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terminology

Definitions of key technical terms as we have used them in this report are presented below. A comprehensive glossary of these and other technical terms is also provided on page 75.

- Drug product A dosage form containing one or more active therapeutic ingredients along with other substances included during the manufacturing process.

- Present compendia standards The official standards for drug excipients and drug products listed in the latest revision of the United States Pharmacopoeia (USP) and the National Formulary (NF).

- New compendial standards Standards to be established for active ingredients,excipients and drug products, including tests relecting the best available technology to be performed before, during and after formulation.

- Chemical equivalents Drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage forms and that meet present compendia standards.

- Pharmaceutical equivalents Drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage form and that meet standards to be established on the basis of the best available technology.

- Bioavailability The extent and rate of absorption from a dosage form as reflected by the time-concentration curve of the administered drug in the systemic circulation.

- Bioequivalents Chemical equivalents which, when administered to the same individuals in the same dosage regimen, will result in comparable bioavailability.

- Therapeutic equivalents Chemical equivalents which, when administered to the same individuals in the same dosage regimen, will provide essentially the same efficacy and/or toxicity.

- Interchangeable drug products Pharmaceutical equivalents or bioequivalents that are accepted as therapeutic equivalents.