



March 21, 2007

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

RE: Docket No. 2006D-0347
Comments on Draft Guidance, *In Vitro Diagnostic Multivariate Index Assays*

Background & Introduction

Hoffmann-La Roche (Roche) is pleased to submit the following comments on the above-referenced FDA draft guidance dealing with In Vitro Diagnostic Multivariate Index Assays (IVD MIAs). This draft guidance was issued by CDRH's Office of In Vitro Diagnostic Device Evaluation and Safety on September 7, 2006.

Roche is one of the world's leading healthcare companies active in the discovery, development, manufacture and marketing of products and services that address prevention, diagnosis and treatment of disease. Roche is devoted to the discovery and development of new diagnostic and products and drug therapies that allow patients to lead longer, healthier, and more productive lives.

Roche understands that diagnostic tests play a critical role in informing patient care decisions. Tests help physicians diagnose disease, choose among available treatment options, and follow the progress of these treatments. As such, these tests, regardless of where they are developed, must be grounded in good science, their measurements must be consistent and accurate, the biological markers that the tests measure must be validated for the intended purpose, and clinical use of tests must be supported by evidence of effectiveness.

While we recognize and support the innovation that springs from clinical laboratories, we are convinced that physicians (and the patients they treat) need assurances that the analytical characteristics of tests developed in-house by these laboratories have been characterized and are monitored and that the use of these tests in the clinical settings in which they are applied has been assessed and found to adequately support clinical decision making. The current regulatory system falls short of this goal, and it puts patients at risk.

Specific Comments

We have reviewed the draft guidance on IVD MIAs and have the following specific comments:

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Roche Diagnostics
Corporation

9115 Hague Road
PO Box 50457
Indianapolis, IN 46250-0457
USA

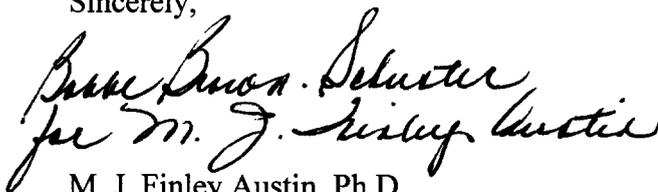
Tel. +1-800-428-5074

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- We understand FDA’s intent as it has identified a new term, “IVD MIAs,” to identify a type of laboratory-developed test that should be subject to regulation by the Agency. We urge the Agency to provide some additional clarification concerning the meaning of this term, so that laboratories understand precisely what tests are subject to regulation.
- It is our view that confusion currently exists with respect to FDA’s role in regulating tests developed in-house by clinical laboratories. We concur with the Agency that it has the authority to regulate these tests as medical devices, and that the laboratories that develop in-house tests are acting as manufacturers, subject to FDA jurisdiction. We also believe that FDA’s exercise of “enforcement discretion” over these tests in its approach to the regulation of ASRs has led some to conclude (incorrectly) that the Agency does not have jurisdiction in this area. We are pleased that the Agency is making clear its regulatory authority in the draft guidance document.
- We support the approach FDA has outlined in the draft guidance document for regulating of laboratory-developed tests in a “least burdensome” way. The way that FDA currently regulates *in vitro* diagnostic tests is based on risk and intended use. We believe that a similar approach is appropriate for the regulation of laboratory-developed IVD MIAs. In particular, we believe that IVD MIAs that are used to define patient populations that are responsive to particular therapeutics, or that influence treatment decisions about whether or not a patient will have access to a critical treatment, should be subject to some type of evaluation by FDA. The details of how this evaluation would ultimately be implemented in a least burdensome way are still open for discussion, but the approach should be intended to ensure both the analytical performance of the test and its clinical validity.

Thank you for the opportunity to comment on this draft guidance. Do not hesitate to contact us if you have any questions.

Sincerely,



M. J. Finley Austin, Ph.D.
Director of US External Science Policy
F. Hoffmann-La Roche AG



Michael Samoszuk, M.D.
Chief Medical Officer
Roche Diagnostics Corporation