February 15, 2018

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**Re: Docket No. FDA-2017-D-6154: Evaluation of Devices Used With Regenerative Medicine Advanced Therapies**

***Submitted via www.regulations.gov***

Dear Sir/Madam:

Biocom is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1,000 members dedicated to improving health and quality of life, Biocom drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products.

In our mission of providing feedback and communication between regulators and industry, we are writing in response to the Food and Drug Administration's (FDA) request for comments on the draft guidance entitled "Evaluation of Devices Used With Regenerative Medicine Advanced Therapies" (the "Draft Guidance").

Biocom commends the agency on its efforts to develop a comprehensive regenerative medicine framework to spur innovation and access to potentially life-saving treatments while ensuring safety and efficacy. The release of this Draft Guidance has provided important information on how the FDA intends to evaluate devices used in the recovery, isolation, or delivery of regenerative medicine advanced therapy (RMAT) products. We respectfully recommend that the agency provide clarity on the following areas:

- To ensure consistency across guidances on the scope of regenerative medicine products, Biocom recommends that FDA clearly define in this Draft Guidance what products are included in the definition of regenerative medicines. The Draft Guidance currently references section 506(g)(8) of the Food, Drug, and Cosmetic (FD&C) Act, which defines a "regenerative

medicine therapy" as including "cell therapy, therapeutic tissue engineering products, human cell and tissue products, and combination products using any therapies or products, except for those regulated solely under section 361 of the Public Health Service Act [42 U.S.C. 264] and [21 CFR Part 1271]." FDA should clarify the inclusion of gene therapies. In the Draft Guidance "Expedited Programs for Regenerative Medicine Therapies for Serious Conditions", the agency states "As FDA interprets section 506(g), gene therapies, including genetically modified cells, that lead to a durable modification of cells or tissues may meet the definition of a regenerative medicine therapy." Biocom recommends that the agency duplicate the same definition in this Draft Guidance to provide consistency and clarity on the inclusion of gene therapy.

- Biocom appreciates the agency's explanation of the types of devices that may be evaluated independently as standalone devices using premarket submission pathways. The examples provide industry with additional clarity on the types of recovery and delivery devices that would be subjected to standalone evaluation. It would be beneficial for industry to also have examples of separately packaged RMAT and specified delivery devices that are labeled for use together but would require separate market applications for each products.

Thank you again for the opportunity to provide these comments. We look forward to further communication with you on this important guidance. If you have any questions about these comments, please contact Brittany Blocker, Manager of Regulatory Affairs at bblocker@biocom.org.

Sincerely,

Joe Panetta
President and CEO
Biocom