Memorandum of Understanding
Between
The Office of Regulatory Affairs
and
The Center for Drug Evaluation and Research
on the Pharmaceutical Inspectorate

FDA oversees the quality of drug products using a two-pronged approach involving review of information submitted in applications as well as inspection of manufacturing facilities for conformance to requirements for current Good Manufacturing Practices (cGMP). These two programs have served the consumer well by helping to ensure the quality of drug products available in the U.S. Now, as we approach the 25th anniversary of the last major revision to the drug cGMP regulations, it is time to step back and evaluate the currency of these programs and implement new ones, as appropriate, so that our resources are used most effectively and efficiently to address the most significant health risks.

To this end, the Office of Regulatory Affairs and the Center for Drug Evaluation and Research have agreed to develop a Pharmaceutical Inspectorate (PI) of highly trained investigators whose primary responsibility will be conducting drug quality inspections.

The PI will conduct inspections of pharmaceutical facilities as assigned by their District Managers. The goal of the program is to eventually have the PI inspect the majority of prescription drug manufacturers and other complex or high risk pharmaceutical operations. The PI will also conduct preapproval inspections and may conduct or assist in investigations that require their particular expertise. Attaining this goal will probably require a number of years in building the staff of the PI. [Bioresearch monitoring (BIMO) inspections and training for the BIMO inspections are not covered by this MOU.] The principles agreed upon for the Pharmaceutical Inspectorate are established below.

- Members of the PI will report directly to the District Managers and will receive assignments from District management in accordance with the work plan.

- Investigators who are interested in becoming a member of the PI will be required to obtain and maintain a Level III Drug Certification to serve as members of the PI. [NOTE: During the initial development of the PI, not all Level III Drug Certification courses may be developed. However, as these courses are developed, each member of the PI will be required to complete the course.]

- The size of the PI will be determined based on the inventory and geographic distribution of facilities that will be subject to inspection. The size of the PI will be adjusted in conjunction with changes in the workload. The following table outlines the estimated phase in period for the PI based on current workload and training capacity.

Anticipated Number of CSOs to be Added Every Year					
	FY 2004	**FY 2005**	**FY 2006**	**FY 2007**	**TOTAL**
Human Drugs	25	10	10	5	50

- Overall, the PI will spend a significant portion of their reportable time conducting drug quality inspections of domestic and foreign facilities. Collectively, we anticipate that the PI will spend 80% of their reportable time conducting drug quality inspections and related activities.

- In order to fulfill requirements and maintain their status as Level III Drug Investigators under the certification program, members of the PI will be authorized and encouraged to participate in professional activities that maintain, broaden, or enhance their knowledge in the area of certification.

- Members of the PI will continue to participate in additional activities which further their expertise in the area of drug quality inspection. This may include activities related to the development and implementation of formal training programs for Agency personnel, industry, and state/local officials, or the development and/or evaluation of the programs, policies, or procedures in their area of expertise, including serving as auditors for the Level II or III Drug Certification programs. The extent and balance of these additional activities will be determined by District Management.

Selection of the Pharmaceutical Inspectorate

- An individual interested in becoming a member of the PI will submit their name to their supervisor for consideration.
- The initial nomination of an individual for the PI will then come from the District with concurrence through the management structure currently in place.
- The Level III Drug Investigator Certification Board will review certification packages and select candidates for Level III Drug Certification and membership into the PI.
- The following criteria may be used to select members of the PI:
  - Candidates should have the necessary critical thinking and communication skills to apply their knowledge to complex problems and to communicate effectively with a variety of stakeholders,
  - Candidates should have at least 3 years experience in inspecting pharmaceutical manufacturing including regulation/inspection of drug facilities, and
  - Candidates should be certified as Level II Drug Investigators (as defined by the ORA certification program). Once all Level III courses have been developed and the Level III

Drug Certification program has been fully implemented, candidates must be certified as Level III Investigators.

Continuing Education of the PI

The Office of Regulatory Affairs and the Center for Drug Evaluation are committed to providing adequate resources and support to allow members of the PI to continue to enhance their knowledge in pharmaceutical manufacturing.

- Each member of the PI must successfully complete continuing education requirements as defined in the Level III Drug Certification document to maintain their Level III Drug Certification. Continuing education may include attendance at technical conferences, or successful completion of training courses, or details to the Center.

Level III Drug Investigator Certification Board

The Level III Drug Investigator Certification Board will be composed as follows:

- 2 Field Investigators operating at Level III in the area of certification being reviewed,
- 2 Experts from the Center for Drug Evaluation and Research,
- 2 Experts from the Center for Veterinary Medicine,
- 1 Division of Field Investigations expert (with appropriate technical expertise and investigational experience),
- 1 ORA Manager from the appropriate Field Committee, and
- 1 Representative from the Division of Human Resource Development (DHRD), ORA.

The Level III Drug Investigator Certification Board will be responsible for:

- Reviewing packages and selecting individuals to participate in the Level III Drug Certification program and PI,
- Identifying auditors for the Level III Drug Certification program,
- Developing, updating, and maintaining the curriculum for the Level III Drug Certification program and the Pharmaceutical Inspectorate, and
- Reviewing packages for the recertification process.

Role of the Center

The Center for Drug Evaluation and Research will:

- Provide funding (amounts to be negotiated annually with the Office of Regulatory Affairs) for the development and implementation of training programs identified in the Level III Drug Certification program for the PI,
- Provide funding for continuing education for the members of the PI to maintain their certification, and
- Provide experts to serve as trainers and auditors for the Level III Drug Certification program.

Role of ORA

- Provide funding to develop the training for the Level II Drug Certification,
- Form the Level II and III Drug Investigator Certification Boards based on membership inclusive of the Center, and
- Provide experts to serve as trainers and auditors for the Level III Drug Certification program.

This MOU will be re-evaluated in one year after implementation and at regular intervals thereafter.

8/22/03

Director Date
Center for Drug Evaluation and Research

8/22/03

Associate Commissioner Date
of Regulatory Affairs