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April 20, 1987

Dr. Erik Millstone
The University of Sussex
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Dear Dr. Millstone:

Dr. Freedman has asked me to respond to your letter of April 8, 1987. I have looked into the three studies cited in your letter, and can tell you these studies have never been repeated, nor did they need to be. These three studies were authenticated by the FDA Task Force to which you refer in 1977.

Authentication of the data and conclusions of 15 pivotal studies was part of a process leading to the Public Board of Inquiry (PBOI) held on January 30, 31, February 1, 1980. The FDA Bureau of Foods Task Force authenticated the three above mentioned studies, and the remaining twelve studies were authenticated by Universities Associated for Research and Education in Pathology (UAREP). The UAREP review took approximately two years (1977 - 1978); completion of the authentication process was prerequisite for convening the PBOI. As you know, the PBOI was devoted to scientific questions, not questions dealing with data authenticity.

The record pertaining to the APM approval process is long and, generally, well known. Should you have further questions regarding either the process or the many studies that form the basis for approval, I trust you will contact me.

Sincerely,

S.V. Molinary
Vice President
Regulatory Affairs

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