Yale University

Marie Louise Landry, M.D.
Professor
Department of Laboratory Medicine
School of Medicine
333 Cedar Street
P.O. Box 208035
New Haven, Connecticut 06520-8035

Telephone: 203 688-3475

Dockets Management Branch (HFA-305) 7583 '01 JUN -5 A9:39
Docket No. 01D-0202
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

May 30, 2001

SUBJ: Least Burdensome Provisions

To Whom it May Concern:

I am writing concerning the **Least Burdensome Provisions of the FDA Modernization Act of 1997**. Unfortunately, most laboratorians are not aware of this document.

From my brief perusal of this document, I am most concerned the the types of information and studies that could be requested by the FDA will be greatly restricted. The FDA would be forced to rely on bench and analytical studies for any assay application's indications for use. Prospective studies could no longer be requested for a particular indication. Package inserts would not be reviewed for accuracy or truthfulness.

I am concerned that these changes will prevent any intelligent discussion of an assay's merits before it is released to the public.

Lastly, I feel very strongly that Laboratorians should be made aware of these changes. Is it possible for the FDA to notify their professional organizations? Otherwise, there is no opportunity for the FDA to obtain feedback, except from industry.

Thank you for your consideration of these comments.

Sincerely,

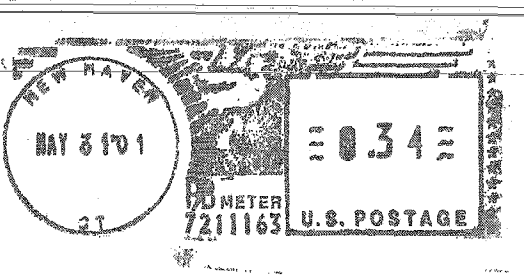
Marie L. Landry, M.D.
Director, Clinical Virology Laboratory

Fax: 203-688-8177
email: marie.landry@yale.edu

cc. S. Gutman
01D-0202

C1

YALE-NEW HAVEN
HOSPITAL
20 York Street
New Haven, CT 06504
Marie L. Landry, M.D.
CB 565



DOCKETS MANAGEMENT BRANCH (HFA-305)
DOCKET No. 01D-0202
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE RM 1061
ROCKVILLE MD 20852