U.S. FOOD & DRUG ADMINISTRATION

Report

Estimating Cost Savings from New Generic Drug Approvals in 2023

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Ensuring patient access to safe, effective, and affordable medications remains a core priority for the U.S. Food & Drug Administration (FDA). Generic drug approvals play a pivotal role in advancing this priority by fostering market competition, which drives down prescription drug costs and alleviates economic strain on both patients and the healthcare system.

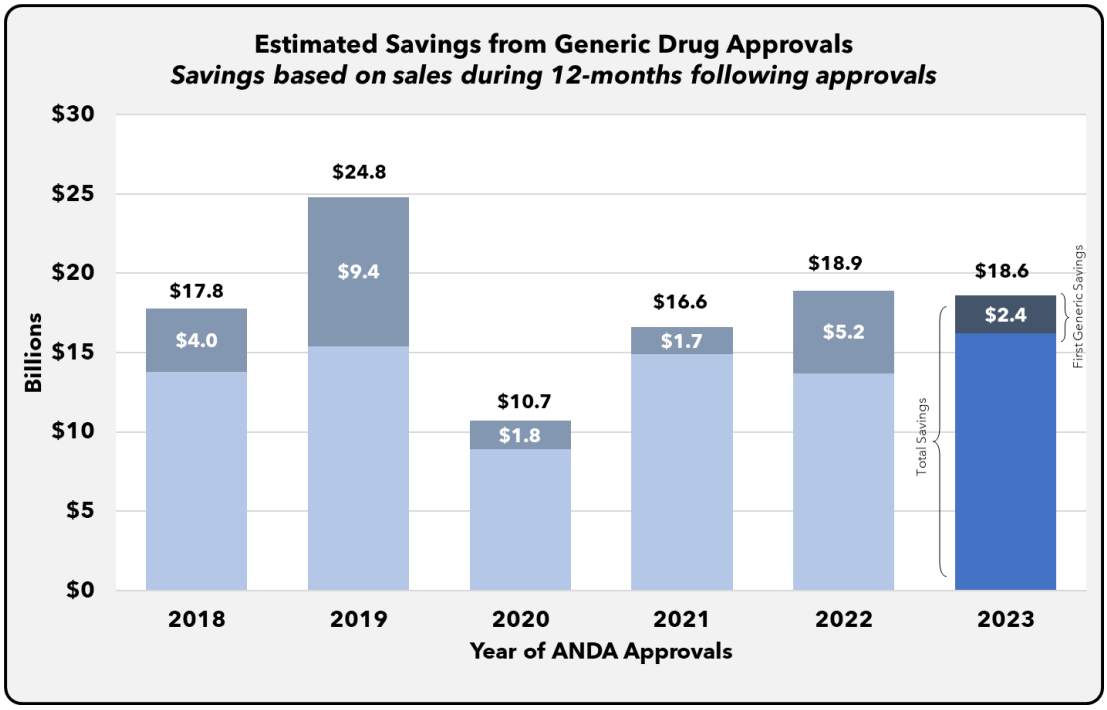
In 2023, the FDA granted full approval to 773 new generic drugs via abbreviated new drug applications (ANDAs).[1] Using methodologies consistent with prior analyses, this study, which is a continuation of previous research to estimate savings from generic drug approvals in earlier years, estimates that these newly approved generic drug applications generated a net $18.6 billion in savings during the twelve months following approval. Notably, $2.4 billion of these savings stemmed from first-generic entrants– the market entry of these products represents a critical milestone that disrupts monopolies held by brand-name drugs and induces price reductions.[2] Subsequent approvals in partially competitive markets also contributed billions in additional savings, underscoring the enduring value of incremental competition even years after initial generic entry. The estimates from the 2023 approval cohort are in line with savings estimates from previous approval years. Current results along with results from 2018-2022 ANDA approval cohorts are shown below.

While the aggregate savings estimate from the 2023 approval cohort highlights the general benefits of generic drug approvals, this analysis also emphasizes the profound impact approvals of generic medications serving smaller patient populations can have on patient access. Though less visible in broad economic terms, these approvals directly enhance affordability at the patient level, improving medication adherence and providing meaningful financial relief for Americans.

These findings reinforce compelling evidence that FDA's robust generic drug approval processes remain one of the most effective tools for curbing prescription drug costs. By sustaining competition, generic drugs continue to safeguard patient access while delivering measurable economic benefits across the healthcare landscape.

[1] This analysis requires sales data observed through December 2024 to capture savings from approvals made in December 2023, hence the release of this report in 2025.
[2] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices

Figure 1. Savings from generic drugs approved in 2023, compared to previous years.



Total annual savings from generic drug approvals are shaped less by the number of approvals in a given year and more by the mix of products approved. Approvals for high-priced, large-market drugs typically generate outsized savings compared to those targeting smaller or niche populations. For example, the 2019 approval cohort produced nearly $25 billion in savings, even though its 836 full ANDA approvals were only modestly higher than the 754 approvals in 2020. The 2020 cohort, which included fewer high-cost, widely used therapies, generated just under $11 billion in savings—highlighting how product composition, rather than approval volume, drives total impact. By comparison, the 2023 cohort of 773 approvals yielded $18.6 billion in savings, reflecting the approval of several major products that contributed disproportionately to overall cost reductions.

The $18.6 billion in savings attributed to 2023 generic approvals aligns with historical trends, both in total savings and the proportion derived from first-generic entrants. First generics accounted for $2.4 billion (13%) of 2023's total savings, while the remaining $16.2 billion stemmed from subsequent approvals. Notably, nine of the top ten drugs by savings in 2023 were not first generics. These later approvals often entered markets with limited competition, where additional manufacturers amplified price declines—a reminder that incremental competition remains critical even after initial generic entry has occurred.

While much of the savings in 2023 came from high-volume markets, the cohort also included approvals for therapies serving smaller patient populations. Though these products contributed minimally to aggregate savings, they delivered sharp price reductions for drugs that were previously prohibitively expensive. For patients dependent on these therapies, such approvals represent a lifeline: lower costs correlate directly with improved adherence and

reduced personal financial hardship,[3] even if these benefits are less visible in population-wide, aggregate terms.

Collectively, these findings reinforce that the competition provided by generic drug approvals—whether targeting blockbuster markets or niche therapies—is indispensable for driving affordability and access across the healthcare system.

1. Data and Methods

We identify all new generic drug applications that were fully approved by FDA in 2023.[4] In some cases, these applications were the first generics ever approved for the drug product. These first generic approvals can yield relatively large price declines when they enter markets with only a brand drug and no existing generic producers. In other cases, new generic approvals enter markets with existing robust competition from previously approved generic drugs. These approvals are usually associated with more modest price reductions.

For each newly approved generic drug, we identify the new drug application (NDA) number of the brand drug that is the reference listed drug (RLD), along with ANDA numbers of all other previously approved generics sharing this RLD.[5] These sets of bioequivalent brand (NDA) and generic (ANDA) drug applications define what we refer to as a "drug product" throughout this work.[6]

Price and market share can vary widely among competing producers of the same drug product. For example, a brand drug may be priced 10 times that of its generic equivalent, yet the generic may hold 90 percent of the market share. Given these variations within the same product, we use the producer-specific prices and market shares to compute a single average price for each drug product.

This price measure is computed using the combined total dollar sales of all brand and generic equivalents of each drug product and dividing by the total unit sales of the product. It represents a weighted average that accounts for within-product differences in price and market share between all competing brand and generic producers of the same drug product. This average price is computed each month, starting with the ANDA approval month through the following 12 calendar months after the approval.

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[3] Rohatgi KW, Humble S, McQueen A, et al. Medication Adherence and Characteristics of Patients Who Spend Less on Basic Needs to Afford Medications. *J Am Board Fam Med*. 2021;34(3):561-570. doi:10.3122/jabfm.2021.03.200361

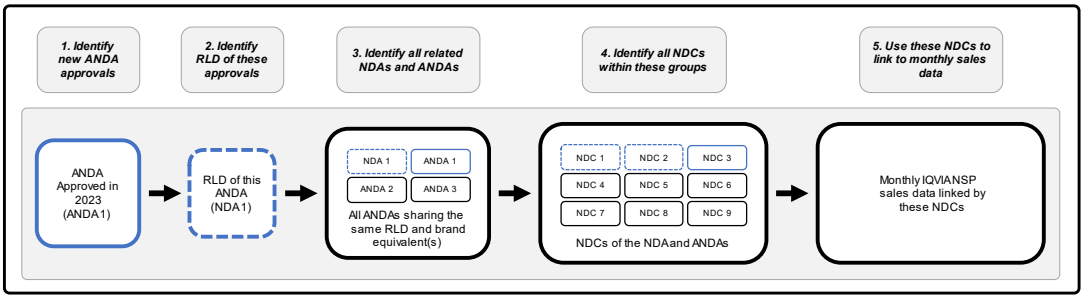
[4] Abbreviated new drug applications (ANDAs) are identified using FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book).

[5] Brand drugs are approved via new drug applications (NDAs); generic drugs are approved via ANDAs. A reference listed drug (RLD) is an approved drug product to which an ANDA applicant must show, among other things, that its proposed generic drug is bioequivalent. A sponsor seeking approval of a generic product must refer to an RLD in its ANDA. The RLD is ordinarily also the reference standard (RS), which is the drug product selected by FDA that ANDA applicants must use in conducting any in vivo bioequivalence testing required to support approval of ANDAs, but if the RLD is no longer marketed, FDA may select a previously approved ANDA product that referred to and is therapeutically equivalent to the RLD as the RS. If the RLD for a newly approved generic included in this study was not marketed, the baseline price was computed using information for the RS.

[6] For this work we consider different strengths to all be the same drug product. For example, lurasidone hydrochloride tablets of 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg are considered the same drug product despite being of different strengths.

Prescription drug unit sales and pricing data are from the IQVIA National Sales Perspective (NSP) database.[7] We use the national drug code (NDC) numbers associated with each NDA and ANDA to identify the correct products in the NSP database. All dollars are inflation-adjusted to a January 2025 base using the Consumer Price Index (CPI) from the Bureau of Labor Statistics, allowing for consistent comparisons across time. The logical process used to identify our sample is summarized in Figure 2.

Figure 2. Data identification process.



Savings estimates depend on both the price decline observed after new generic drug approvals and the unit sales of the product in each month. A baseline price is computed for the 6 months prior to the ANDA approval. For products that had a first generic entry, the baseline price includes only brand sales prior to generic entry as no generics were yet on the market. If generics were already approved, the baseline price includes sales of all generic equivalents along with the brand equivalent. This baseline price is computed similarly to the monthly weighted average product price described earlier except we combine sales for the 6 months prior to the generic drug approval. Using 6 months rather than a single month helps to mitigate any month-to-month price variations. The baseline price used for each approval does not change over time.

Using the monthly product price and the baseline price we can estimate savings associated with price reductions from new generic drug approvals. Monthly savings for each drug product are calculated by first taking the difference of the baseline price and the observed price, and then multiplying this price difference by the units sold in the given month.

Savings for product i in month t are estimated as:

$$Savings_{i,t} = Units_{i,t} * (Price_{i,base} - Price_{i,t})$$

Total savings for a given product i are computed by summing each monthly savings estimate for the product over the full 12 months of follow-up:

$$Savings_i = \sum_{t=1}^{12} Savings_{i,t}$$

Finally, we can calculate total savings for the 2023 approval cohort by summing these product-level savings from all products (N_Y) in the given year:

[7] See this IQVIA NSP fact sheet (pdf) for a complete description of the data. NSP data represent invoice-based wholesale prices reflecting pharmacy acquisitions, and may not perfectly reflect out-of-pocket costs faced by patients given the presence of insurance-based copays, coinsurance, rebates, and other price adjustments.

$$Savings_Y = \sum_{i=1}^{N_Y} Savings_i$$

The Technical Appendix explains in more detail how these price measures and savings estimates are computed, including a discussion on how drug products that have multiple ANDAs approved throughout the year are handled.

2. Results

FDA fully approved 773 ANDAs in 2023, representing 444 unique drug products. Sales data are available for 428 of these drug products, which include 729 ANDAs from the 2023 approval cohort.[8,9] Of the 428 drug products with 2023 approvals and available sales data, 396 had sales for at least one ANDA product. The remaining 32 had approved generics but no observed generic sales—only sales of the brand-name product. Accordingly, savings estimates are calculated only for products with observed generic sales in NSP. This sample composition is similar to those analyzed in previous years.

Table 1. Summary of yearly generic drug approvals and savings, 2018-2023.

	2018	2019	2020	2021	2022	2023
ANDAs fully approved	810	836	754	633	742	**773**
ANDAs with available sales data	755	788	708	604	673	**729**
Unique drug products with sales data	413	430	404	384	379	**428**
Total 12-month savings for ANDA approvals (billions)	**$17.8**	**$24.8**	**$10.7**	**$16.7**	**$18.9**	**$18.6**

a. Savings

Savings tend to be concentrated with the top-ten products by total savings accounting for about two-thirds of total savings: $12.4 billion of the $18.6 billion total. These results are summarized above in Table 1 along with results from previous ANDA approval cohorts for comparison.

First generic approvals yielded about $2.37 billion in savings during the first twelve months after their initial approval, about 13% of the net savings from the 2023 approval cohort. While there were more drug products with first generic approvals in the 2023 approval cohort than in the 2022 approval cohort (40 vs. 32), they accounted for a smaller share of the total net savings compared to the previous year. One first generic approval yielded savings of greater than $1 billion: the generic approval for lisdexamfetamine dimesylate (brand: *Vyvanse*), which resulted in over $1.68 billion in savings. Two other first generics, including teriparatide

[8] Sales data are limited to prescription drugs; over-the-counter products are excluded. NSP data also may exclude certain products with limited distribution and low revenue.

[9] Because we identify sales from all ANDAs and NDAs in each product family, ANDAs approved in the study period need not actually enter the market to be included in the sample data as sales from other sponsors in the product family are included. Products with no generic sales are excluded.

(brand: *Forteo*) and plerixafor (brand: *Mozobil*) subcutaneous solutions, yielded over $100 million in savings within the first 12 months after their generic approvals in 2023.

Of the 40 first generics in the 2023 approval cohort, 14 are for generic versions of brand drugs that were new molecular entities (NMEs).[10] These approvals represent the first ever generic versions containing those active pharmaceutical ingredients (APIs), and account for $2.01 billion in net savings. Lisdexamfetamine dimesylate, plerixafor, and tiotropium bromide (brand: *Spiriva*), account for 96% of the 12-month net savings from NME first generic approvals. The remaining 26 non-NME first generics represent generic entry for brand products that contain APIs used in previously approved drugs but that differ from those products in some way, such as a reformulation or novel dosage form. These non-NME first generics generated about $368 million in net savings. Table 2 shows savings from first generics, along with savings attributed to generic versions of NME products and includes results from previous ANDA approval cohorts for comparison.

Table 2. Summary of yearly savings attributed to first generic approvals

	2018	**2019**	**2020**	**2021**	**2022**	**2023**
Drug products with first generic approvals	*42*	*60*	*46*	*48*	*32*	***40***
12-month savings from first generic approvals (billions)	$4.00	$9.40	$1.80	$1.69	$5.22	**$2.37**
NME drug products with first generic approvals	*22*	*32*	*15*	*21*	*18*	***14***
12-month savings for NME first generic approvals (billions)	$2.70	$7.10	$1.10	$1.37	$3.85	**$2.01**

The top ten products in terms of savings accounted for over two-thirds of the total savings, about $12.4 billion, reflecting their status as high-revenue drugs that experienced significant price reductions after generic approvals (Table 3). The largest impact came from lurasidone hydrochloride tablets (brand: *Latuda*), which alone generated $5.2 billion in savings—more than a quarter of the total. Although ANDAs for this product were first approved in 2022, generics did not launch until February 2023. Once they did, the price per tablet fell from $43 to about $1, and the large patient population amplified the savings. Among the other top ten products, only lisdexamfetamine dimesylate (brand: *Vyvanse*) was a first generic approval—and notably for a new molecular entity. Despite only a moderate price decline (from $12 to $9 per tablet), its broad use yielded $1.7 billion in savings. Teriflunomide tablets (brand: *Aubagio*) also surpassed $1 billion in savings, falling from $305 to $36 per tablet after generics finally entered the market in March 2023, despite first approvals dating back to 2018.

[10] New molecular entities (NMEs) are products for which the active pharmaceutical ingredient (API) has never previously been used in an approved drug.

Table 3. Savings from drug products. Top ten products in 2023 generic approval cohort.

Product	Brand Name	Savings After 2023 Approvals (Millions)	Price: Before 2023 Approvals	Price: 12 Months After 2023 Approvals	First Generic in 2023
Lurasidone Hydrochloride | Oral Tablet	*Latuda*	$5,155	$43	$0.80	
Lisdexamfetamine Dimesylate | Oral Capsule	*Vyvanse*	$1,686	$12	$9	✓
Teriflunomide | Oral Tablet	*Aubagio*	$1,561	$305	$36	
Amphetamine; Dextroamphetamine Salts | Oral ER Capsule	*Adderall XR*	$859	$3	$1	
Regadenoson | Intravenous Solution	*Lexiscan*	$678	$46	$4	
Varenicline Tartrate | Oral Tablet	*Chantix*	$610	$5	$0.77	
Lenalidomide | Oral Capsule	*Revlimid*	$598	$891	$800	
Cyclosporine | Ophthalmic Emulsion	*Restasis*	$518	$24	$20	
Fingolimod Hydrochloride | Oral Capsule	*Gilenya*	$379	$128	$36	
Methylphenidate Hydrochloride | Oral ER Tablet	*Concerta*	$368	$5	$3	

Although only one of the top ten savings products was a first generic, first generic approvals in 2023 contributed about $2.37 billion of the $18.6 billion total savings as noted above. More than two-thirds of the first-generic savings are from a single drug: lisdexamfetamine dimesylate (brand: *Vyvanse*). There were 13 ANDAs approved for this product during 2023, which yielded a moderate price decline from about $12 per capsule down to about $9 per capsule. Although many other products saw larger price declines, with almost 520 million capsules sold annually the total savings are substantial at $1.7 billion. Other first generic approvals that yielded notable savings were teriparatide subcutaneous solution (brand: *Forteo*) which saw its price fall from about $1,250 per unit down to $850 for a total savings of about $190 million, and plerixafor subcutaneous solution (brand: *Mozobil*), which saw its price fall from $8,600 per unit down to around $1,000 per unit for a total savings of around $165 million.

b. Prices

The total savings generated by any given product depends on both the magnitude of price reduction following generic approval and the size of its market. When prices decline, high-revenue products naturally generate greater aggregate savings compared to products with smaller sales volumes.

Products serving niche or smaller patient populations may experience substantial percentage price declines that provide meaningful cost relief for individual patients, but these reductions may not translate to significant total healthcare system savings due to limited market size. Conversely, even modest price reductions in high-volume markets can yield substantial aggregate savings.

We highlight products that experienced significant price declines following generic entry in Table 4. While all these products generated meaningful savings for individual patients, their contribution to total healthcare savings varies considerably based on market size and utilization patterns. Generic competition typically intensifies over time as additional manufacturers enter the market, often leading to further price erosion beyond the initial

reductions. The timing and extent of these savings depend on factors such as manufacturing complexity, regulatory barriers, and the number of generic applicants. First generic approvals often trigger the most dramatic initial price reductions, while subsequent generic entries contribute to sustained competitive pricing that benefits patients long-term.

Table 4. Top ten products with the largest price declines in percentage terms, 2023 ANDA approvals

Product	Brand Name	First Generic	Price: Before Approval	Price: 12 Months After Approval	Percentage Reduction of Price	Savings (millions)
Lurasidone Hydrochloride | Oral Tablet	*Latuda*		$43	$0.80	98%	$5,155
Diclofenac Sodium | Topical Solution	*Pennsaid*		$12	$0.89	93%	$185
Regadenoson | Intravenous Solution	*Lexiscan*		$46	$4	92%	$678
Sildenafil Citrate | Oral Suspension	*Revatio*		$4	$0.44	90%	$11
Plerixafor | Subcutaneous Solution	*Mozobil*	✓	$8,626	$1,006	88%	$167
Teriflunomide | Oral Tablet	*Aubagio*		$305	$36	88%	$1,561
Famotidine; Ibuprofen | Oral Tablet	*Duexis*		$13	$2	88%	$17
Varenicline Tartrate | Oral Tablet	*Chantix*		$5	$0.77	86%	$610
Darunavir | Oral Tablet	*Prezista*		$42	$9	79%	$238
Vigabatrin | Oral Solution	*Sabril*		$80	$18	78%	$114

Shown in this table as price per unit, i.e., a single tablet or one mL of a solution.

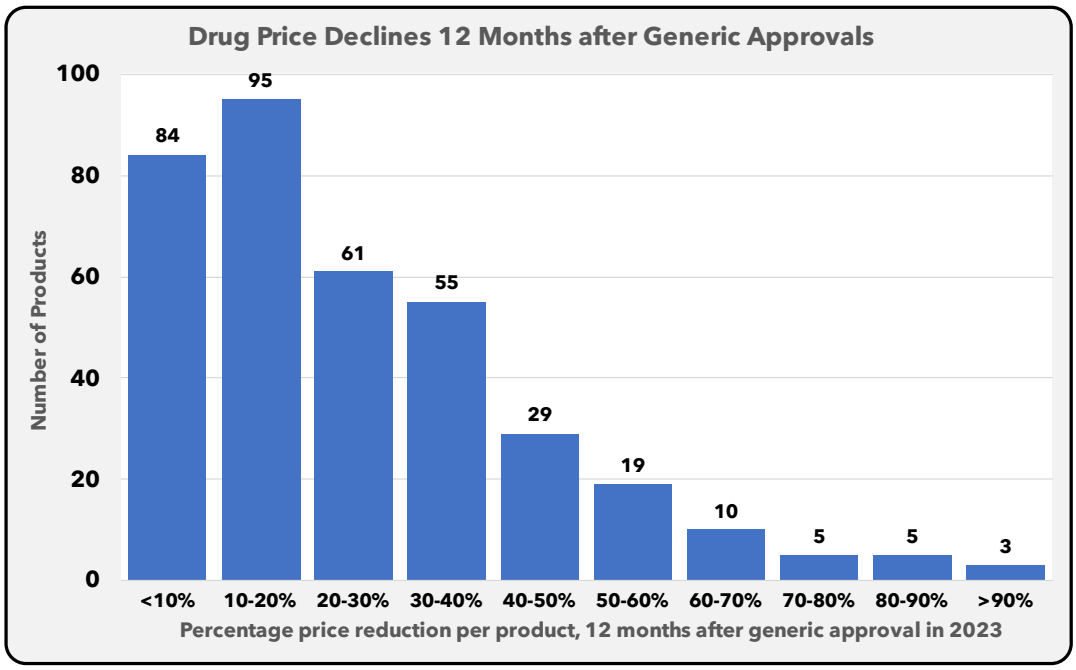
Several products with relatively large price declines also resulted in substantial total savings, including the previously discussed lurasidone hydrochloride oral tablets and the teriflunomide tablets. For example, the average price of a tablet of lurasidone fell from about $43 before the first 2023 generic approval to $0.80 12 months after that approval. This continues the downward trend that generic approvals had on the price of lurasidone hydrochloride tablets that started with the 2022 generic approvals; prior to the 2022 generic approvals the drug was priced at around $47 per tablet. The price declines from the 2023 generic approvals translate to an average 30-day prescription of one tablet per day falling from nearly $1300 to $24. Given the large patient population for this product, this yields a savings of nearly $5.2 billion.

However, price declines for products serving smaller markets may result in meaningful savings for individual patients even though they contribute less significantly to overall savings. For example, the combination oral tablet of famotidine and ibuprofen (brand: *Duexis*), fell 88% from $13 to about $2 per unit. While this drug did not serve a particularly large patient population and only yielded $17 million in total savings, the reduction in price amounted to a savings of just over $1,000 per month for patients on a standard 30-day prescription of 3 tablets per day.

Most of the above discussion is focused on the largest savings and price declines. We also acknowledge that many of the 2023 generic drug approvals were for products entering markets with existing robust generic competition, and so many of the approvals yielded relatively small price declines. As can be seen in Figure 3, price reductions varied significantly across these products. Of the 428 unique drug products for which sales data were available, 84 products experienced modest price decreases of less than 10%, while 95 products saw reductions ranging from 10-20%. An additional 61 products had price decreases between 20-

30%. This sustained competition helps to ensure patients have continued access to affordable medicines.

Figure 3. Distribution of products grouped by percentage price reduction, 2023 generic approvals.



Every generic drug approval contributes to improving patient access, with first generics playing a particularly important role. These initial approvals often drive a disproportionate share of total savings, since without the first entry, no generic alternatives would exist and brand-name prices would remain in place.

Most ANDA approvals, however, are not first generics but instead represent additional entrants into already competitive markets. In such markets, where generic prices are typically low, new approvals may not cause dramatic shifts in cost. Yet even modest price declines accumulate over time—especially for widely used therapies—and this ongoing competition helps preserve affordable access for patients.

In sum, generic drugs remain a cornerstone of affordable access to medicines, and although FDA does not set or regulate drug prices, the agency supports affordability and access by facilitating competition through the generic drug approval process as well as through initiatives like the Drug Competition Action Plan. Sustained attention to fostering competition and supply chain resilience are essential parts of the agency's efforts to ensure high-quality, affordable medicines are available to the American public.

Technical Appendix

A1. Data Sources

The analysis in this report used several publicly available and proprietary data sources:

- FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database (commonly known as the Orange Book): Identifies ANDAs approved in 2023, along with their reference listed drug (usually an NDA) and other bioequivalent generic approvals (ANDAs). Includes approval dates.[11]
- FDA's National Drug Code (NDC) Directory: Links ANDA and NDA numbers to their NDC product identifiers.[12]
- IQVIA National Sales Perspectives: Sales volume ($) and quantity sold (units) at the drug product level, monthly.[13] Links to NDAs and ANDAs via NDCs.
- Bureau of Labor Statistics, Consumer Price Index: Used to inflation-adjust all dollar values, set to a January 2025 base period.[14]

A2. Methods

The analytic dataset in this report was prepared using the following methodology:

- ANDAs approved in 2023 are identified in the Orange Book.
- The reference listed drug (RLD) is identified for each of these ANDAs. The RLD is usually an NDA (brand drug) but can be an ANDA.[15]
    - All other ANDAs sharing these RLDs are identified.
- NDC numbers for each of these NDAs and ANDAs are identified using NDC Directory.
- These NDC numbers are linked to the IQVIA NSP database, and then aggregated to the drug product level, to identify monthly sales for each drug product. All dollars are inflation adjusted to a January 2025 base.

From this analytic dataset we then calculated monthly prices and a baseline price for each product.

- A monthly price for each product, equal to the total dollar sales divided by the total unit sales, is calculated.

[11] https://www.accessdata.fda.gov/scripts/cder/ob, data extracts downloaded May 2025.
[12] https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/default.htm, data extracts downloaded May 2025.
[13] https://www.iqvia.com/locations/united-states/commercial-operations/essential-information/sales-information, data extracts downloaded May 2025.
[14] https://www.bls.gov/cpi/, data extracts downloaded May 2025.
[15] See footnote 3.

The baseline price for each product market was calculated by taking the aggregate sales volume up to 6 months prior to the ANDA approval and dividing that value by the aggregate units sold in the same period:

- If the ANDA approval is the first generic equivalent ever approved for that market, the baseline period is 6 months and will include sales of only the brand product.
- If the ANDA approval was for a product for which there were existing generic approvals, the baseline period includes both brand and generic sales (if any). In addition, the baseline period only includes the months prior to the approval in which the number of competitors was stable (i.e., no new generics entered), up to 6 months.
- Monthly cost-savings, per market, are calculated monthly, starting with the approval month, and continuing for 12 months.

Special calculations were used for the baseline price when there are multiple ANDAs approved for the same RLD in different months throughout the year:

- Multiple ANDAs sharing the same RLD are often approved at different times throughout a year.
- Savings for each ANDA are followed for 12 months. Savings accrued during the overlapping 12-month periods of two ANDAs are not double counted.
    - For example, savings from ANDAs sharing the same RLD approved in January 2023 and June 2023 are calculated using sales data from January 2023 through July 2024.
- The baseline price in place for the 12 months January 2023 through January 2024 is equal to the baseline price prior to the January 2023 approval.

Total overall savings are calculated by taking the sum of all monthly savings across all markets, aggregated by approval year cohorts.

The calculations used to measure prices and savings are formally shown below. We define indices to track approval year cohorts, drug products, months elapsed since ANDA approval, the number of unique producers of each product, and the appropriate number of months used in calculation of the baseline prices.

$Y = [2023]$. Index of approval year cohorts.

$i_Y = [1, 2, \dots, N]$. Index of drug products approved in year Y.

$t = [1, \dots, 12]$. Index of the 12 months following an ANDA approval.

$p_{i,Y} = [1, 2, \dots, P]$. Index of producers making drug product i in year Y.

$a = [1, \dots, A_{i,Y}]$. Index of the months with an ANDA approved for product i in year Y. If ANDA approvals occur in only a single month, then $a = [1]$. If ANDAs for a product are approved every month of the year, then $a = [1, \dots, 12]$.

$b_{i,Y}^{a} = [-m, \dots, -1]$. Index of the months used to calculate the base-period price, for each of the A ANDAs approved for product i in year Y; $m \leq 6$. If no other ANDAs were

approved during the 6 months prior to this approval, then $m = 6$. But if, for example, another ANDA was approved 3 months earlier then $m = 3$. This is necessary so that the base price is calculated during periods when there were no other ANDAs approved which could change the monthly prices.

Using this notation, we can then explicitly write the pricing and savings calculations as follows:

(1) The baseline price for ANDA approval A, for product i in year Y is calculated as:

$$Baseline\ Price = \widehat{Price}_{i,a,Y} = \frac{\sum_{b_{i,Y}^{a}=-m}^{-1}(DollarSales_{i_Y,b,Brand} + DollarSales_{i,b,Generic})}{\sum_{b_{i,Y}^{a}=-m}^{-1}(UnitSales_{i,b,Brand} + UnitSales_{i,b,Generic})}$$

This baseline price is composed of sales observed no more than 6 months prior to the approval, i.e., $m \leq 6$. In the case of first generic approval, the baseline price calculation uses only sales from the brand product, so the dollar and unit sales of the generic products are both taken as zero.

(2) The average price of for product i, in month t, in year Y is calculated as the sum of all sales from all P brand and generic producers of the product:

$$Price_{i,t,Y} = \frac{DollarSales_{i,t,Y}}{Units_{i,t,Y}} = \frac{\sum_{p_{i,Y}=1}^{P}(DollarSales_{i,t,p,Brand} + DollarSales_{i,t,p,Generic})}{\sum_{p_{i,Y}=1}^{P}(UnitSales_{i,t,p,Brand} + UnitSales_{i,t,p,Generic})}$$

This does not need to be indexed by the ANDA approval a as this calculation is simply price observed in each month of the product.

(3) Savings for product i, in month t, in year Y after ANDA approval a is calculated as:

$$Savings_{i,a,t,Y} = Units_{i,t} * (\widehat{Price}_{i,a,Y} - Price_{i,t,Y})$$

(4) Savings from the 12 months following ANDA approval a, for product i, approved in year Y is calculated as:

$$Savings_{i,a,Y} = \sum_{t=1}^{12} Savings_{i,a,t,Y}$$

(5) Total savings from all ANDAs approved in year Y is calculated as the sum of all product-level savings:

$$Savings_Y = \sum_{i=1}^{N_Y}\sum_{a=1}^{A_{i,Y}} Savings_{i,a,Y}$$