**St Peter’s Institute of Pharmaceutical Sciences**

**Course : Bachelor of Pharmacy**

**Subject : Pharmaceutical Regulatory Science**

**Subject Code:** **BP804ET**

 **ORANGE BOOK**

Approved Drug Products With Therapeutic Equivalence Evaluations (known as the Orange Book), identifies drug products approved on the basis of the safety and effectiveness of the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FD & C) The law).

The main condition for the inclusion of any product is that the product is the subject of an application that has not been issued for security or efficiency reasons.

The inclusion of products in the Orange Book is independent of any current regulatory measures taken by administering or judicially against the drug product. In addition, the Orange Book contains therapeutic equivalence evaluations of prescription drug products. These evaluations are designed to be used as public information and advice to state health agencies, prescribers, and pharmacists to promote public education in the area of ​​drug product selection and to promote health care costs. Therapeutic equity tests in this publication are not official FDA actions that affect the legal status of products under FD&C law.

**Content and Exclusion**

The Orange Book is made up of four sections: (1) approved prescription drug products with therapeutic equivalence evaluations; (2) approved over-the-counter (OTC) drug products for those drugs that may not be marketed without the NDA or ANDA because they are not covered under existing OTC monographs; (3) drug products approved under Section 505 of the FD&C Act administered by the Center for Biologics Evaluation and Research; and (4) a compilation of approved products that have not been marketed, exported, used for military use, discontinued for marketing and we have not determined that they should be discontinued for safety or efficacy reasons, or their authorization may be revoked for non-safety or effective reasons.

 These publications include prescriptions of prescription drugs and OTC drug products in the name of the proprietary (brand name or trade name) or, if no proprietary name available, the invention of the active ingredient and the name of the applicant, abbreviated in this document.

The appendix contains proprietary and specialized information for Prescription, OTC, discontinued drug Lists, and Drug Products approved under Section 505 of the FD&C Act administered by the Center for Biologics Evaluation and Research. Publications may include additional information which the Agency deems appropriate for distribution.

**Therapeutic Equivalence Evaluations Codes**

Typically, drug products that the Agency considers multisource are given a therapeutic equivalence code. The code is designed to allow users to quickly decide whether the Agency have evaluated a certain approved product (e.g. certain pharmacological powers) as an equivalent therapeutcally with other equivalent pharmaceutical products (first book) and provide additional information on the basis of FDA evaluations (second volume).

The two basic categories of multidisciplinary treatment are indicated by the first letter of the appropriate treatment code as follows:

**A.** Drug products which FDA considers to be **therapeutically equivalent** to other pharmaceutical equivalent products, i.e.,for:

(1) No known or suspected bioequivalence problems. These are designated as AA, AN, AO, AP, or AT, depending on the dosage form; or

(2) The actual or potential problems of bioequivalence have been adequately resolved with in vivo and / or in vitro evidence supporting bioequivalence. These are designated as AB.

**B**. Drug products which FDA considers **not to be therapeutically equivalent** to other pharmaceutical equivalent products, i.e.,for:

(1) drug products with actual or potential problems of bioequivalence that have not been resolved with sufficient evidence of equality. Often the problem lies in the dosage forms and not on the active ingredients. These are selected as BC, BD, BE, BN, BP, BR, BS, BT, BX, or B \*.

Each drug product has been evaluated as a therapeutic equivalent to the reference product according to the definitions and policies outlined below:

 **"A" CODES**

Drug products are considered therapeutically equivalent with other pharmaceutical equivalent products.

 (1) For those active ingredients or dosage forms that are not available in any known or suspected use of in vivo bioequivalence, the information required to indicate the balance between drug-equivalent products is taken and is considered reasonable (based on other information on the use of other dosage forms (e.g. solutions), or satisfied to indicate that an acceptable in vitro method is being met. The equivalent treatment is provided for such products as long as they are complied with in accordance with Current Good Manufacturing Practice rules and meet the other requirements for their approved applications (these are AA, AN, AO, AP, or AT, depending on the volume, as described below).; or

(2) those drug products in the Drug Efficacy Study Implementation (DESI) containing active ingredients or dosage forms identified by the FDA as actual or potential problems with bioequivalence, and post-1962 drug products that indicate a potential bioequivalence problem, evaluation of therapeutic equivalence is given to pharmaceutically equivalent drugs only if the approved application contains adequate Scientific evidence establishing in vivo and / or in vitro bioequivalence studies to selected reference product (these products are referred to as AB).

**"B" CODES**

Drug products which FDA considers not to be therapeutically equivalent to other pharmaceutical equivalent products

Drug products selected by code "B" are subject to one of three policies:

(1) Drug products containing active ingredients or are made in dosage forms identified by the Agency such as documented bioequivalence problems or significant effects on those problems and inadequate studies showing bioequivalence submitted to the FDA; or

(2) insufficient quality standards or the FDA does not have a sufficient basis for determining therapeutic equivalence; or

(3) Drug products which are subjected to regulatory reviews.

**References**

1. Laurie. Hill Ph.D.(2005) The Orange book. “Nature Reviews Drug discovery.” Vol 4, pp. 621.
2. Hare, Don; Foster, Thomas (July 1990). "The Orange Book: The Food and Drug Administration's Advice on Therapeutic Equivalence". *American Pharmacy*. 30 (7), pp. 35–37.