

Understanding Skinny Labels

A Key to Generic Drug Access

What is a skinny label?

Skinny labeling, a provision of the Hatch-Waxman Act, is a process that allows generic drug manufacturers to seek FDA approval for uses of a drug no longer protected by patents.

This approach was designed to balance innovation with competition in the pharmaceutical industry.

How does it work?



Generic drug manufacturers file an abbreviated new drug application with the FDA.



Manufacturers must include studies showing that the generic drug has bioequivalence and pharmaceutical equivalence to the brand-name drug.



The FDA approves the generic drug for uses that are not protected by patents.



The generic carries a label that “carves out” the still-patented uses.

How does it benefit patients?

Skinny labeling allows generic drugs to enter the market sooner, meaning patients can benefit from:

- Lower drug prices
- More treatment options
- Increased competition

Skinny labels saved Medicare patients nearly \$15 billion from 2015 to 2020.

How can lawmakers encourage generic competition?

Skinny labels were established more than forty years ago as a part of the Hatch-Waxman Act. Policymakers should affirm that “skinny labeling” is permitted under Hatch-Waxman to:

- Ensure the continued availability of approved skinny label generic medicines.
- Provide a clear regulatory framework that supports innovation and competition.
- Improve timely access to generic medications.