

EXHIBIT 4

-----Original Message-----

From: McKenna, Kevin

Sent: Tuesday, October 14, 2003 11:48 AM

To: Minnick, Jim G; Mullen, Jamie A; Doran, Nigel M; Fitton, Lesley R; Duff, David J; Campbell, Denise; Leong, Ronald; Melville, Margaret G; Brecher, Martin; Melville, Margaret G; Abbott, Brian M; Davies, Laura J; Manning, Julia W

Subject: Privilege and Confidential - Attorney/Client Communication Revision #4 of the October 15 FDA Letter

Importance: High

All,

Attached please find Revision #4 of the October 15th correspondence to the FDA. I have removed reference to Trial 125 and proposed appropriate language that is more explicit in our desire to meet with the FDA prior to taking any action with respect to updating the label.

May I please have your comments by 3:30 pm US time? This tight deadline is necessary if the team is to meet our October 15th submission date.

Thanks in advance for your time and attention to this matter.

Kevin

<< File: revisedOct15FDAresponse10_14.doc >>