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November 28, 2000

Nycomed Amersham

Nycomed Amersham Imaging

101 Carnegie Center
Princeton, NJ 08540-6231

609 514 6000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: DOCKET NO. 00D-1424

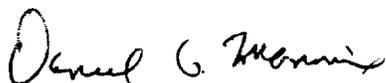
Dear Sir or Madame:

Thank you for the opportunity to comment on the draft guidance for industry entitled "Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation". Nycomed Amersham would like to provide the following comment:

1. Introduction – Page 2 - second paragraph – Please clarify what is meant by "container closure components, and other materials" in Lines 46 - 47. By "container closure components" do you mean both product-contact items and secondary packaging? What are the "other materials"? It would be a huge burden to industry if every single method used for testing all materials involved in drug substance / drug product manufacture had to be validated.

If you have any questions concerning these comments, please contact me at 609-514-6494.

Sincerely yours,



Daniel G. Mannix, Ph.D.
Vice President, Regulatory Affairs

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NYCOHEM AMERSHAM
181 CARNEGIE CENTER
PRINCETON NJ 08540
(609)514-6539

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