

process. Once the team resolves the issues internally, the review is finalized and signed by the team leader, the primary reviewer, and the APM. The finalized review, including a list of deficiencies, is forwarded to the Deputy Director for concurrence. The Deputy Director or, in some cases, the Division Director completes the tertiary review. After all issues are resolved within the Chemistry Divisions, it is the responsibility of the APM to communicate the status of the application to the applicant. After the chemistry deficiencies are classified as either “minor” or “major,” the deficiencies are communicated (usually by fax) to the applicant. When the chemistry portion of the application is ready for approval, the approval package is assembled by the APM and routed for the final administrative reviews through the office. The Chemistry Divisions coordinate with all of the review disciplines for each application to make sure each portion of the application is acceptable before approval.

## **LABELING REVIEW PROCESS**

After an ANDA has been accepted for filing by the RSB, the Labeling section of the application is assigned to the appropriate labeling reviewer based on the therapeutic category of the drug product. The Labeling Review Branch is part of the DLPS. A team leader oversees the work of four to six reviewers.

The basis for the labeling review is to ensure that the generic drug labeling is the “same as” the RLD labeling. There are several exceptions to the “same as” regulation. Exceptions are allowed for the following: differences due to changes in the manufacturer or distributor, unexpired patents, or exclusivities and other characteristics inherent to the generic drug product, such as tablet size, shape, or color.

The labeling reviewer also identifies and resolves concerns that may contribute to medication errors. For example, the labeling reviewer may identify drug names that are similar or that sound alike. In addition, the labeling reviewer may address concerns associated with the prominence and/or legibility of drug names on a container label. To ensure that the proposed labeling in an ANDA is the “same as” the RLD, the labeling reviewer must first identify the RLD. The next step is to find the most recently approved labeling for the RLD. If the RLD labeling is not the most recently approved, it is considered discontinued labeling. Hence, it is not acceptable for the labeling review. It is very important to monitor FDA’s database and website on a regular basis to determine the most recent labeling approvals.

One allowed difference between the generic and the RLD labeling is the omission of information protected by patents and exclusivity. The labeling reviewer ensures that the applicant properly addresses all patents and exclusivities by verifying the information in the “Orange Book.” The applicant’s patent certification and exclusivity statement determines the way the proposed labeling will be drafted.

The applicant may submit 4 copies of draft labeling or 12 copies of final printed labeling as proposed labeling. Draft copies may also be submitted for tentative approval. The labeling branch supports the submission of electronic labeling. This practice is preferred and strongly encouraged.