

January 18, 2007

Dear Members of the FDA Part 15 Hearing Panel,

It is our understanding that, following the FDA Part 15 Hearing, the panelists had some questions. What follows is additional information that we believe will clarify these points.

Dr. Lutter raised a question regarding access to CRIX services. As we discussed at the hearing, CRIX services are intended for open use by any person or entity, with or without a service contract. While access to public or FOIA information may be provided *without* a service contract, access to most services will require the establishment of a service contract to ensure privacy, confidentiality, and the equal application of system liability rules for all CRIX service users.

The CRIX International Board will establish a pricing framework for these services, based upon two elements:

1. Service offering type
2. User's service category (e.g., private sponsor, government sponsor, clinical investigator, etc.)

To assure open access, the pricing approach discussed to date will strive for affordability. In certain instances, services may be offered at no charge. As an example, Clinical Investigators will not be charged for their use of the FIREBIRD service even though, they and their staff benefit greatly in terms of time, process, and cost savings.

Dr. Olivo's question concerned competition within the CRIX system. Our intent has been to promote competition through both the approach and structure of CRIX International, particularly for the development and support of CRIX service modules. No particular provider is favored in the development of these modules. Instead, it is likely that CRIX will engage many different providers in the development of the various service modules, with each module created to ensure support from providers other than the original developer. In addition, all providers within a given service offering will be required to enter into an agreement with and to become accredited by CRIX International. These steps will ensure service quality, performance, and system interoperability requirements are upheld, while allowing for healthy competition within the CRIX system

Lastly, we would like to provide an additional comment on the structure of CRIX International. As presented at the Hearing, CRIX International is a non-profit organization committed to the oversight of various accredited Service Delivery Providers. CRIX International does *not* intend to provide operational or technical services directly to the users of any exchange-related services. All operational and/or technical services will instead be provided solely by accredited CRIX Service Delivery Providers. Based on this structure, we believe that, should the FDA or NIH divisions choose to engage with or

participate in any of the development working groups and/or Board oversight activities of CRIX International, they will not be in conflict with future service delivery selections made by the same organizations.

We hope that these comments help clarify our position on these matters. If the panelists would like further clarification on these or other matters, we would be pleased to discuss them at your convenience.

Best regards,

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