

Food and Drug Administration  
Center for Biologics Evaluation and Research

## *Recommended Reading*

for the

Oncologic Drugs Advisory Committee Meeting  
December 5, 2001

The Development of Diagnostic Immunohistochemistry (IHC) and  
Fluorescence *in situ* Hybridization (FISH) Assays Intended to  
Identify Patients Who Might Benefit from Treatment with a  
Particular Therapeutic Product

Focus on Characterization and Interpretation of Assay Results

### *Additional References:*

O'Leary, Timothy J. Standardization in Immunohistochemistry. *Applied Immunohistochemistry and Molecular Morphology* 9(1): 3-8, 2001.

Test and Technology Transfer Committee: Watson, Michael S., Buchanan, Philip D., Cohen Maimon M., DeWald, Gordon W., Ledbetter, David H., Goldberg, James D., Wapner, Ronald J. Technical and clinical assessment of fluorescence *in situ* hybridization: An ACMG/ASHG position statement. I. Technical considerations. *Genetics in Medicine*: 2(6), 2000.

Barker, Peter E., Watson, Michael S., Ticehurst, John R., Colbert, Jennifer C., O'Connell, Catherine D. NIST Physical Standards for DNA-Based Medical Testing. *Journal of Clinical Laboratory Analysis*, vol 16 (1)- in press, pagination to be determined