Elemental Research Inc.

Excellence in Research & Analytical Services

27 Feb 06

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

2653 6 MAR -7 P 2:53

Comment on Draft Guidance for Industry
INDs — Approaches to Complying with CGMP During Phase 1

Section F.1 states "Analytical tests used in production (e.g., testing of components, in-process material, packaging, drug product) should be scientifically sound (e.g., specific, sensitive, and accurate) and reproducible for the specified purpose." Contract laboratories are typically not informed of the specified purpose for analyses requested, and their clients may request cGMP compliance without having a method qualification or validation performed. Please clarify your expectations for proving that a method is "scientifically sound and reproducible". Please provide examples of specified purposes which would be deemed acceptable for each of the following cases:

a) a one day method qualification,
b) a full method validation over several days, or
c) no method qualification or validation.

Thank you,

Mercedes Stuart
QA Manager

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