APPROVED DRUG PRODUCTS
With Therapeutic Equivalence Evaluations

The "Orange Book"

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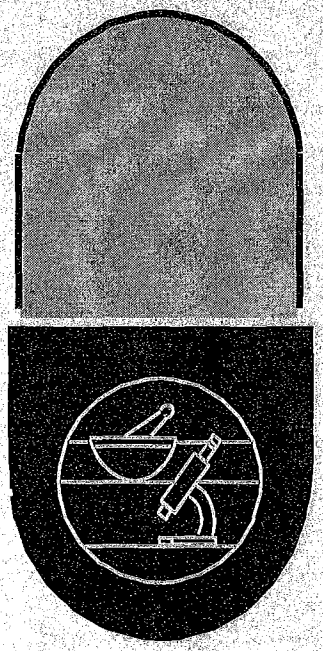
CUMULATIVE SUPPLEMENT 12
DECEMBER 2002



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

22nd EDITION

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs

2002

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

22ND EDITION

Cumulative Supplement 12

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1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 22nd Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to place an asterisk (*) to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement.

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision. [Strength(s) which already exist in the List will not be repeated for context.]

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 22nd Edition List will then be added to the "Discontinued Drug Product List" appearing in the 23rd Edition. The current edition Section 2. How To Use The Drug Product Lists describes the layout and usage of the List.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >**A**>. The Patent and Exclusivity Data are indicated by the symbol **>ADD>** to the left of the line on which new information exists. The **>ADD>** symbol is then dropped in subsequent Cumulative Supplements for that item.

New deletions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol **>D>** (DELETE) to the left of the line. The information line with the **>D>** symbol is dropped in subsequent Cumulative Supplements for that item.

1.2 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
DANBURY PHARMACEUTICALS INC (DANBURY PHARMA)	WATSON LABORATORIES INC (WATSON LABS)
DURAMED PHARMACEUTICALS INC (DURAMED)	DURAMED PHARMACEUTICALS INC SUB OF BARR LABORATORIES INC (DURAMED PHARM BARR)
DERMIK LABORATORIES INC (DERMIK LABS)	DERMIK LABORATORIES DIVISION OF AVENTIS PHARMACEUTICALS INC (DERMIK LABS)
DERMIK LABORATORIES INC SUB RORER (DERMIK LABS)	DERMIK LABORATORIES DIVISION OF AVENTIS PHARMACEUTICALS INC (DERMIK LABS)
JANSSEN RESEARCH FDN (JANSSEN)	JANSSEN PHARMACEUTICA PRODUCTS LP (JANSSEN PHARMA)
JANSSEN RESEARCH FDN DIV JOHNSON AND JOHNSON (JANSSEN)	JANSSEN PHARMACEUTICA PRODUCTS LP (JANSSEN PHARMA)
JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC (JOHNSON AND JOHNSON)	ORTHO MCNEIL PHARMACEUTICAL INC (ORTHO MCNEIL PHARM)
MCNEIL CONSUMER HEALTHCARE DIVISION (MCNEIL CONS)	MCNEIL CONSUMER AND SPECIALTY PHARMACEUTICALS DIVISION MCNEIL PPC (MCNEIL CONS SPECLT)
MOVA PHARMACEUTICALS CORPORATION (MOVA)	CLONMEL HEALTHCARE LTD (CLONMEL HLTH)
NMC LABORATORIES INC	ALPHARMA US PHARMACEUTICAL DIV (ALPHARMA US PAHRM)
PARKE DAVIS PHARMACEUTICALS LTD (PARKE DAVIS PHARMS)	PFIZER PHARMACEUTICALS LTD (PFIZER PHARM LTD)
RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE (JOHNSON RW)	ORTHO MCNEIL PHARMACEUTICAL INC (ORTHO MCNEIL PHARM)
RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIV ORTHO PHARMACEUTICAL CORP (JOHNSON RW)	ORTHO MCNEIL PHARMACEUTICAL INC (ORTHO MCNEIL PHARM)
THAMES PHARMACAL COMPANY INC (THAMES)	TARO PHARMACEUTICALS NORTH AMERICA INC (TARO PHARMS US)
WHITEHALL LABORATORIES INC DIV AMERICAN HOME PRODUCTS CORP (WHITEHALL LABS)	WYETH CONSUMER HEALTHCARE (WYETH CONS)
WHITEHALL ROBINS HEALTHCARE (WHITEHALL LABS)	WYETH CONSUMER HEALTHCARE (WYETH CONS)

1.3 WAIVED EXCLUSIVITY

Waived exclusivity - If a new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (Act) qualifies for exclusivity under sections 505(c)(3)(D) and 505(j)(5)(D), the exclusivity is listed in the Patent and Exclusivity Section of the Orange Book. If a drug product has received this exclusivity, the FDA will delay the approval of a 505(b)(2) application or an abbreviated new drug application (ANDA) under section 505(j) of the Act until the expiration of the exclusivity. If the listed drug is also protected by one or more patents, the approval date for the 505(b)(2) application or ANDA will be determined by the latest expiring patent or exclusivity listed in the Orange Book.

However, the holder of the NDA may waiver its exclusivity as to any or all 505(b)(2) and ANDA applications referencing the protected drug product. If an NDA sponsor waivers its right to the exclusivity protection, qualified 505(b)(2) or ANDA applications may be approved without regard to the NDA holder's exclusivity. An NDA for which the holder has waived its exclusivity as to all 505(b)(2) and ANDA applications will be coded with a W in the Patent and Exclusivity Section of the Orange Book and be referred to this section. The applicant referencing this listed drug should indicate in the exclusivity statement that the holder of the listed drug has waived its exclusivity

1.4 TRAMADOL HYDROCHLORIDE TABLETS. Tramadol Hydrochloride 50 mg tablet products approved under section 505(j) are marked with a (*) because there are special considerations governing the substitution of these products. The tramadol hydrochloride 50 mg tablets marked with a (*) are therapeutically equivalent (AB) to RW Johnson's Ultram (Tramadol Hydrochloride) 50 mg tablets. However, because of RW Johnson's exclusivity and patent protection for the 25 mg titration dosing regimen, tramadol hydrochloride drug products approved under section 505(j) may not carry the labeling for the 25 mg titration dosing regimen. Ultram 50 mg tablets are scored for use in the 25 mg titration schedule; tramadol hydrochloride 50 mg tablets approved under 505(j) are not scored. Prescribers and dispensers should be aware of this scoring difference between Ultram and other tramadol hydrochloride tablets and take it into account when writing a prescription or practicing drug product selection.

1.5 AVAILABILITY OF THE EDITION

The 22nd Edition of the Orange Book and its monthly cumulative supplements are available by subscription from the Government Printing Office:

Superintendent of Documents
Government Printing Office
P.O. Box 371954
Pittsburgh, PA 15250-7954

The telephone number to charge your subscription is 202-512-1800. The cost is $105.00 annually.

The Approved Drug Products with Therapeutic Equivalence Evaluation (Orange Book) and related drug information is also available on the Internet at the Food and Drug Administration, Center for Drug Evaluation and Research, Drug Info page.

There is an Electronic Orange Book Query (EOB) at http://www.fda.gov/cder/ob. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder or applicant number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product. The data is updated concurrently with the publication of the annual edition or monthly cumulative supplements.

The Internet version of the hard copy Orange Book annual edition is at http://www.fda.gov/cder/orange/adp.htm.

The Internet version of the hard copy monthly supplement is at http://www.fda.gov/cder/orange/supplement/cspreface.htm. Changes to the annual edition are listed separately by month.

There are ASCII text files of the Orange Book drug product data at http://www.fda.gov/cder/orange/obreadme.htm. The drug product text files are zipped into zipobtxt.exe. The files are updated concurrently with the publication of the annual edition or monthly cumulative supplements. Appendix A and Appendix B are updated quarterly.

The 22nd annual edition of the 2001 Orange Book Patent and Exclusivity List is at http://www.fda.gov/cder/orange/22bookpub.pdf.

The current year Patent and Exclusivity cumulative supplement list that denotes the current month additions is at http://www.fda.gov/cder/orange/supplement/patents.pdf.

The Patent Term Extension and new Patents, Docket Number *95S-0117, is at http://www.fda.gov/cder/orange/docket.pdf. It is updated monthly as soon as available and as otherwise needed.
The Drug Price Competition and Patent Term Restoration Act requires that patent information be filed with all newly submitted Section 505 drug applications. To facilitate industry submission of the information, a patent submission sample format is available in HTML and PDF format at:
http://www.fda.gov/cder/orange/patdecl.pdf
http://www.fda.gov/cder/orange/patdecl.html

The current listing of the Orphan Product Designations and Approvals is available at http://www.fda.gov/orphan/designat/list.htm.

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under section 505 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 2001) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product