

# THE AUTHORIZED *generic*

The Leading Source of Authorized Generics

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The brand and the Prasco Authorized Generic are identical.

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Your questions simply yet accurately answered.

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Identical doesn't need to be complicated. Let us help you understand Authorized Generics.

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## Authorized Generics, the Brand-Identical Generic



As the generic marketplace continues its steady growth, patients are requiring more of your time to explain product characteristics. Wouldn't you like a generic option that provides the identical experience as the brand? Why not save yourself valuable time and explanations during the generic conversion process by simply offering your patients an Authorized Generic?

Authorized Generics are prescription drugs produced by brand companies under a New Drug Application (NDA) and authorized to be marketed as generics under private label. Prasco Authorized Generics are identical in size, shape, color, taste, smell, mouth feel, active ingredients, and unlike a typical generic, the Authorized Generic has the identical inactive ingredients as the brand. With a Prasco Authorized Generic, you and your patients can rely on the brand identical experience.

Authorized Generics are growing in popularity and preference with your patients. With Authorized Generics, you can avoid lengthy explanations about

product characteristics and provide your customers with the identical product experience as they would have with the branded product.

Through the distribution of Prasco Authorized Generics, consumers receive the brand quality they have come to expect at the lower generic prices. This is the reason 87% of consumers want the option of taking an Authorized Generic version of a prescription drug that is produced by the brand company.<sup>1</sup>

With over 90% of consumers expecting their pharmacist to tell them when an Authorized Generic version of a generic prescription drug is available,<sup>1</sup> Prasco makes it easy to provide your customers with the option they prefer.

Enjoy the benefit of saving valuable time by simply explaining the facts — the brand and the Prasco Authorized Generic are identical.

<sup>1</sup> Roper National Poll. Data on file at Prasco, LLC.



# Authorized Generics Question & Answer

Answers to the most commonly asked questions regarding Authorized Generics

## What are Authorized Generics?

The term Authorized Generics refers to prescription drugs produced by brand companies under a New Drug Application (NDA) and marketed as generics under a private label.

Authorized Generics compete on pricing, quality and availability with generic products approved by the FDA as substitutable for specific brand products. Authorized Generics are marketed to consumers during and after what is commonly known as “the 180-day exclusivity period.”

## What is the difference between Authorized Generics and other generics?

An Authorized Generic is a brand name prescription drug — already approved as a New Drug Application (NDA) by the FDA — marketed as a generic under a private label. The Authorized Generic is sold and distributed as a generic product by the private label company.

Generics are produced and marketed under Abbreviated New Drug Application (ANDA). According to the FDA, “A generic drug is a copy that is the same as the brand-name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use.”

## What is the consumer advantage of Authorized Generics?

Simply put, Authorized Generics provide consumers the highest brand quality at generic prices. The FDA answers this best, stating, “Marketing of Authorized Generics increases competition, promoting lower prices for pharmaceuticals.”

Competitively speaking, the entrance of an Authorized Generic is the same as the entrance of a second ANDA. This is no different than multiple ANDA filers on the same day sharing the 180-day exclusivity.

The consumer impact is stated best by the Federal Trade Commission (FTC), which states, “The entry of a second generic drug product generally doubles the price decrease introduced by the first generic product from the branded drug product’s price. Three or more companies offering a generic version of a listed drug can lower the price at least fifty percent, if not substantially more.”

With Authorized Generics, consumers benefit from the brand-identical product experience as well as the additional cost savings a second generic competitor provides during the 180-day exclusivity period.

## Research Underlines Consumer Demand to have Authorized Generic Prescription Drugs Available

More than eight in ten Americans want the option of choosing Authorized Generic prescription drugs, a nationwide study finds. Americans, according to a survey carried out by Roper Public Affairs & Media, have a strong desire to have Authorized Generic prescription drugs available to them.

An Authorized Generic is a drug manufactured by the brand name drug company and marketed as a generic, with generic pricing, under a private label.

According to the survey, 87% of Americans say they want the option of taking an Authorized Generic version of a prescription drug made by the original manufacturer. Nearly all Americans (90%) say they would like to be told specifically by their pharmacist when an Authorized Generic is available. This study suggests when brand quality is available at generic prices, Americans want to know about it. The study also revealed if given the choice, three in four Americans say they would be more comfortable taking an Authorized Generic prescription drug as opposed to a standard generic. Even consumers who say authorized versions make “no difference” in their comfort with generics would still feel more comfortable with an Authorized Generic drug than with another manufacturer’s copy. Most significantly, eight in ten Americans would prefer the Authorized Generic if the price of an Authorized Generic and a standard generic were the same. ■



# The Authorized Generic Facts

## A Long Standing Practice

As long as there have been NDAs, there have been Authorized Generics. More recently, 19 Authorized Generics were launched from 1992 - 2002;<sup>1</sup> and since 2003, 121 Authorized Generics have been launched,<sup>1</sup> 64% were launched by generic drug companies and only 36% were launched by brand subsidiaries.<sup>1</sup> Brand products with over \$138 billion in sales could face generic competition between now and 2015.<sup>2</sup> Additionally, \$42 billion could face generic competition within the next two years.<sup>2</sup>

## The Practice of Authorized Generics

14 generic companies are in the Authorized Generics business,<sup>1</sup> twelve of which are members of the Generic Pharmaceutical Association (GPhA).<sup>3</sup> 73 of the 77 Authorized Generics launched by generic companies were launched by members of the GPhA.<sup>1</sup>

## Broader than Exclusivity

34% of all Authorized Generics were products granted the statutory 180-day exclusivity period.<sup>1</sup> 66% of the Authorized Generics were products with no statutory 180-day exclusivity period.<sup>1</sup>

## Healthy Generic Marketplace

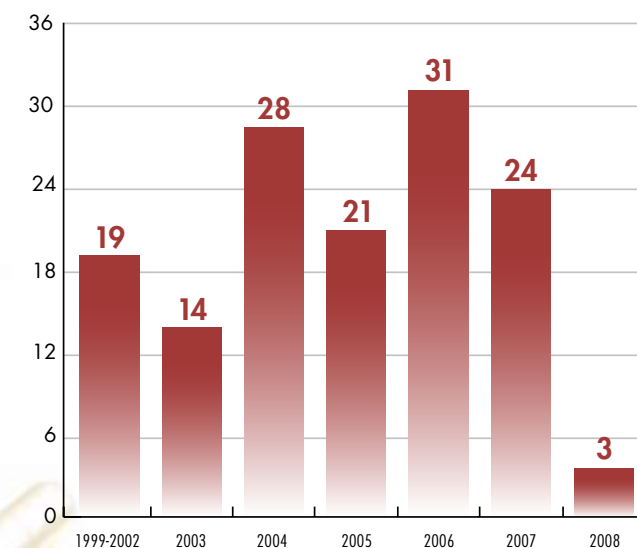
There is no evidence that Authorized Generics slow the filing of ANDA’s or Paragraph IV challenges. ANDA filings have increased every year since 2002. In fact, filings in 2007 were nearly five times the filings in 2002. Paragraph IV filings have remained steady from 2003 – 2006,<sup>1</sup> and almost doubled in 2007. The number of companies filing Paragraph IV challenges has increased from 42 to 78 between 2003 to 2007.<sup>1</sup> The generic marketplace is healthy and growing.

## Here to Stay

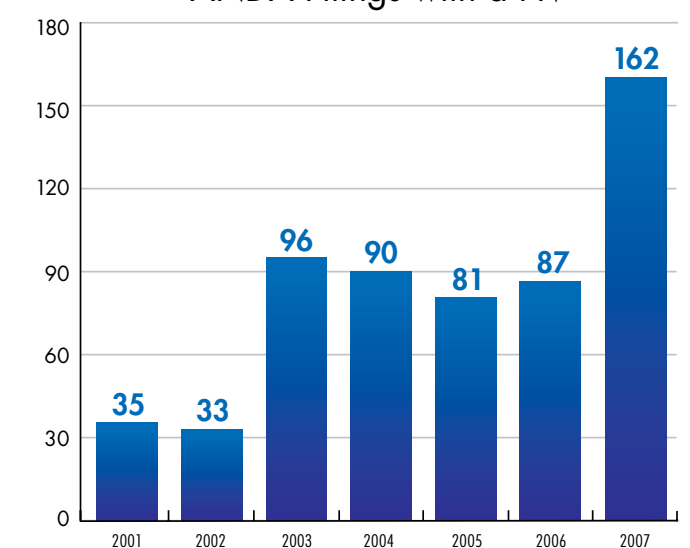
Of the 121 Authorized Generics launched since 2003, 92% are still marketed today.<sup>1</sup> No Authorized Generic has been pulled from the marketplace at the end of the statutory 180-day exclusivity period.<sup>1</sup> Statutory exclusivity has expired for 38 of those products, yet all 38 remain in the market.<sup>1</sup> ■

<sup>1</sup> IMS Health; Company Reports; Medi-Span; First DataBank; FDA Orange Book;  
<sup>2</sup> Merrill Lynch, *Generic Industry Perspectives*. 14 December, 2006. <sup>3</sup> GPhA Website.

Authorized Generic Launches



ANDA Filings with a PIV



If you would like additional information on any of the articles in this issue, please visit [www.authorizedgenerics.com](http://www.authorizedgenerics.com).



*simply*

**IDENTICAL**

**The Option Patients Prefer**

When providing generic options for your patients,  
look to the one that is more than just the same.  
Choose the generic that is identical to the brand  
– the Prasco Authorized Generic.™

Prasco Authorized Generics provide your patients with  
the identical brand experience they prefer at the  
generic price they expect. That's the identical size, shape,  
color, taste, smell, mouth feel, active and inactive  
ingredients. So, when presenting generic options to  
your patients, select the one that's simply identical.

**The Prasco Authorized Generic.**

For more information about Prasco Authorized Generics, visit  
[www.authorizedgenerics.com](http://www.authorizedgenerics.com) or stop by NACDS booth #1116.



**PRASCO**

*The Authorized Generics Company™*