that do not meet all of the criteria in 21 CFR 1271.10(a), and therefore are not regulated solely under section 361 of the Public Health Service Act (PHS Act) and the regulations in 21 CFR Part 1271. Specifically, the products do not meet the minimal manipulation criterion set forth in section 1271.10(a)(1) and defined in section 1271.3(f)(1), due to the process, which alters the original relevant characteristics of the structural tissue relating to the tissue's utility for reconstruction, repair or replacement. In addition, your amniotic-membrane based products do not meet the homologous use criterion set forth in 21 CFR 1271.10(a)(2) and defined in section 1271.3(c), because the labeling, advertising, or other indications of your objective intent collected during the inspection, indicate that these products are intended for general surgical indications as well as tissue repair and wound healing, which are not homologous uses of amniotic membranes. Homologous uses of amniotic membrane include covering, retaining fluid in utero, or physically protecting. As a result, your HCT/Ps are drugs as defined under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(g)] and biological products as defined in section 351(i) of the PHS Act [42 U.S.C. 262(i)].

Please be advised that in order to lawfully market a drug that is also a biological product, a valid biologics license must be in effect [42 U.S.C. 262(a)]. Such licenses are issued only after a showing of safety and efficacy for the product's intended use. While in the development stage, such products may be distributed for clinical use in humans only if the sponsor has an investigational new drug (IND) application in effect as specified by FDA regulations [21 U.S.C. 355(i); 42 U.S.C. 262(a)(3); 21 CFR Part 312]. None of the amniotic-based products described in this letter are the subject of an approved biologics license application (BLA), nor are there INDs in effect for any of these products. Based on this information, we have determined that your actions have violated the Act and the PHS Act.

This letter is not intended to be an all-inclusive review of the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and the PHS Act and their implementing regulations.

We request that you notify this office, in writing, of the steps you have taken or will take to address the violations noted above and to prevent their recurrence. Your response should be sent to me at the following address: U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, HFM-600, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

If you have any questions regarding this matter, you may contact Ms. Najma Khan at (240) 402-9155. Please be advised that only written communications are considered official.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research