From: Woollen, Stan - OC
Sent: Monday, July 28, 2003 4:46 PM
To: [redacted]
Subject: Retention of Study records

Dear [redacted],

I am responding to your inquiry regarding FDA record retention requirements for clinical trials. The information you have regarding our requirements as being 15 years, with intention to increase it to 25 years is incorrect. Our record retention requirements for clinical investigators have not changed and remain in our regulations found at 21 CFR 312.62 (c) which I have reproduced below for your reference. As you can see they are linked to the approval of the product or discontinuation of the study and can be considerably shorter than 15 years. I am unaware of any plans to change this requirement. You can find the regulations in 21 CFR 312 in their entirety on our web site at
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312

21 CFR 312.62

(c) Record retention. An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

I hope this information is helpful.

Sincerely,
Stan W. Woollen
Associate Director for Bioresearch Monitoring
Good Clinical Practice Programs
OSHC, Office of the Commissioner

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.