

F.K.

Pub.

APR 27 2004

Billing Code 4160-01F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DELEGATION OF AUTHORITY

25 10 04 APR 26 10:17

Notice is hereby given that I have delegated to Commissioner Food and Drugs, the authority vested in the Secretary of the Department of Health and Human Services, under Section 353 of the Public Health Service Act (42 U.S.C. 263a), as amended, to implement CLIA's complexity categorization provisions as they apply to commercially available tests to the Commissioner of Food and Drugs (FDA). This authority includes, but is not limited to the following:

- (a) Interpreting the CLIA provisions related to complexity categorization;
- (b) Holding public workshops and meetings on CLIA complexity categorization; and,
- (c) Developing and issuing implementing rules and guidance for CLIA complexity categorization.

The Administrator of the Centers for Medicare & Medicaid Services (CMS) will provide funding to implement CLIA's complexity categorization provisions as set forth in the Agency Agreement between FDA and CMS (CMS IA-04-01; FDA 224-04-6052), as amended.

Except as provided above, the existing delegation of authority to the Administrator of CMS concerning CLIA is unaffected.

This delegation supersedes the delegation of authority memorandum dated October 31, 2003, from the Secretary to the Commissioner of Food and Drugs, titled "Delegation of Authority for the Clinical Laboratory Improvements Amendments of 1988 (CLIA)," Section 353 of the Public Health Service Act, as amended."

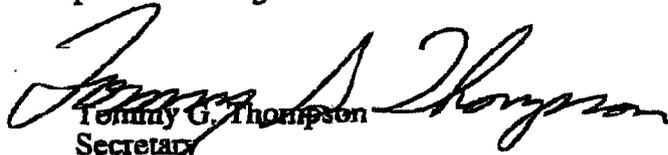
This delegation shall be exercised under the Department's existing delegation and policy on regulations. In addition, I ratified and reaffirmed any actions taken by you or your

OC 049999

NI

subordinates which involved the exercise of this authorities prior to the effective date of this delegation.

This delegation was effective upon date of signature.


Tommy G. Thompson
Secretary
Department of Health and Human Services


CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

APR 21 2004