Once the RSB completes the filing review of the ANDA and verifies that the application contains all the necessary regulatory requirements, an "acknowledgment" letter is issued to the applicant indicating its acceptance for filing and the official filing date. The application is then assigned to the technical reviewers. If the ANDA does not meet the criteria for filing, a "refuse-to-receive" letter is issued to the applicant with a list of deficiencies.

Upon filing an ANDA, the RPM forwards an Establishment Evaluation Request to the Office of Compliance. The Office of Compliance then determines if the drug product manufacturer, the drug substance manufacturer, and the outside testing facilities are operating in compliance with current Good Manufacturing Practice (cGMP) regulations as outlined in 21 CFR Parts 210 and 211. Each facility listed on the request is evaluated individually and the Office of Compliance makes an overall evaluation of all facilities listed in the application. Furthermore, a preapproval inspection may be performed to assure the data integrity of the application.

Currently, ANDAs can be submitted entirely electronically via the Electronic Submissions Gateway. Applicants can also submit electronic submissions of bioequivalence data along with the traditional paper application. The electronic document room staff processes the electronic files, so that the reviewers can access them. The data contained in the electronic submission are copied onto the CDER's computer network. Additional processing may occur to populate the electronic tools used by the reviewers.

All applicants who plan to submit ANDAs electronically should consult CDER's website for electronic submissions at www.fda.gov/ForIndustry/ElectronicSubmissions Gateway//default.htm.

COORDINATION OF THE GENERIC DRUG REVIEW PROCESS

Once the ANDA is accepted for filing, the application enters the review queue. This means that the application is assigned to a bioequivalence division and team, a chemistry team, and a labeling reviewer.

Each chemistry team consists of a team leader, a project manager, and several reviewers. In this section, the emphasis will be placed on the chemistry project manager's role in the generic drug review process.

The chemistry project manager serves as the "application" project manager (APM). Although APMs are located within the chemistry review teams, they are actually a part of the Review Support Branch within the DLPS. Specifically, they plan, organize, and coordinate all of the review activities for the applications that they manage. This requires the coordination of all discipline reviews, which include chemistry, bioequivalence, labeling, and sterility assurance (microbiology) for sterile products. Furthermore, the APMs monitor the compliance evaluation (field inspections) of all the facilities associated with the ANDA to assure they are in compliance with cGMP requirements. The APMs serve as coleaders for the chemistry review teams. They assure timely resolution of scientific and regulatory conflicts to prevent delays in the review process. The APMs also make every effort to meet the review goals set by the OGD management.