

Authorized Generics™

FREQUENTLY ASKED QUESTIONS

Q: What are Authorized Generics?

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

Authorized Generics compete on a pricing, quality and availability basis 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.”

Q: What is the difference between Authorized Generics and other Generics?

A: An Authorized Generic is a brand-name prescription drug—already approved as a New Drug Application (NDA) by the FDA—and marketed as a generic under a private label. The Authorized Generic is sold and distributed as a generic product by the private label company. It has the identical size, shape, color, taste, smell, mouth feel, active ingredients and unlike a generic, the Authorized Generic has the identical inactive ingredients.

According to the FDA, “A generic drug is a copy that is the same as a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use.”¹ Generics are produced and marketed under an Abbreviated New Drug Application (ANDA).

Q: What are the similarities between the NDA Authorized Generic and ANDA Generics?

A: As generics, both provide consumer savings, and are approved by the FDA to be marketed to the consuming public. Both types of generic products are highly regulated and undergo a rigorous approval process resulting in a safe and effective treatment methodology.

Q: What is the consumer advantage of Authorized Generics?

A: Simply put, Authorized Generics provide consumers the highest brand quality at lower generic prices. The FDA answers this best, stating: “Marketing of Authorized Generics increases competition, promoting lower prices for pharmaceuticals...”²

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

The consumer impact of increased competition is detailed 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 by at least fifty percent, if not substantially more.”³

Today, “generic medicines account for more than 69% of all prescriptions dispensed in the United States,”⁴ and “the total generic revenue will grow to \$67.2 billion by 2018.”⁵ According to the Congressional Budget Office (CBO), “consumers save \$10 billion annually because of generic prescription products.”⁶



Authorized Generics™

FREQUENTLY ASKED QUESTIONS

Authorized Generics provide consumers brand quality at generic prices. The availability of raw materials and production capacity for Authorized Generics reduces the possibility of marketplace supply interruptions. Consumers also have the identical product experiences with Authorized Generics as they do with brand products in areas such as taste, color, mouth feel and shape. And, by being an additional generic competitor, Authorized Generics reduce the cost of prescription drugs more than the reduction offered by the first generic entrant in the market.

Q: What is the 180-day exclusivity period?

A: "Section 505(j)(5)(B)(iv) of the Federal Food, Drug and Cosmetic Act (FDCA) establishes a 180-day period following the approval of abbreviated new drug applications ("ANDAs"), during which FDA may not approve other ANDAs for the same drug product. While this is commonly referred to as "180-day exclusivity," in practice this period has never been truly "exclusive" as the NDA holders and its distributors and licensees have always been authorized to continue to sell the originally approved drug product throughout this 180-day period and beyond. If there are multiple ANDAs submitted on the same day as the first ANDA qualifying for the 180-day exclusivity, they all share the 180-day exclusivity."⁷

Q: Are Authorized Generics only offered during 180-day exclusivity period and then taken off the market after the 180-day expires?

A: 146 of the 172 Authorized Generics launched since 2003, are still marketed today.⁸ 48 of these products were launched during a statutory 180-day exclusivity period,⁸ and while exclusivity has expired on 44,⁸ all of them are still in the marketplace today.⁸ Four are currently in an exclusivity period that has not expired.⁸ **NO Authorized Generic has been pulled from the marketplace at the end of a statutory 180-day exclusivity period.**⁸

Q: When have Authorized Generics been launched – prior, during or after the 180-day exclusivity?

A: All of the above:

- 48 of the products were granted statutory 180-day exclusivity periods⁸
- 37 were launched during the 180-day exclusivity period⁸
- 11 were launched after the 180-day exclusivity period⁸
- 109 of the products did not have statutory 180-day exclusivity periods⁸
- 15 of the products were antibiotic products not subject to Hatch-Waxman provisions⁸

Q: How many Authorized Generics have been launched, and are they still in the marketplace?

A: Since 2003, 172 Authorized Generics have been launched by 33 different pharmaceutical companies.⁸ 146 of these products are still being marketed today.⁸ Of the products removed, three were replaced with the ANDA product,⁸ and 23 were discontinued.⁸

Q: Are Authorized Generics ever on the market all by themselves?

A: Authorized Generics, as an FDA approved product, can enter into the marketplace at any time upon the decision of the NDA holder.



Q: How are Authorized Generics brought to market?

A: Authorized Generics can be brought to the marketplace a number of ways: three of the most common are identified below:

- Brand companies establish agreements with private label marketing and distribution companies to market and distribute Authorized Generic products. This type of agreement usually results in two generics competing in the marketplace.
- Brand pharmaceutical companies can establish subsidiaries to market Authorized Generics of their own brands. Several companies have launched Authorized Generics this way, but some have abandoned this approach for other options. This usually results in two generics competing in the marketplace.
- Brand companies establish agreements (oftentimes a result of a patent challenge settlement) with a generic drug manufacturer to permit them to offer the Authorized Generic product until the generic company gets its ANDA approval. Once the ANDA is approved, the generic company stops offering the Authorized Generic. This strategy generally results in just one generic drug in the marketplace.

According to industry experts Robert P. Reznick and James B. Kobak, “History suggests there is no shortage of generic manufacturers ready to make a product otherwise likely to be the subject of an Authorized Generic.”⁹ The presence of an Authorized Generic in the market provides consumers with a lower priced alternative to an otherwise monopolistic generic price.

These economic realities are underscored by Jonathan Siegel, vice president of pharmaceuticals equity research at Bear Stearns. In a presentation at a Food and Drug Law Institute generic drug conference he said that, “even with an Authorized Generic on the market, the 180-day exclusivity period still provides a significant return on investment,”¹⁰ which he estimated to be approximately 470% for the generic drug firm operating under such exclusivity.¹⁰

Generic Marketplace Facts

- In 2008, the U.S. generic market* was \$48 billion,⁴ and is projected to grow to \$67.2 billion by 2018⁵
- Generics account for more than 69% of total prescriptions dispensed in the United States⁴
- Generics save consumers approximately \$10 billion annually⁶
- Generics are responsible for less than 16% of every dollar spent on pharmaceuticals⁴
- Nineteen Authorized Generics were launched between 1992 – 2002, 14 in 2003, 28 in 2004, 21 in 2005, 31 in 2006, 24 in 2007, and 23 in 2008, and two to date in 2009⁸
- Average retail price of a brand (\$111.02)⁴ vs. average retail price of a generic (\$32.23)⁴ equates to an average cost savings of \$78.79 per prescription

* The term “Generics and generic market” include both generic and Authorized Generic pharmaceutical products.

“Products representing approximately \$156 billion of annual branded sales could face first time generic competition between 2009–2018. If we apply a generic penetration rate of 85% and an average generic price discount of 80%,¹⁵ this \$156 billion in brand sales could equate to generic revenue of approximately \$106.08 billion and more importantly a potential consumer savings of \$49.92 billion.

In short, the market for generic drugs has grown and will continue to grow because consumers are demanding more, not less, competition among pharmaceutical manufacturers. Authorized Generics are just one more competitor in the marketplace bringing cheaper drugs faster to consumers.

Q: Aren't Authorized Generics an effort by large pharmaceutical companies and their partners to circumvent the intent of the Hatch-Waxman Act which created the 180-day exclusivity period for the first generic drug approvals?

A: No. The intent of Hatch-Waxman was to promote competition and allow low cost generic drugs to reach the marketplace. There is nothing in Hatch-Waxman to suggest that Authorized Generics are against public policy. In addition, Hatch-Waxman always contemplated more than one generic company during the exclusivity period. The original statute gave preference to the first to file, but Congress, in 2003, specifically provided for multiple ANDA filers on the same day to share the 180-day exclusivity. The presence of a second generic competitor in the 180-day exclusivity period is good for consumers and was clearly contemplated by Congress.

Q: What are other interested parties saying about this?

A: FDA

"Marketing of Authorized Generics increases competition, promoting lower prices for pharmaceuticals particularly during the 180-day exclusivity period in which the prices for generic drugs are often substantially higher than after other generic products are able to enter the market."²

"FDA considers Authorized Generics legal and pro-competitive. Appears to promote competition in the pharmaceutical marketplace, in furtherance of a fundamental objective of the Hatch-Waxman amendments."¹¹

FTC

"FTC's position historically has been that Authorized Generic arrangements are pro-consumer because they allow multiple generic entrants sooner."¹²

Federal Courts

"Nothing in the statute provides support for the argument that the FDA can prohibit NDA holders from entering the market with a brand generic drug during the exclusivity period."¹³

"The Court can not fathom any reason to apply section 355(j)(5)(B)(iv), a provision clearly addressing only ANDAs, to limit the introduction into the market of a generic drug of a NDA holder."¹⁴

The National Center for Public Policy Research

"An 'Authorized Generic' can come into the market very quickly to provide consumers with lower prices because the know-how of the medicine's original developers can be quickly and efficiently transferred." "...the competition should be welcome because it serves the needs of consumers. The original brand-name medicine now faces two competitors – the 'Authorized Generic' and the copy made by the first traditional generic drug maker who enters the market. Because consumers now have more choices, all of the drug companies are forced to price their products lower to stay competitive. This can only benefit consumers."¹⁵

Industry Financial Analyst

"Even with an Authorized Generic on the market, the 180-day exclusivity period... still provides a significant return on investment... Without an Authorized Generic, a generic firm with 180-day exclusivity could reap 1,000 percent [return on investment] ROI. With an Authorized Generic product on the market, the ROI declines by about one-half to approximately 470 percent."¹⁰

Authorized Generics™

FREQUENTLY ASKED QUESTIONS

National Economists

"...The practice of Authorized Generics provides no meaningful disincentive for generic pharmaceutical companies to challenge questionable patents...competition from Authorized Generics reduces prices and increases the availability of safe and lower priced generic medicines, which benefits American consumers."¹⁶

Industry Trade

"In addition to lowering costs for consumers and payers, the entry of an Authorized Generic product at patent expiration often helps with the market transition from brand to generic, reducing risks associated with some generic launches, including inventory supplies."¹⁷

Q: Generic drug companies argue 1) that Authorized Generics undercut the generic companies' expected profit if they enter during the 180-day exclusivity period, thereby reducing profit—and eventually lowering the incentive to pursue patent challenges; and 2) such lowered incentive results in fewer generic products for consumers and restricted access to inexpensive generic pharmaceuticals. What is Prasco's viewpoint on these arguments?

A: The pharmaceutical marketplace is large and dynamic with vast room for patent challenges. The history of paragraph IV challenges, in fact, proves that the economic benefits of limited competition are so strong that generic manufacturers will take the investment risk of filing challenges even if they are not the first to file. See *Figure 2*.

According to Jonathan Siegel of Bear Stearns, "without an Authorized Generic, a generic firm with 180-day exclusivity could reap a 1,000% [return on investment] ROI. With an Authorized Generic on the market, the ROI declines by about one-half."¹⁰

Watson - Drug Firms Split Over Authorized Generics

"...Authorized Generics are pro-competition...They bring another generic drug to market sooner. It's beneficial for the consumer."¹⁸

Barr- Barr Sees Rapid Uptake of Allegra Generic, Downplays Impact from Competition

Barr senior VP-sales & marketing Tim Catlett maintained during an analyst briefing in New York September 20... "It's a \$1.5 billion marketplace, probably a little bit bigger, because sanofi-aventis took almost a 10% price increase two weeks ago when Teva launched...This is a very large marketplace. There is room for two competitors."¹⁹

Watson and Par- Drug Makers Use New Tactic to Ding Generic Drug Firms

"Some companies, such as Watson and Par, have courted the deals, pitching themselves as a partner to the branded companies." Joseph C. Papa, president and chief operating officer of Watson, doesn't see the gambit as teaming up with the enemy or weakening the generics industry. "This is just one part of our overall corporate strategy," he said. "It's helping us to bring out additional new products."²⁰



Authorized Generics™

FREQUENTLY ASKED QUESTIONS

Mylan - Mylan Reverses Authorized Generics Stance, Says It Intends to Participate in That Market

"It is Mylan's intention, going forward, to participate in the Authorized Generics market, as appropriate," Robert J. Coury, Mylan's vice chairman and chief executive officer said.²¹

The Hatch-Waxman legislation and the free enterprise marketplace it supports have been successful by bringing low cost pharmaceuticals to the market and have actually provided the platform for the generic industry to become one of very large, growing and global organizations rivaling that of the brand pharmaceutical industry. In fact, many generic companies have brand subsidiaries. As you can see, generic manufacturers are no longer the old "mom and pop" operations of years ago that had limited resources to pursue their business strategies. In fact, the top 10 generic companies today have a combined market capitalization of more than \$19.45 billion.²²

Q: What will the Authorized Generic marketplace look like over the next five years?

A: Nineteen Authorized Generics were launched between 1992 – 2002, 14 in 2003, 28 in 2004, 21 in 2005, 31 in 2006, 24 in 2007, and 23 2008 and two to date in 2009.⁸ See Figure 1.

Since 2001, 11 blockbuster drugs have lost patent protection. As of 2004, 8,730 of 11,487 drugs listed in the FDA's Orange Book have generic counterparts.⁴ And generic sales are projected to grow to \$67.2 billion by 2018.⁵

The marketplace for Authorized Generics will continue to respond to significant consumer demand for high quality, lower cost pharmaceuticals. Authorized Generics is taking its position as a major factor in reducing prices for consumers within the generic marketplace.

Q: Will competition from Authorized Generics further drive down the price for off-patent pharmaceuticals, giving consumers alternatives to purchasing their drugs from foreign suppliers?

A: Yes. Authorized Generics add to competition and competition lowers prices. Supply, demand and pricing are by-products of market conditions.

Q: Opponents of Authorized Generics contend that such products violate anti-trust laws. Is this so?

A: No. The appropriate agencies of the federal government, the FDA and FTC, have both examined the consumer impact, the anti-trust implications, and other relevant federal statutes and regulations, and have subsequently allowed the marketing of Authorized Generics.

"Marketing of Authorized Generics increases competition, promoting lower prices for pharmaceuticals, particularly during the 180-day exclusivity period in which the prices for generic drugs are...substantially higher than after other generic products are able to enter the market."²

The top five largest generic companies²² have at least 49 Authorized Generic products themselves.⁸ Most of these products were obtained as a result of legal settlements between them and the branded companies.



Authorized Generics™

FREQUENTLY ASKED QUESTIONS

Q: Is it anticompetitive to allow a brand company to compete with generic versions of its own brand product?

A: No. The FTC, which governs conduct that restricts competition, has reviewed Authorized Generics and concluded that they are in fact pro-competitive in the short term and is currently doing a study to ensure they are good for the consuming marketplace for the long term.

Q: Doesn't the marketing of Authorized Generics offer consumers benefits during the 180-day exclusivity period while preserving the value of patent challenges?

A: Yes. The introduction of Authorized Generics in the marketplace lowers prices during the 180-day exclusivity period, and the presence of Authorized Generics does not eliminate the economic incentive for challenging patents. As stated before, if an Authorized Generic is available during the 180-day period, the patent-challenging generic still has a potential return on investment of approximately 470%.¹⁰ There is no evidence that patent challenges are discouraged.

In fact, Tim Catlett, Barr's Senior Vice President of Sales and Marketing, said, "This is a very large marketplace. There is room for two competitors."¹⁹

Q: Isn't the 180-day exclusivity period a way for generic companies to recoup their development and legal costs?

A: Sure. Generic companies have a substantial return on their investment and that is true even if they face competition during the 180-day exclusivity period. Moreover, generic companies do not make their investment decisions solely on their ability to obtain the exclusivity period. In many cases, they are not the first to file, and yet they still make legal and development investments. The economic investments of a non-monopolistic generic pharmaceutical marketplace more than reward companies for their sensible and successful investments.

Q: Won't generic companies stop challenging brand drug patents if Authorized Generics are allowed to continue?

A: No. Generic manufacturers continue to compete and challenge patents. But now, the consumer will receive a further break in prices and access to brand quality products.

An Authorized Generic product simply adds one competitor to a generic market. A generic company able to gain 180-day exclusivity through a successful patent challenge currently has no competition absent an Authorized Generic. Without an Authorized Generic on the market, there is no incentive to lower price more than a small margin from the brand product price.



Authorized Generics™

FREQUENTLY ASKED QUESTIONS

Authorized Generics have been in the market for years and generic companies have continued to invest in patent challenges. Historically, generic companies have invested in patent challenge because the return on investment has been potentially enormous when challenging drugs with blockbuster revenues. In the instances where generic companies made such investments, they did so with the knowledge that they were seeking access to a market. As discussed above, even when the generic company has one competitor during the exclusivity period, the opportunity for return on investment is considerable and worth the investment. That is why, even with Authorized Generics in the market over the years, and even with the uncertainty of a first to file status, generic companies will very likely continue to invest in patent challenges. With patent challenges, the potential returns far outweigh the costs of patent challenges.

Q: Are Authorized Generics subject to pay higher Medicaid rebates than standard ANDA's?

A: Yes. CMS allocates rebates based on ANDA or NDA numbers. Since Authorized Generics are listed under an NDA number and marketed under a private label, they are subject to pay the 15.1% rebate, which equates to additional rebate dollars for the government on NDA Authorized Generics compared to ANDA Generics.

Q: Hasn't legislation been recently introduced to prohibit Authorized Generics during the 180-day exclusivity period?

A: Yes, however it is Prasco's belief passing this legislation would be bad for consumers, increase prices for pharmaceuticals and would be premature until the FTC study focusing on the long-term implications of Authorized Generics, requested by Congress is completed.

Q: Are Authorized Generics only offered by brand companies with generic subsidiaries?

A: No, more Authorized Generics come from Prasco, an independent Authorized Generic company than any other company.

Not all Brand Companies have generic subsidiaries. Some establish commercial supply/licensing agreements with private label marketing and distribution companies to market and distribute the Authorized Generic product. The benefit of aligning themselves with a specialty company like Prasco brings a unique set of marketing skills and focus to ensure a maximum marketplace penetration. In fact, many generic companies have Authorized Generics.

Q: How does an independent held company like Prasco fit into the pharmaceutical marketplace?

A: Prasco is a specialty pharmaceutical company focused on filling the greater need of competition and consumer choice through Independent Authorized Generics. Prasco's focus is helping consumers gain access to high quality pharmaceuticals at low cost generic prices, sooner.



Authorized Generics™

FREQUENTLY ASKED QUESTIONS

Sources

- 1 U.S. Food and Drug Administration. Facts About Generic Drugs. 30 March 2006. <http://www.fda.gov/cder/consumerinfo/generic_FactsAbout_text.htm>
- 2 U.S. Food and Drug Administration. FDA Talk Paper. FDA Supports Broader Access to Lower Prices Drugs, 2005. 30 March 2006. <<http://www.fda.gov/bbs/topics/answers/2004/ans01296.html>>
- 3 Federal Trade Commission. Comment off the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission, 1999. Docket No. 85N-0214. 6 January 2005. <<http://www.ftc.gov/be/v990016.htm>>
- 4 IMS Us Pharmaceutica Market Trends, Issues & Outlook as presented to GPhA, February 25, 2009.
- 5 Merrill Lynch. Generic Perspectives 2009. 02 March 2009, pg. 2, 4.
- 6 The Federal Trade Commission. Generic Drug Entry Prior to Patent Expiration: An FTC Study. July 2002. Chapter 1, pg 9.
- 7 Johnson & Johnson. Office of General Counsel. Letter to the Food and Drug Administration Dockets Management Branch. Subject: Docket No. 2004P-0075 (Citizen Petition submitted by Mylan Pharmaceuticals, Inc.) 11 May 2004, pg. 1, 3.
- 8 Publicly Available Data as of February 2009. Authorized Generic Launches Since 2003. First Databank; MediaSpan; Orange Book; FDA; Merrill Lynch; Company Reports.
- 9 Reznick, Robert P, and James B. Koback Jr. Are "Authorized Generics" Lawful? Abstract: Permission Granted Generics Manufacturers Think Authorized Generics are Unfair. Does the Law Agree? Pharmaceutical Executive, May 2004.
- 10 FDA News. Generic Line. "Pharma Analysts: Authorized Generics Here to Stay." 15 December 2004, pg. 12.
- 11 FDC Reports. The Pink Sheet. "Medicaid 'Best Price' May Be Avenue to Challenge 'Authorized' Generics"; "FDA Signs Off on 'Authorized' Generics; Mylan Expected to Sue." 12 July 2004. Volume 66, No. 28, pg. 6,7.
- 12 FDC Reports. The Pink Sheet. "Bristol/Teva 'Authorized' Generic Agreement Approved by FTC." 31 May 2004. Volume 66, No. 22, pg. 7.
- 13 Sutter, Sue. FDC Reports. The Pink Sheet. "Teva Legal Challenge Against 'Authorized' Generics Rejected by D.C. Court." 3 January 2005.
- 14 Walton, Reggie B., United States District Judge; United States District Court for the District of Columbia. Teva Pharmaceuticals Industries, LTD., et al., v. Food and Drug Administration, et al. Civil Action No. 04-1416 (RBW). Memorandum Opinion, pg. 11.
- 15 Almasi, David W. National Center for Public Policy Research. "FDA Helped America's Drug Consumers by Not Banning Authorized Generics." 12 July 2004.
- 16 Hasset, Kevin A. and Robert Shapiro. Sonecon. "Independent Study Confirms Authorized Generic Pharmaceuticals Reduce Prices without Discouraging the Marketing of Other Generic Drugs." 2 May 2007.
- 17 Supplement to Drug Topics. Generic Pharmaceuticals: Adding Value and Access; A Roundtable Discussion. January 2006, pg. 9.
- 18 Lau, Gloria. "Drug Firm Split Over Authorized Generics, And it's Off to Court They Go; Brand-name Drug Makers Eye Loopholes in the Law; Generic Rivals aren't Happy." Investor's Business Daily, 12 April 2004.
- 19 Walker, Elizabeth. FDC Reports. The Pink Sheet. "Barr Sees Rapid Uptake of Allegra Generic, Downplays Impact from Competition." 20 September 2005.
- 20 Abboud, Leslie. "Drug Makers Use New Tactic to Ding Generics." The Wall Street Journal, 27 January 2004.
- 21 Pharmaceutical Law and Industry Report. "Mylan Reverse Authorized Generics Stance, Says it Intends to Participate in the Market." 24 June 2005. Volume 3, No. 25.
- 22 Drugstore Management: State of Industry Report "Top 10 Generic Pharmaceutical Companies by Total Prescriptions." 2008-2009 pg. 167-168.
- 23 Paragraph IV Activities. Paragraph IV Information: General Reports. 24 March 2008. <<http://www.paragraphfour.com/forums/index.php?showtopic+107>>
- 24 The Paragraph Four Report. October 2008, p. 1.

