BIOTECHNOLOGY INDUSTRY ORGANIZATION
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July 1, 2009

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

Re: Docket No. FDA- 2009-D-0132

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the draft *Guidance for Industry: Somatic Cell Therapy for Cardiac Disease*.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

A large number of patients is typically needed in Phase 3 trials to demonstrate a statistically significant and clinically meaningful treatment effect for primary endpoints such as mortality or subsequent hospitalizations. For novel cardiac cellular therapies that require interventional delivery, the scope of these trials may be prohibitively large, and may preclude the development of such therapies in an area of high unmet medical need. We request that the guidance explicitly acknowledge the sponsor's option to seek approval for certain new products under the regulations at 21 CFR 314 Subpart H, based on "a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity". A description in the guidance of specific potentially acceptable surrogate endpoints would also be helpful.

Once again, we appreciate the opportunity provide comment. We would be pleased to clarify or expand our comments, as needed.

Respectfully submitted,

/s/

Sara Radcliffe
Vice President
Science and Regulatory Affairs
Biotechnology Industry Organization (BIO)