The APMs manage and coordinate the work of the review teams to assure that reviews are performed in a timely manner. In addition, the APMs identify and resolve potential problems such as the inequality of individual workload and regulatory issues. The OGD makes a concerted effort to comply with the statutory 180-day review cycle mandated by the Federal FD&C Act. The APMs play a key role in coordinating the various disciplines to review the applications within 180 days from the submission date. In attempt to achieve the OGD's management goals, the APMs may recommend redistribution of work according to the policies and procedures within the OGD.

The APMs enter key information about their applications into various databases, including the Document Archiving, Reporting & Regulatory Tracking System and the Establishment Evaluation System. These databases allow the OGD staff to access the status and outcome of discipline reviews and the status of the field and compliance inspection reports. The APMs use the information to provide applicants and OGD management the status of applications.

Because communication plays a large role in the generic drug review process, the APMs are designated as the primary contacts for all issues relating to the review of the application. As such, they communicate the status of all aspects of the applications that they manage. The APMs attempt to address all applicant inquiries within 2 working days of receiving a request. If the questions from the applicant are of a technical nature and require further evaluation by a reviewer and/or team leader, the APMs make the appropriate arrangements for either a telephone conference or a meeting. The APMs generally request applicants to submit a proposed agenda before the telephone conference or meeting. The APMs and the review teams work with the applicants to resolve scientific issues that may delay the approval of applications.

BIOEQUIVALENCE REVIEW PROCESS

After an ANDA is accepted for filing by the RSB, the bioequivalence section is assigned to one of the DBs to review based on the therapeutic category of the drug product. The bioequivalence project managers (BPM) access a list of pending ANDAs and assign them to individual reviewers according to the "first-in, first-reviewed" policy. Typically, the dissolution testing portion of the submission is assigned and reviewed before that of the bioequivalence study. The BPMs also randomly assign other review documents such as bioinvestigational new drug applications (bio-INDs), protocols, and correspondence.

The DB's responsibilities include the review of the bioequivalence section of ANDAs, supplemental ANDAs, bio-INDs, protocols, and controlled correspondence. Structurally, the DB is organized into 10 review teams; each team consists of approximately five reviewers, who are supervised by a team leader. The team leaders complete a secondary review of all bioequivalence submissions assigned to their team. In addition, they ensure the consistency of the recommendations provided to the applicants. A BPM is assigned to each team and is responsible for processing all