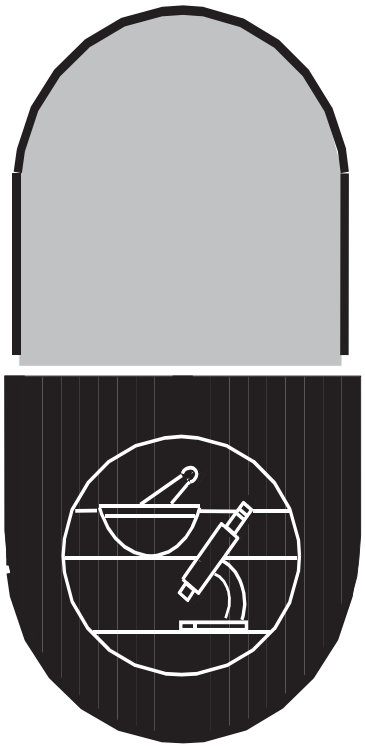

APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC EQUIVALENCE EVALUATIONS

37th EDITION

THE PRODUCTS IN THIS LIST HAVE BEEN APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS
OFFICE OF GENERIC DRUG POLICY

2017

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This volume is current through December 31, 2016.

37th EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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APPROVED DRUG PRODUCTS
With
Therapeutic Equivalence Evaluations

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PATENT AND EXCLUSIVITY INFORMATION ADDENDUM

This *Addendum* identifies drugs that qualify under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) for periods of exclusivity and provides patent information concerning the listed drug products. During exclusivity periods, certain abbreviated new drug applications (ANDAs) and applications described in Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (505(b)(2) applications) for those drug products in some instances may not be submitted or approved as described below. Those drugs that have qualified for Orphan Drug Exclusivity pursuant to Section 527 of the FD&C Act, those drugs that have qualified for Pediatric Exclusivity pursuant to Section 505A of the FD&C Act, and those drugs that have qualified for Generating Antibiotics Incentives Now (GAIN) exclusivity pursuant to Section 505E of the FD&C Act are also included in this *Addendum*. This section is arranged in alphabetical order by active ingredient name followed by the trade name. Active ingredient headings for multiple ingredient fixed-combination drug products are arranged alphabetically. For an explanation of the codes used in the *Addendum*, see the *Patent and Exclusivity Terms* Section. The exclusivity codes are general shorthand descriptions and do not necessarily identify, with specificity, the actual scope of exclusivity. These exclusivities do not prevent the submission or approval of an application submitted pursuant to Section 505(b)(1) of the FD&C Act that would otherwise be blocked if it had been submitted pursuant to Section 505(b)(2) or 505(j), except in the case of Orphan Drug Exclusivity. Drugs that may qualify for periods of exclusivity include:

(1) A new chemical entity, submitted in a new drug application under section 505(b) of the FD&C Act and approved after September 24, 1984. A new chemical entity is an active ingredient that contains "no active ingredient (including any ester or salt of the active ingredient)" that has been approved by FDA in any other application submitted under section 505(b) of the FD&C Act. No subsequent ANDA or 505(b)(2) application for a drug that contains the same "active ingredient (including any ester or salt of the active ingredient)" may be *submitted* for a period of *five years* from the date of approval of the original application, except that such an application may be *submitted* after *four years* if it contains a certification that a patent claiming the drug is invalid or will not be infringed by the product for which approval is sought. See sections 505(j)(5)(F)(ii) and 505(c)(3)(E)(ii) of the FD&C Act.

(2) A new drug application approved after September 24, 1984, for a drug product containing "an active ingredient (including any ester or salt of the active ingredient)" that has been approved in an earlier new drug application and that includes reports of new clinical investigations (other than bioavailability studies). Such investigations must have been conducted or sponsored by the applicant and must have been essential to approval of the application. If these requirements are met, a subsequent ANDA or a 505(b)(2) application may not be approved for the exclusivity-protected "conditions of approval of such drug" before the expiration of *three years* from the date of approval of the original application. If a NDA or 505(b)(2) applicant has exclusivity only for a new indication or use, this exclusivity generally does not preclude the approval of an ANDA or 505(b)(2) application for indications and uses not covered by the exclusivity, assuming the

proposed drug product will be safe and effective as labeled. See sections 505(j)(5)(F)(iii) and 505(c)(3)(E)(iii) of the FD&C Act.

(3) A supplement to a new drug application for a drug containing a previously approved "active ingredient (including any ester or salt of the active ingredient)" approved after September 24, 1984, that contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the applicant. A subsequent ANDA or 505(b)(2) application may not be approved for an exclusivity-protected change approved in the supplement for *three years* from the date of approval of the original supplement. See sections 505(j)(5)(F)(iv) and 505(c)(3)(E)(iv) of the FD&C Act.

The FD&C Act requires that patent information be filed with all newly submitted Section 505(b) drug applications. No NDA may be approved after September 24, 1984, without the submission of patent information to the Agency. Effective August 18, 2003, this information must be filed using Form FDA 3542a "Patent Information Submitted with the Filing of an NDA, Amendment or Supplement".

Effective August 18, 2003, upon approval of an application, patent information for purposes of listing in the Orange Book must be submitted to the Agency within 30 days of the date of approval on Form FDA 3542 "Patent Information Submitted Upon and After Approval of an NDA or Supplement." Please note that the date of approval for an NDA for which FDA recommends controls under the Controlled Substances Act is the later of the date on the approval letter for the NDA or the date of issuance of the interim final rule controlling the drug (see section 505(x)(1) and (2) of the FD&C Act). Patent information on unapproved applications or on patents beyond the scope of the FD&C Act (i.e., process or manufacturing patents) will not be published. Form FDA 3542 will be the only form used for the purposes of this publication.

The patents that FDA regards as covered by the statutory provisions for submission of patent information are: patents that claim the active ingredient(s); drug product patents, which include formulation/composition patents; method-of-use patents that claim one or more approved methods of using the approved drug product; and certain other patents as detailed on Form FDA 3542. This information, as provided by the sponsor on Form FDA 3542, will be published as described above. As of December 5, 2016, an NDA holder submitting information on a patent that claims both the drug substance and the drug product (and is eligible for listing on either basis) is required only to specify that the patent claims either the drug substance or the drug product.

A requirement for submission of patent information to FDA for certain old antibiotics became effective October 7, 2008 under section 4(b)(1) of the QI Program Supplemental Funding Act (Public Law 110-379) (QI Act).

Upon approval, patent numbers and expiration dates, in addition to certain other information on appropriate patents claiming drug products that are the subject of approved applications, will be published daily in the Electronic Orange Book. The Addendum lists patent and exclusivity information up to January of the Edition year. The monthly Cumulative Supplements to the annual edition list patent and exclusivity information changes since the Annual Edition Addendum. Since all parts of this publication are subject to changes, additions, or deletions, the Electronic

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