All Content Dashboard

**SESSION NAVIGATOR**
Move between Practice Areas.

**PRACTICE AREAS**
Access content grouped by category.

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Practice Area Dashboard - Food, Drug & Cosmetics

REFINE SEARCH SCOPE
Select filters prior to your search.

CUSTOMIZE
Select which items you want to see, within each group, on your dashboard.

HISTORY
Access documents and searches from prior research.

WORKLISTS
Organize your research findings in folders.

SEARCH TIPS
Use operators, connectors and wildcards in searches.

PRACTICE TOOLS
Compare topics across jurisdictions, perform calculations, navigate to topics, etc.

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Receive breaking news alerts plus a daily report of court decisions and legislative and regulatory developments.

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Practice Area Dashboard - Medical Devices

REFINE SEARCH SCOPE
Select filters prior to your search.

HISTORY
Access documents and searches from prior research.

SEARCH TIPS
Use operators, connectors and wildcards in searches.

WORKLISTS
Organize your research findings in folders.

CUSTOMIZE
Select which items you want to see, within each group, on your dashboard.

SEE ALL
View all titles available under the category.

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Search Results

- **FILTERS**: Refine search results by Document type, Court, Jurisdiction and more.
- **RECORD KEEPING OPTIONS**: Select documents to Add (Worklist or Favorites), Print, Email or Download.
- **QUICK ANSWER**: Read a brief definition of common search expressions.
- **SAVED ITEMS**: View your saved searches, notes & highlights, and favorites.
- **SORT BY**: Arrange search results by Relevance, Most Recent or Document Type.
- **COLOR-CODED RESULTS**: Find document types quickly and easily.

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Quick Start Card

Document View

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Food, Drugs and Cosmetics Guide: Drugs and Biologics

Abbreviated New Drug Applications

$1,131, Eligibility

Summary

A drug is eligible for approval as an abbreviated new drug product (generic) if it is comparable to a listed innovator new drug product. A generic drug is not required to demonstrate a new therapeutic effect or superior safety and effectiveness compared to the listed drug. It is sufficient that the generic drug is comparable in strength, route of administration, quality, performance characteristics, and intended use.

Equivalent to a Listed Drug

If a new drug can be considered equivalent to a new drug that has been listed by the Food and Drug Administration as approved for safety and effectiveness (see §1,133), it may be approved on the basis of an abbreviated new drug application (ANDA). The applicant must demonstrate that the ANDA product is comparable to the ANDA product (generic) to provide a safe, effective, low-cost alternative to the American public.

Statutory provisions for ANDA applications are set forth in the Federal Food, Drug, and Cosmetic Act by the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-412). Prior to that time, Food and Drug Administration regulations permitted the filing of ANDAs for pre-1982 drugs only. Generic versions of pre-1982 new drugs were approved under the FDA’s “paper ANDA” policy (see §1,153).

Difference from Listed Drug

If a drug differs from an approved new drug in the identity of one active ingredient of a combination or in the route of administration, dosage form, or strength, a petition may be submitted to the FDA to request a determination of the suitability of filing an ANDA (see §1,133). ANDEAs may not be used for approving new indications and other changes from a listed drug that would require safety or effectiveness studies; however, these changes may be approved through a Section 505(b)(2) application (see §1,151). Section 505(b)(2) applications are filed after the section in the Food, Drug, and Cosmetic Act in which they are mentioned, is deemed a hybrid between a new drug application (NDA) and an ANDA. They rely in whole or in part on investigations for safety and effectiveness that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference (21 CFR §314.50 to 21 CFR §314.54).

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