



1225 Eye Street NW, Suite 400
Washington, D.C. 20005

December 8, 2006

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: Docket No. 2006N-0464

Electronic Submission of Regulatory Information, and Creating an Electronic Platform for Enhanced Information Management; Public Hearing

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) requests an opportunity to make a brief presentation (5-10 minutes) at the FDA E-Submissions public meeting on December 18th, 2006.

Over the last several years, BIO has been actively working with FDA and other stakeholders towards the development of an electronic review environment and we feel we could offer the unique perspective of small-to-mid size biotechnology companies that submit regulatory information to the agency. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. States and 33 other nations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

We are currently in the process of drafting a presentation and vetting it through our membership. Please let me know if there is an opportunity to participate and I will forward our remarks in advance of the meeting. Some of the questions we hope to address in our statement include:

- Since January 1999, we have accepted the voluntary electronic submission of certain premarket applications. If you are not voluntarily submitting such applications electronically, what is the reason(s)?

- What are the major impediments to an all-electronic submission environment?
- How can FDA best address these impediments?
- Are there specific issues related to electronic submission of premarket applications that are unique to small companies, academic institutions, and government agencies? If so, what are they and why are they unique?
- In your opinion, what internal expertise is needed for firms to make the transition to an all-electronic premarket submission? Do firms have this expertise?
- How would an all-electronic submission environment benefit you?
- Would an all-electronic submission environment change your ability to initiate in a timely manner the studies supporting your regulatory submission?
- How much time would you need to make a smooth transition to a new electronic system?
- Should we consider an incremental phase-in implementation strategy for an all-electronic submission environment? If so, what should the strategy include? What is the order of priorities for phasing in implementation?
- What steps can we take to minimize the cost or other burdens of transitioning to an all-electronic submission environment?
- What are your general viewpoints on a third party entity or entities providing services related to such an electronic platform?

Sincerely,

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