

*Approved Drug Products With Therapeutic Equivalence  
Evaluations 2002*

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The Drug Price and Competition Act (Hatch-Waxman Act) requires FDA to publish Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The Orange Book identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act.

[FDA's orange book and ab ratings of pharmaceutical drug ...](#)

highly similar to the already FDA-approved biological "reference product" have been shown to have no clinically meaningful differences from the reference product. Therapeutic Equivalence. Drug products are considered to be "therapeutic equivalents" only if: they are pharmaceutical equivalents and

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The publication Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by ...

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

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The main criterion for the inclusion of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons. Contains therapeutic equivalence evaluations for approved multisource prescription drug products.

[Orange Book: Approved Drug Products with Therapeutic ...](#)

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contains the list of all drugs approved in the United States as safe and effective. It is also the authoritative source of information on the therapeutic equivalence of drug products. The orange book consist of five main sections: an introduction, a "how to use" section, the drug product lists, appendices and a patent and exclusivity ...

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Approved drug products list Title from homepage: Approved drug products with therapeutic equivalence evaluations (orange book) Frequency Annual Vol/date range Print began with 6th ed. (1985). Note Distributed to some depository libraries in print, <1987->; distributed to some depository libraries in microfiche, 1985-2001.

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Please send general questions related to the drug data in these files to the Center for Drug Evaluation and Research, Division of Drug Information: [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov). Current through April 2019. For more information on the Orange Book update frequency, see the Orange Book FAQs.

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