Information for Consumers on the New Requirements for Prescribing Information

Prescribing information is approved by FDA and contains the necessary information for the safe and effective use of a prescription drug. Prescribing information is used by healthcare professionals, such as physicians, pharmacists, and nurses, as a reference for questions such as:

- What diseases or conditions does the drug treat?
- What dose is needed?
- Which patients should not receive the drug?
- What other drugs should not be taken together with the drug?
- What side effects can occur?
- How should the drug be stored?

FDA has revised the requirements on what must be included in prescribing information and how it must be organized to make it easier for healthcare professionals to access, read, and use the information. These changes are intended to help inform healthcare professionals about the drugs they prescribe for their patients. In addition, the new prescribing information emphasizes the importance of counseling patients about their prescription drugs. For example, one new feature is that the information that healthcare professionals use when counseling patients is presented in a new section called "Patient Counseling Information." This should facilitate communication between healthcare professionals and patients about their prescription drugs.

New prescribing information will be phased in gradually. The requirements will apply to new or recently approved prescription drugs (not to "over-the-counter drugs").