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CENTER FOR DRUG EVALUATION AND RESEARCH

# Guidance for Industry

*The FDA published Good Guidance Practices in February 1997.  
This guidance was developed and issued prior to that date.*

Additional copies are available from:  
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(Tel) 301-827-4573  
(Internet) <http://www.fda.gov/cder/guidance/index.htm>

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

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TO ALL NDA, ANDA AND AADA APPLICANTS

OCT 14 1994

Dear Sir or Madam:

The Center for Drug Evaluation and Research (CDER) and the Office of Regulatory Affairs (ORA) have been working together to clarify roles and delineate areas of responsibility of the CDER chemistry review scientists and the ORA field investigators in the new and abbreviated drug approval processes. As a result of this effort, the *Compliance Program/Pre-Approval Inspections, 7346.832*, has been revised to elucidate individual responsibilities. The revised document will be distributed to FDA's District Offices.

IDENTIFICATION AND ELIMINATION OF REDUNDANCY IN THE PROCESS:

Certain information previously submitted in the application has been determined to be more appropriately evaluated by the field investigator as part of the pre-approval inspection/data audit. Such information need not be submitted to the drug application except where specifically indicated below; however, it must be maintained in a readily retrievable manner at your firm for review and verification by the field inspection staff:

1. Manufacturing Facilities, Personnel and Equipment Qualification: The field investigator will be responsible for determining the adequacy of the facility, personnel and equipment qualification information as part of the cGMP inspection of the particular facility.
2. Ancillary Facilities: The field investigator will be responsible for determining the adequacy of this information as part of the cGMP inspection of ancillary facilities (contract testing laboratories, contract packagers and labelers).

Note: The name and address of each primary and ancillary facility to be used in the manufacture, processing, packaging, labeling and control of the drug product should still be indicated in the application. This information will allow the Establishment Evaluation Request (EER), which originates in the Center, to accurately reflect the actual facility(ies) where the operations are performed.

3. Raw Material Controls, Laboratory Controls, and Packaging and Labeling Controls: The field investigator will be responsible for determining the adequacy of the storage system controls, sampling controls, and qualification procedures for raw materials, in-process materials and finished products, including SOP's, as part of the cGMP inspection of the particular facility.

The Center for Drug Evaluation and Research will continue to evaluate the test methods, specifications, and data generated from these methods for adequacy and appropriateness. The field investigator will audit the data.

Note: For sterile processes; facilities, equipment qualification, process and controls information should be submitted to the NDA/ANDA/AADA as part of the sterile process validation package for review by the CDER microbiologist.

#### CLARIFICATION OF ROLES:

As stated in the Background section of the *Compliance Program/Pre-approval Inspections; 7346.832* "...CDER's role in the pre-approval process is to review data submitted to the agency as part of pre-market new drug applications and generic drug applications, and establish specifications for the manufacture and control of the resulting drug product based on the submitted data. The Districts' role is to assure cGMP Compliance and to verify the authenticity and accuracy of the data contained in these applications."

#### INCREASED COMMUNICATION:

An important aim of the new *Compliance Program/Pre-approval Inspections* is to increase the emphasis on communication among the review scientists and the field investigators with regard to individual application issues. In addition, we will continue to seek opportunities for greater interactions among agency components.

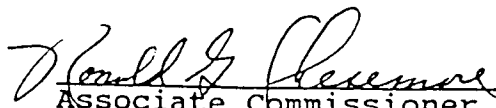
#### IMPLEMENTATION OF THE AGREEMENT:

Once implemented, the Center for Drug Evaluation and Research will no longer require that information designated to be the responsibility of the field investigator (as outlined above) be submitted to the application. In addition, scientists in the Center will no longer review such information submitted prior to implementation of the agreement. Any deficiencies noted in "Not Approvable" letters from the Center for Drug Evaluation and Research to applicants which request this information should be addressed as "no longer required to be submitted to the application."

We intend that these changes in the responsibilities of the review scientists and field investigators fulfill the desired goal of simplifying the application submission process, resolve confusion and eliminate any redundant/duplicative review.



Director, Center for Drug  
Evaluation and Research



Associate Commissioner  
for Regulatory Affairs