From: Lee, Bonnie
Sent: Friday, October 17, 2003 10:33 AM
To: [Redacted]
Subject: Certified Translations

Dear [Redacted], It was great hearing your voice message and I apologize for not checking my voice mail more frequently. First, in terms of whether FDA requires certified translations of consent documents, the answer is no. We would certainly expect that you would do what you could to ensure that the translation accurately reflects the information in the English version, but there is nothing in our regulations that requires the translation to be done by an individual who is certified. I do not know whether State law may address this issue or not.

[Redacted]

My best,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy, GCPP, FDA