

SALAMANDRA LLC
4600 North Park Avenue, Suite 100
Chevy Chase, Maryland 20815 - 4518
telephone (301) 652 - 6110 • facsimile (301) 652 - 6739
kkook@salamandra.net

December 10, 2001

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

RE: Docket No. 01N-0496, Notice of Pilot Project involving the testing of the **Patient Profile Viewer**

FDA Contact: Randy Levin, Center for Drug Evaluation and Research (HFD-001)

Sir/Ms:

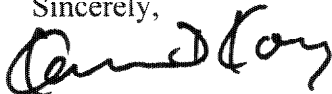
This is to express our interest in participating on a volunteer basis in the subject project.

Our company develops and produces regulatory documents for FDA submission, including massive NDAs, in paper, electronic, and hybrid modes, which include patient CRT datasets. Because we share FDA's interest in encouraging our clients to move towards a complete electronic format to the extent feasible, we would be happy to work with you on a volunteer, unpaid basis to assist in the development of the Patient Profile Viewer.

Please let us know what additional steps you need us to take and the associated time lines.

Your contact at Salamandra, LLC is Dr. Richard Krasnow, Operating Director, reachable at the same address and telephone number and at rkrasnow@salamandra.net.

Sincerely,



Karin A. Kook, Ph.D.
Managing Director

cc: Randy Levin, FDA/CDER by email

01N-0496

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