APPROVED DRUG PRODUCTS
With Therapeutic Equivalence Evaluations

The "Orange Book"

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FOOD AND DRUG ADMINISTRATION
APPROVED PRESCRIPTION DRUG PRODUCTS
WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS
CUMULATIVE SUPPLEMENT

I. PREFACE

This cumulative supplement is one of a series of monthly updates to the Approved Prescription Drug Products with Therapeutic Equivalence Evaluations, 2nd Edition, (the List) to cover interim revisions to the annual publication of the List in its entirety. The List is comprised of several parts and some by their nature are identified by the term "list". The cumulative supplements routinely provide updates to two of these lists: The Drug Product List and the Addendum: DESI Pending List.

The List cannot be used effectively without the current cumulative supplement. Users may wish to place an asterisk (*) in the List to the left of the ingredient(s) in the Drug Product List and the product name in the Addendum to indicate that changes to that entry appear in the cumulative supplement. It is also suggested that earlier cumulative supplements be discarded to avoid possible confusion. In this way, only the List and current cumulative supplement need be referenced.

A. DRUG PRODUCT LIST

The Drug Product List cumulative supplements include the changes made since August 1, 1981. Each subsequent cumulative supplement replaces the previous month's cumulative supplement.

Information in this cumulative supplement follows the format of the Drug Product List. 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.)

Context information on drug products is provided in each cumulative supplement for completeness to assist in locating the proper place in the Drug Product List for the revision. A page number in parentheses referring to the Drug Product List is located to the right of the ingredient(s).

Additions to the Drug Product List are indicated by new information in the cumulative supplement. Additions new to the current cumulative supplement are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is dropped in subsequent cumulative supplements for that item.

Deletions from the Drug Product List are indicated by overstruck print in the cumulative supplement. Deletions new to the current cumulative supplement are indicated by the symbol >DLT> (DELETE) to the left of the line containing the overstruck print. The >DLT> symbol is dropped in subsequent cumulative supplements for that item.

A newly approved product is identified by the lozenge (¤) to the right of its strength. This identifier remains throughout all cumulative supplements for this edition.

B. Addendum: DESI PENDING LIST

Information in this cumulative supplement follows the format of the Addendum. Additions and deletions are indicated in the same manner as in the cumulative supplement to the Drug Product List. A change in Current Status of a DESI product is also indicated by an addition and a deletion.

II. SPECIAL NOTES

A. The INTRODUCTION to the 2nd Edition (1981 publication) of the Approved Prescription Drug Products with Therapeutic Equivalence Evaluations (Section II.F.5.) stated that "Protein hydrolysate injections are omitted because of safety problems." The safety problems have been resolved. Publication on this subject appeared in the FEDERAL REGISTER of July 14, 1981 (46 FR 36249). Therefore, a parenteral protein hydrolysate (see Amigen) now is approved and marketed as well as the existing related parenteral amino acid mixture solutions.

B. FUROSEMIDE The change in the therapeutic equivalence code for Cord Laboratories' Furosemide tablets from BX to AB reflects receipt of additional data from the firm; examination of other information on file with the Agency; and a determination that the initial bioequivalence study performed by the firm was satisfactory for demonstrating product bioequivalence so that a subsequent additional study was not necessary.

C. APPENDICES: ROUTES OF ADMINISTRATION

Added term: PERFUSION, CARDIAC

D. APPLICANT (NAME) CHANGES Because 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, the cumulation of these transfers and name changes will be identified in this Special Notes section only. Where only partial approved product lines are transferred between applicants, each approved product involved will appear as an applicant name change in the cumulative supplement.

APPLICANT (NAME) CHANGES

Former Applicant (Name)	New Applicant (Name)	New Abbreviated Name
CIS RADIOPHARMACEUTICALS INC	SYNCOR INTL CORPORATION	SYNCOR INTL
D-M PHARMACEUTICALS INC	LEMMON COMPANY	LEMMON
DOME LABORATORIES DIV MILES LABORATORIES INC	MILES PHARMACEUTICALS DIV MILES LABORATORIES INC	MILES PHARMS/MILES
LEMMON PHARMACAL COMPANY	LEMMON COMPANY	LEMMON
PHILIPS ROXANE LABORATORIES INC	ROXANE LABORATORIES INC	ROXANE LABORATORIES
UNION CARBIDE CORPORATION	CINTICHEM INC	CINTICHEM

The reader should consult this special list each month to become aware of such transfers and changes. By referring to the Applicant Index in the 2nd Edition, the transferred products can be identified. The reader might wish to flag these products in the List as a reminder that the applicant has been changed.