



July 27, 2004

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

BIOCOM is the regional trade association representing the Greater San Diego life science industry. Our mission is to position the Greater San Diego life science community to achieve individual and collective success on the world stage of scientific and technological innovation, and in the development of products that improve global health and quality of life. We represent more than 200 member life science companies involved in R&D and commercial activities in the fields of biotechnology, medical device and diagnostics. There is no public or private entity more important to the success of our companies than the Food and Drug Administration.

We are hereby submitting this letter in support of FDA's efforts regarding the Critical Pathway. We would like to thank you for engaging the life science industry to participate in the formulation of policies that will guide both the Agency and industry as we move forward together to assure that innovation in drug discovery and development can occur in balance with the proper assessment of efficacy and risk. Many of our companies have participated in the sessions you have held to gather input on the science based regulatory approach and are very encouraged at the direction in which the Agency is moving.

We find it particularly encouraging that the FDA is aware of the challenges that companies continue to face when bringing novel products to market, that compounding these challenges with inadequate tools will only create further barriers to patients accessing innovative therapies, and that a more science-focused approach to the regulatory process for the review of novel drugs and technologies should be considered..

As you may know, San Diego is home to not only one of the largest life science industry clusters in the world, but also the most diverse. We have several companies that are working in the area of toolbox technology that are seeking to address many of the hurdles in drug discovery through their products. We do encourage you to view them as partners, as well as the companies who utilize their products, as you continue to evaluate the industry and make recommendations for more efficient interactions with the Agency.

We look forward to working with the Agency as this proposal continues to progress.

Sincerely,

Joseph D. Panetta  
President & CEO  
BIOCOM

Duane J. Roth  
Chairman  
BIOCOM

Gerald Yakatan  
Chair  
BIOCOM FDA Committee

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