EMCYTE® CORPORATION
From impossible to indispensable

Dear Valued Customer,

This letter is written to provide additional information on the clearance of EmCyte concentrating systems in relation to the FDA issued document "Advancing the Development of Safe and Effective Regenerative Medicine Products".

The FDA has recently issued an article, "Advancing the Development of Safe and Effective Regenerative Medicine Products" by Peter Marks, M.D., Ph.D., Director, Center for Biologics Evaluation and Research which states their intent of enforcement for certain **Human Cell, Tissue, and Cellular and Tissue-Based Products (HCT/Ps)**, including **Regenerative Medicine Therapies**. This is an effort by the FDA to the engage industry, in a manner to address the "broad marketing of unapproved products for the treatment or cure of a wide range of diseases or medical conditions".

The following define the product types that are being referenced in the issued article and how EmCyte products are positioned and regulated through the FDA system.

Human Cell, Tissue, and Cellular and Tissue-Based Products (HCT/Ps) are human cell, tissue and cellular and tissue-based products that are manufactured by a foreign or domestic establishment that is registered with the FDA as a Tissue Establishment. These tissue establishment manufacturers (more commonly known as tissue banks) are regulated solely under section 361 of the Public Health Service (PHS) Act and are required to register and list their HCT/Ps with the Food and Drug Administration (FDA) pursuant to 21 CFR part 1271.

Regenerative Medicine Therapies (RMTs) is established in section 506(g)(8) of the Food Drug & Cosmetic Act as a drug defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using any such therapies or products, except for those regulated solely under section 361 of the Public Health Service Act (42 U.S.C. 264) and Title 21 of the Code of Federal Regulations Part 1271 (21 CFR Part 1271). These drugs are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. As described in Section 3033 of the 21st Century Cures Act, these drugs are eligible for a Regenerative Medicine Advanced Therapy (RMAT) designation after an FDA submission of an Investigational New Drug (IND) application.

EmCyte 510(k) Concentrating Systems are class II products cleared by the FDA under the 510(k) premarket notification pathway for its indicated use. These products are strictly regulated under Good Manufacturing

Practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for medical devices. EmCyte Concentrating Systems are **not** HCT/P products. EmCyte Corporation is **not** an HCT/P manufacturer and therefore outside the scope of 21 CFR part 1271 regulation.

Additionally, EmCyte Concentrating Systems are class II medical devices and biologics cleared by the Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) divisions of the FDA for its intended use. EmCyte Concentrating Systems are **not** drugs and **not** defined as a Regenerative Medicine Therapy (RMT) and **not** eligible for Regenerative Medicine Advanced Therapy designation.

For these outlined reasons, EmCyte Concentrating Systems, when used according to its indicated use and according to Good Medical Practice in the best interest of the patient when the intent is the practice of medicine, are not subject to the regulations and enforcements outlined in the "Advancing the Development of Safe and Effective Regenerative Medicine Products" letter.

We remain committed to developing and providing FDA compliant products to our customers. We appreciate your business and look forward to a continued long-term relationship with your firm.

Warm regards,

Devina

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