AMERICAN MEDICAL SYSTEMS

August 3, 2001

U.S. Food and Drug Administration
Office of Device Evaluation/DRARD
Center for Devices and Radiological Health
9200 Corporate Blvd. HFZ –470
Rockville, MD 20850

To Whom It May Concern:

American Medical Systems Inc., manufacturer of the Acticon™ Neosphincter, authorizes the U.S. Food and Drug Administration to release public information about this device for Advisory Panel meeting scheduled for August 17, 2001. This public information was submitted to FDA by the manufacturer and includes:

- Draft Summary of Safety and Effectiveness for P010020
- *Important Information for Patients Considering the Acticon Neosphincter*
- *Learning to Use Your New Prosthesis – Guide for Women*
- *Learning to Use Your New Prosthesis – Guide for Men*
- *Acticon Operating Room Manual*

In accordance with federal law, the information included in PMAA P010020 remains confidential while the application is under review. AMS does not authorize the release of information contained in the PMAA.

Please contact me if you have questions or need additional information.

Sincerely,

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