DEPARTMENT O. /EALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date July 22, 1992

From Associate Commissioner for Regulatory Affairs
(HFC-1)

Subject FDA-483 List of Inspectional Observations Policy

To Regional Food and Drug Directors
District Directors
Directors, Investigation Branches

As you are well aware, regulatory uniformity has always been a goal in FDA's enforcement strategies and policy, therefore, it is essential that the FDA-483s we issue be understandable, consistent and contain only significant observations. I would like to reiterate long-standing ORA policy concerning the issuance of FDA-483s.

Simply stated, all FDA-483s will adhere to the following general principles:

* Observations which are listed must be significant and correlate to specific regulated products or processes being inspected.

* Observations of questionable significance are not to be listed in the FDA-483, but will be discussed with the firm's management so that they understand how uncorrected problems could become a violation. This discussion will be detailed in the EIR.

Our FDA-483s must have certain characteristics to be useful and credible documents. These are as follows:

* Each observation must be clear and specific.
* Each must be significant. Length is not necessarily synonymous with significance.
* Observations should not be repetitious.
* The worst observations should be listed first.
* All copies of the FDA-483 must be legible.

Finally, ORA policy requires that inspectional observations will continue to be presented in writing at the close of inspections when mandated by law or when otherwise necessary to promptly inform the firm of conditions observed during inspections. When guidance is needed to determine if an observation should be included on the FDA-483, the IOM and compliance programs provide specific guidance. Supervisory consultation may also be sought prior to issuing the FDA-483 when any question arises.

Please share this guidance with everyone who participates in inspections. Thank you for your continued assistance in assuring nationwide uniformity of operations.

Ronald G. Chesemore