glossary*

- Abbreviated New Drug Application (ANDA) Shortened application for obtaining approval from the Food and Drug Administration to market a drug. The ANDA may require information on characteristics of the drug such as method of use, method of manufacture, adverse reactions, physical and chemical stability, packaging, extent of use.

- Active ingredient That portion of a drug product intended to produce a therapeutic effect.

- 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.

- 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.

- Crossover study An experimental plan for comparing two treatments which reduces the influence of the variation in individual responses.

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* The meanings of some of the terms used in this report are subject to various interpretations. The definitions given here are those used by the Panel.

Each individual is tested on both treatments at different times. Initially half of the individuals receive each drug product; each is then "crossed over" to the other drug product at a later time.

- Deaggreagation The breaking up of granules or aggregates into fine particles in aqueous fluid.

- Disintegration The breaking up of a tablet or capsule into granules or aggregates in aqueous fluid.

- Dissolution The breaking down of fine particles into molecules or ions homogeneously dispersed in aqueous fluid.

- Dosage form The form of the completed drug product (such as tablet, syrup, or suppository).

- Drug Any chemical administered to produce a pharmacologic effect.

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

- Efficacy The ability to produce the purported therapeutic effect.

- Endogenous compounds Products of the chemical processes that occur in the organism.

- Excipient An inert substance used to give a preparation a suitable form or consistency.

- Formulation A complex mixture containing a selected chemical derivative of the drug compound, in proper physical form, together with excipients, diluents, stabilizers, preservatives, or a variety of other components.

- In vitro tests Tests carried out in laboratory apparatus.

- In vivo tests Tests carried out within living organisms by administering drug products to man *or* experimental animals.

- Investigational New Drug Application (IND) Application to begin clinical studies of the safety and efficacy of a new drug.

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

- Kinetic model An analysis of some process as a function of time,

- Margin of safety of drug The difference between a minimally effective and a toxic dose of a drug. The therapeutic index (q.v.) is frequently used as an indicator of the margin of safety.

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

- New Drug Application (NDA) Application for approval from the Food and Drug Administration to market a drug based on extensive documentation of safety and efficacy.

- 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.

- Pharmacokinetics The discipline that treats the rates of absorption, distribution, metabolism and excretion of drugs.

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

- Radioactive labeling The introduction of a radioactive atom into a molecule to allow detection of the molecule by measurement of its radioactivity.

- Therapeutic index The ratio of the toxic dose to the minimally effective dose of a drug.

- 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.

- Tolerance The state in which the quantity of drug required to produce a specific biological effect in a particular individual has increased.

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