

Andrzej Sawicki, M.D., Ph.D.
Warsawskie Centrum Osteoporozy I
Arki Wapniowej Osteomed
Ul. Bialobrz,
Warszawa, Poland

JUL 19 2001

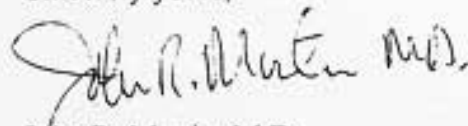
Dear Dr. Sawicki:

Between May 21 and May 25, 2001, Mr. Kenneth Merritt and Dr. Roy Blay, representing the Food and Drug Administration (FDA), met with you to review your conduct of a clinical study (Protocol # B3D-MC-GHAC) of the investigational drug Forteo (teriparatide), performed for Eli Lilly & Co. This inspection is part of FDA's Bioresearch Monitoring Program, which includes inspections designed to validate clinical studies on which drug approval may be based and to assure that the rights and welfare of the human subjects of those studies have been protected.

From our evaluation of the inspection report and the documents submitted with that report, we conclude that you adhered to all pertinent federal regulations and/or good clinical investigational practices governing your conduct of clinical investigations and the protection of human subjects.

We appreciate the cooperation shown Investigators Merritt and Blay during the inspection. Should you have any questions or concerns regarding this letter or the inspection, please contact me by letter at the address given below.

Sincerely yours,



John R. Martin, M.D.
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