



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

April 4, 2002

Kenneth E. Brody
Senior Counsel
Pennsylvania Department of Health
PO Box 90
Harrisburg, PA 17108

Re: Docket No. 01A-0375

Dear Mr. Brody,

This is in response to your inquiry regarding the request for an advisory opinion that you submitted on August 24, 2001 and that the Food and Drug Administration (FDA) filed on August 30, 2001. Due to competing priorities, we have been unable to complete a response. We expect to have a final response ready for you very shortly. Please excuse this delay.

If you would like to discuss this, please give me a call at (301) 827-2974.

Sincerely yours,

Joseph M. Sheehan

Joseph M. Sheehan
Chief, Regulations Staff
Center for Devices
and Radiological Health

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