DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, Maryland 20850

August 2, 2006

Re: FDA Registration Form
Owner/Operator No: 9045610

Mr. William Kotys
Kotys & Company
1698 Laramie Drive
Powell, OH 43065

Dear Mr. William Kotys:

We have received your form FDA 2891, Initial Registration of Device Establishment, and form FDA 2892, Medical Device Listing for the following medical device establishment:

Emerald Instruments
Factory Roras Road
P.O.Box 766
Sialkot, Punjab Pakistan

This information has been entered into our Establishment Registration database. We will forward your establishment registration number to you after the Field Investigations, Office of Regional Operations, Food and Drug Administration (FDA) assigns it. Nevertheless, until that time, you are still considered registered.

Please refer to the Owner/Operator Number when you or your United States Agent contacts our Branch with any subsequent correspondence.

FDA sends form FDA 2891a, Annual Registration, to all registered firms annually to be verified, corrected, and returned to us. Your copy of Part 1 is proof of registration for the coming year.

We do not acknowledge receipt of device listing forms received subsequent of an establishment initial registration. Please keep the yellow copy, or a photocopy, of each form FDA 2892 as proof of your listing. The listing form document number in the upper left corner specifically identifies the listed device. The document number should be included on all shipping invoices.

Any inquiries regarding your registration status or device listing should be directed to the registration and listing staff at 240-276-0111 or email at reglist@cdrh.fda.gov.

Center for Devices and Radiological Health