For United States Pharmacopeia (USP) products, the labeling reviewer uses the USP to evaluate the established name, molecular structure, molecular weight, structural formula, chemical name, and the storage conditions of the proposed drug product.

As the container label or carton label is reviewed, the labeling reviewer decides if the labeling is easy to read and positioned in accordance with the regulations. In addition, the labeling reviewer encourages applicants to revise their labeling to decrease the likelihood of confusion with other drug products.

After completing the review of the proposed labeling, the labeling reviewer drafts a review that either identifies labeling deficiencies or recommends approval. A tentative approval may be issued for an application with outstanding patent and exclusivity issues. The team leader completes a secondary review of the application. If he or she is in agreement with the review, the review is sent back to the labeling reviewer to finalize. The labeling reviewer then forwards the review back to the team leader for concurrence.

If the proposed labeling is deficient, the APM or the labeling reviewer communicates the deficiencies to the applicant. If the proposed labeling is acceptable, an approval or tentative approval summary is forwarded to the APM.

PUTTING IT ALL TOGETHER

After the final office-level administrative review, where all individual disciplines have resolved their deficiencies and all of the facilities associated with the ANDA have received an acceptable compliance evaluation, the application will either receive a full approval or a tentative approval letter (see ANDA Approval Chart).

The APMs are instrumental in assembling an approval package. This package includes all reviews supporting final or tentative approval. When the review of an ANDA is completed, the APMs draft the appropriate approval letter and circulate it with the reviews and application for concurrence. The APMs communicate with the OGD management on a weekly basis to update them on the progress of reviews.

A full approval letter details the conditions of approval and allows the applicant to market the generic drug product. A tentative approval letter is issued if there are unexpired patents or exclusivities accorded to the RLD. The tentative approval letter details the circumstances associated with the tentative approval and delays the marketing of the product until all patents and/or exclusivities expire. Once the Office Director or his designee has signed the final approval letter, the APM calls and faxes a copy of the approval letter to the applicant. The document room staff then mails the final approval letter to the applicant.

As one can see, the generic drug review process incorporates a series of checks and balances to ensure the integrity of the reviews. The OGD is comprised of bioequivalence reviewers, chemists, labeling reviewers, microbiologists, medical officers, and project managers. These individuals work together as a team to accomplish the OGD's mission of providing safe and effective generic drugs to the American People.