



May 25, 2004

Celsion Clarifies FDA Warning Letter

COLUMBIA, MD - May 25, 2004: CELSION CORPORATION (AMEX: CLN) announced today that it has received a warning letter from the Food and Drug Administration (the FDA) regarding the Phase I and Phase II clinical trials of its Prolieve™, a Thermodilatation system for the treatment of benign prostatic hyperplasia, or BPH. The FDA granted Premarketing Approval (PMA) to Celsion for the Prolieve system earlier this year, and the system currently is being marketed under a distribution agreement between Celsion and Boston Scientific Corporation.

The warning letter reflects matters that arose during the course of a pre-approval inspection conducted by the FDA's Baltimore regional office from December 9 through December 18, 2003 under a program designed to ensure that data and information contained in certain submissions to the Agency are scientifically valid and accurate and to ensure that human subjects are protected from undue hazard or risk during scientific investigations.

According to Carolyn Finkle, Celsion's Vice President-Regulatory, "We are committed to taking whatever actions are necessary to address fully the issues raised by the FDA. We are taking the FDA's letter very seriously and already have initiated short- and long-term corrective and compliance measures in response to the Agency's concerns. In addition, we have had two separate discussions with the Agency regarding both the actions that we have taken to date and those that we intend to take in the near future. Based on those discussions, we believe that we will be able to satisfy the Agency's concerns on a timetable that is achievable by us and acceptable to the FDA. So long as we succeed in fully addressing the issues raised by the FDA in a timely manner, and in light of the nature of the issues raised by the FDA, we do not anticipate that any further action by the FDA, including any actions that would affect the Prolieve PMA, will be warranted."

The warning letter addressed four general areas--monitoring, investigational agreements, provision of information to certain investigators, and FDA reporting--in connection with the Prolieve studies, both of which were completed by January 2002. The corrective and compliance measures initiated by the Company since receipt of the warning letter are in addition to certain corrective and compliance actions taken earlier by the Company to address observations made by the FDA inspector in connection with the December inspection. These earlier actions were detailed in a written submission by the Company to the FDA on December 23, 2003.

Anthony Deasey, Celsion's Executive Vice President and Chief Operating Officer said, "Celsion is a growing company, committed to operating in full compliance with applicable FDA regulations. While receipt of a warning letter is not generally considered a positive development, I expect that the actions that we are taking and the systems and procedures that we are implementing in response to the FDA's letter ultimately will make us a stronger, more effective company going forward."