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Report

Estimating Cost Savings from New Generic Drug Approvals in 2022

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Access to affordable medicines is an ongoing public health priority for FDA. Each year FDA approves hundreds of new generic drugs that help to stimulate market competition and lower drug prices. The result is improved access to care for millions of Americans.

This study estimates cost savings associated with the 742 generic drug applications fully approved by FDA in 2022. It is a continuation of previous research that used similar methodology to estimate savings from generic drug approvals in earlier years. These results demonstrate that market entry of generic drugs continues to play an important role in lowering drug prices.[1]

In this report, we estimate the total savings accrued during the 12 months following each generic drug approval made in 2022.[2] We highlight savings estimates from approvals that are the first generic versions of the brand product, as these first entrants often yield substantial cost savings. We also discuss how some price declines may benefit individual patients even if they have a relatively small impact on overall savings.

Estimates show that generic drugs approved in 2022 yielded $18.9 billion in total savings during the 12 months following their approvals, of which $5.2 billion is attributed to first generic approvals. The estimates from the 2022 approval cohort are in line with savings estimates from previous approval years. Current results along with results from 2018-2021 abbreviated new drug application (ANDA) approval cohorts are shown below.

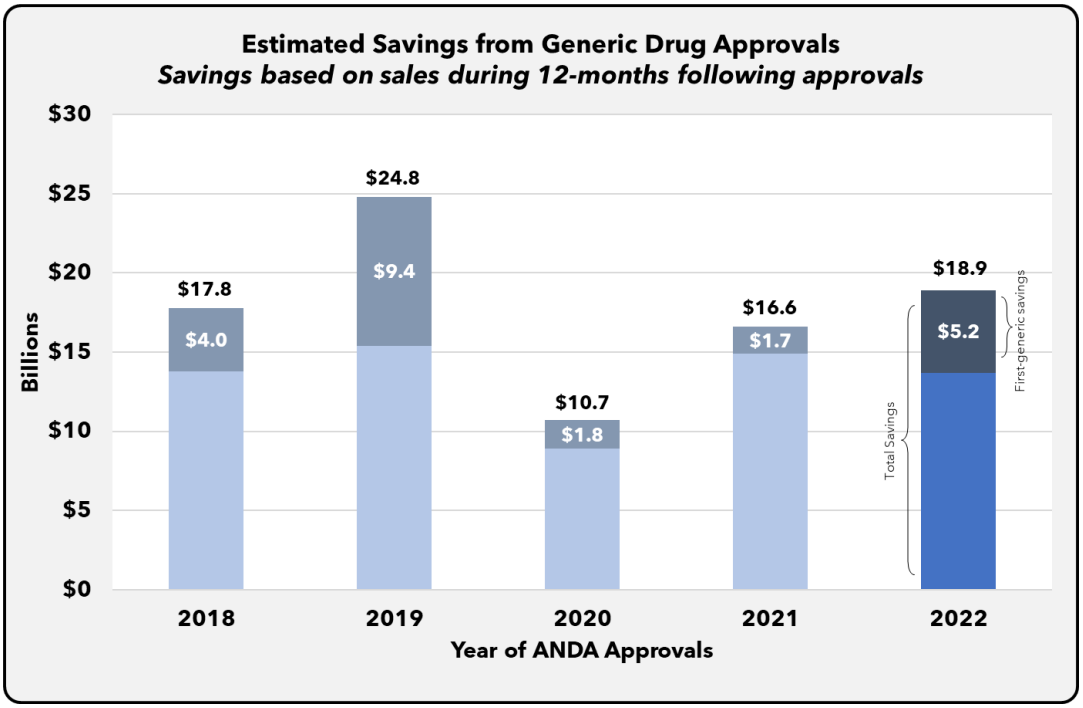
We recognize that in recent years there has been increasing attention on whether business practices in the health care sector that can drive low prices for generic drugs, including purchasing practices, may place pressure on generic companies to adopt strategies to reduce manufacturing costs to potentially unsustainable levels, which in turn may lead to supply disruptions and shortages.[3] This paper focuses on the savings from generic drug approvals in 2022 and this larger policy question it is not the focus of this analysis.

[1] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices

[2] This requires observed sales data through December 2023 to capture savings from approvals made in December 2022, hence the release of this report in 2024.

[3] See U.S. Department of Health and Human Services White Paper: Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States, April 2024, available at https://aspe.hhs.gov/reports/preventing-shortages-supply-chain-vulnerabilities.

Figure 1. Savings from generic drugs approved in 2022, compared to previous years.



Variations in savings over time are largely associated with the mix of products for which generics were approved each year. For example, high-priced, large-market products tend to yield more savings when new generics enter the market compared to products serving smaller markets. Total savings from new generic approvals in years when more of these high-revenue products have generics approved can be significantly larger than in years when relatively few high-revenue products have generic approvals.

Much of the savings from the 2022 approval cohort were driven by first generic approvals and by products with ANDAs approved in 2022 that had first generics approved in earlier years, but whose first commercial marketing of generic versions occurred during our study period.[4]

Along with total savings we also highlight the importance of price reductions associated with these generic approvals. Several products experienced price declines of more than 80%, helping to provide tangible savings for patients relying on these medicines.

[4] Generic drug sponsors with ANDAs approved in previous years may have had market entry delays for various reasons, including as a result of how they resolved any challenges to unexpired patents protecting the brand drug.

1. Data and Methods

We identify all new generic drug applications that were fully approved by FDA in 2022.[5] 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.[6] These sets of bioequivalent brand (NDA) and generic (ANDA) drug applications define what we refer to as a "drug product" throughout this work, representing all approved applications of each drug product.[7]

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.

Prescription drug unit sales and pricing data are from the IQVIA National Sales Perspective (NSP) database.[8] We use the national drug code (NDC) numbers

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

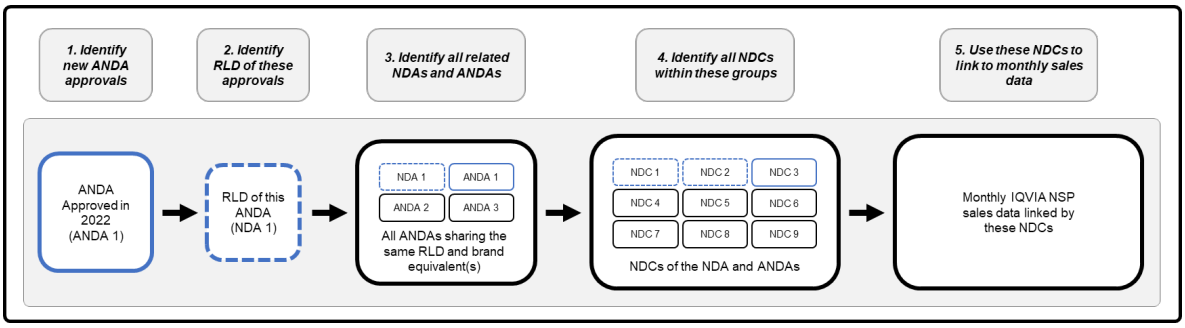
[6] Brand drugs are approved via new drug applications (NDAs); generic drugs are approved via ANDAs. A reference listed drug (RLD) is an approved drug product to which an ANDA applicant must show, among other things, that its proposed generic drug is bioequivalent. A sponsor seeking approval of a generic 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.

[7] 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.

[8] 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.

associated with each NDA and ANDA to identify the correct products in the NSP database. All dollars are inflation-adjusted to a January 2024 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 2022 approval cohort by summing these product-level savings from all products (N_Y) in the given year:

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

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

In 2022 FDA fully approved 742 ANDAs. These ANDAs represent 407 unique drug products. Generic sales data are available for 379 of these drug products, encompassing 673 of the newly approved ANDAs.[9,10]

Table 1. Summary of yearly generic drug approvals and savings, 2018–2022.

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

[9] 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.

[10] 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.

a. Savings

Tracking the sales and prices of these products for the 12 months after each ANDA approval, we estimate that associated price declines led to yearly savings of $18.9 billion. The current results are summarized above in Table 1 along with results from previous ANDA approval cohorts for comparison.

First generic approvals yielded about $5.2 billion in savings during the first twelve months after their initial approval – more than a quarter of the total savings from the 2022 approval cohort. First generics accounted for a greater share of total savings than in previous years as several of these approvals were in relatively large markets, with savings from three of these first generics greater than $1 billion each. Specifically, first generic approvals for lacosamide tablets (brand: Vimpat) yielded over $2 billion in savings, while first generic approvals for pemetrexed (brand: Alimta) and bortezomib (brand: Velcade) each yielded more than $1 billion. Several other first generics each generated savings well over $100 million.

Of the 32 first generics in the 2022 approval cohort, 18 are for generic versions of brand drugs that were new molecular entities (NMEs).[11] These approvals represent the first ever generic versions containing those active pharmaceutical ingredients (APIs), and account for $3.8 billion in savings. The remaining 14 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 $1.4 billion in 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**
Drug products with first generic approvals	*42*	*60*	*46*	*48*	***32***
12-month savings from first generic approvals (billions)	$4.00	$9.40	$1.80	$1.69	**$5.22**
NME drug products with first generic approvals	*22*	*32*	*15*	*21*	***18***
12-month savings for NME first generic approvals (billions)	$2.70	$7.10	$1.10	$1.37	**$3.85**

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

The top ten products in terms of savings account for nearly two-thirds of the total savings, about $12.5 billion. These tend to be high revenue products that saw meaningful price reductions after generic approvals. Six of these products are first generic approvals, while the other four had first generics approved in earlier years but the initial commercial launch of generics did not occur until during this study period when subsequent, non-first generic ANDAs were approved in 2022.

Table 3. Top ten products by estimated 12-month savings, 2022 ANDA approvals.

Drug product	Savings (Millions)	First generic	NME	Share of total savings
Lurasidone Hydrochloride, Tablet;Oral	$4,417		✓	23%
Lacosamide, Tablet;Oral	$2,246	✓	✓	12%
Pemetrexed Disodium, Powder;Intravenous	$1,296	✓	✓	7%
Fingolimod Hydrochloride, Capsule;Oral	$1,190		✓	6%
Bortezomib, Injectable;Intravenous, Subcutaneous	$1,133	✓	✓	6%
Cyclosporine, Emulsion;Ophthalmic	$547	✓		3%
Vasopressin, Solution;Intravenous	$499		✓	3%
Pirfenidone, Tablet;Oral	$451	✓		2%
Lenalidomide, Capsule;Oral	$365		✓	2%
Regadenoson, Solution;Intravenous	$314	✓	✓	2%

Generic versions of lurasidone hydrochloride tablets (brand: Latuda) yielded the greatest savings of any single product. Competition during the 12 months following 2022 generic approvals led to over $4.4 billion in savings. The ANDAs approved in 2022 are not the first generic approvals for this product, as ANDAs were initially approved in 2019. However, no generic sponsors from either the 2022 approval cohort or earlier approval cohorts entered the market until early 2023. Its average price fell by about 95%, while generic market share grew to 9 out of every 10 prescriptions. As a result of the more than 325,000 monthly prescriptions filled for this product, the price decline due to generic entry and robust competition, and the substantial generic market share, generic versions of this product yielded the most savings among all 2022 ANDA approvals.

b. Prices

The total savings from any given product depends on its price before and after generic approval and its market size. Given a price decline, high-revenue products will generate more savings compared to products with less sales. Because of this, some products serving smaller markets can see price declines that yield meaningful savings for individual patients but may not necessarily generate significant total savings.

Here we highlight products with significant price declines. These products all yielded significant savings for individual patients, while the contribution to total savings from each product depends on its market size.

Table 4. Top ten products with the largest price declines in percentage terms, 2022 ANDA approvals.

Product	First Generic	Price: Before Approval	Price: 12 Months After Approval	Percent Reduction of Price	Savings (millions)
Lurasidone Hydrochloride: Tablet;Oral		$47.71	$1.87	96%	$4,417
Bortezomib: Injectable;Intravenous, Subcutaneous	✓	$1,418.31	$101.72	93%	$1,133
Lacosamide: Tablet;Oral	✓	$16.48	$1.34	92%	$2,246
Pemetrexed Disodium: Powder;Intravenous	✓	$1,722.09	$142.15	92%	$1,296
Vigabatrin: For Solution;Oral		$88.26	$9.46	89%	$68
Diclofenac Sodium: Solution;Topical		$15.59	$2.06	87%	$238
Roflumilast: Tablet;Oral		$14.46	$1.95	86%	$211
Lacosamide: Solution;Oral	✓	$2.10	$0.30	86%	$310
Regadenoson: Solution;Intravenous	✓	$45.09	$6.88	85%	$314
Fingolimod Hydrochloride: Capsule;Oral		$289.04	$56.44	80%	$1,190

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 lacosamide tablets and lurasidone hydrochloride tablets. For example, the average price of a tablet of lurasidone fell from about $47 down to less than $2. This translates to an average 30-day prescription falling from about $1400 to less than $60. Given the relatively large number of patients using this medicine, the end result was a total savings of more than $4.4 billion.

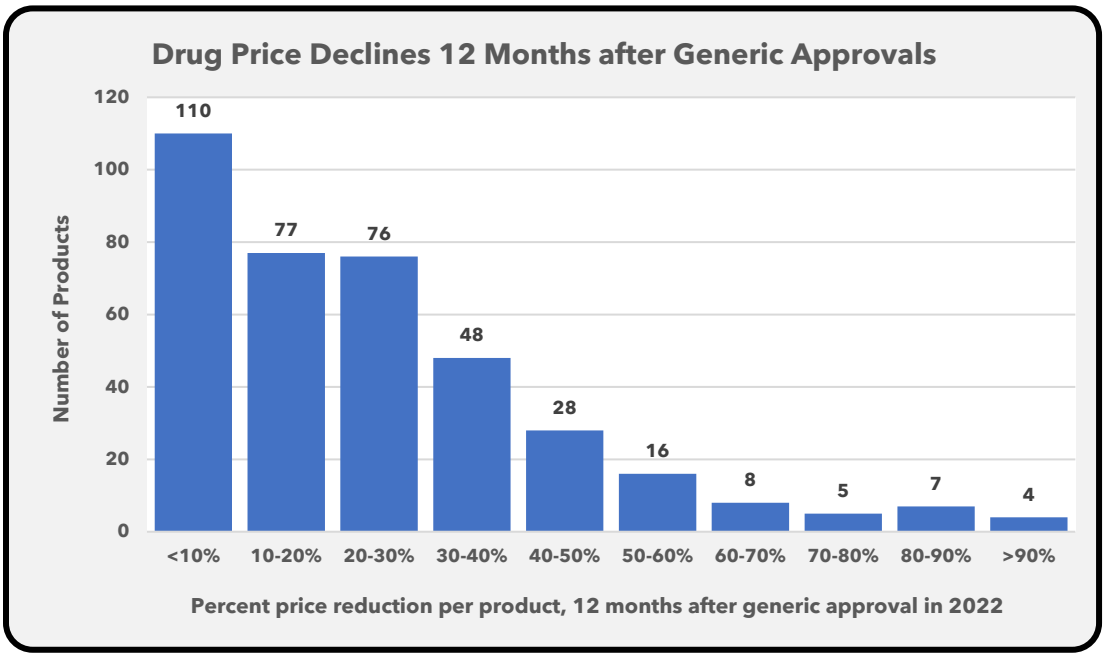
However, price declines for products serving smaller markets may result in meaningful savings for individual patients but a less significant contribution to overall savings.

For example, the price of vigabatrin oral solution (brand: Sabril) fell by about 90% after additional generic versions were approved in 2022. Generics were first approved and marketed in 2017 with subsequent generics approved since then. Soon after the 2022 approvals its price fell from about $88/mL to less than $10/mL. This translates to the average 30-day prescription price falling from around $3800 down to around $500. Given its smaller patient population this price decline yielded $68 million in total savings – a relatively small share of the total. But for patients relying on this medicine this lower price generated an average savings of about $3300 per prescription.

Most of the above discussion is focused on the products with the largest savings and price declines. We also acknowledge that many of the 2022 generic drug approvals were for products entering markets with existing robust generic competition, and so many of the approvals yielded relatively small price declines.

Of the 379 unique drug products for which sales data were available, the price reductions for 110 of the products were less than 10% after generic approvals in 2022. For 77 of the products, the prices fell by between 10-20%, with another 76 products having price reductions of between 20-30%.

Figure 3. Distribution of products grouped by percentage price reduction, 2022 generic approvals.



All generic drug approvals play a role in expanding access to care. This includes the subset of first generics approved each year that often account for an outsized share of total savings. Clearly these first approvals are vital, as without first generic entry there will be no generic versions available and higher prices will persist.

Most ANDAs approved are not first generics and they enter markets that are competitive. Because generic drug prices are often relatively low in these well-established markets, many of these approvals may not have an immediate effect on price. However, even small price reductions promote savings over time, especially for products serving a large patient population. This sustained competition helps to ensure patients have continued access to affordable medicines.

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 2022, along with their reference listed drug (usually an NDA) and other bioequivalent generic approvals (ANDAs). Includes approval dates.[12]
- FDA's National Drug Code (NDC) Directory: Links ANDA and NDA numbers to their NDC product identifiers.[13]
- IQVIA National Sales Perspectives: Sales volume ($) and quantity sold (units) at the drug product level, monthly.[14] 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 2024 base period.[15]

A2. Methods

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

- ANDAs approved in 2022 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.[16]
    - 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 2024 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.

[12] https://www.accessdata.fda.gov/scripts/cder/ob, data extracts downloaded May 2024.
[13] https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/default.htm, data extracts downloaded May 2024.
[14] https://www.iqvia.com/locations/united-states/commercial-operations/essential-information/sales-information, data extracts downloaded May 2024.
[15] https://www.bls.gov/cpi/, data extracts downloaded May 2024.
[16] See footnote 5.

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 2022 and June 2022 are calculated using sales data from January 2022 through July 2023.
- The baseline price in place for the 12 months January 2022 through January 2023 is equal to the baseline price prior to the January 2022 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.

$Y = [2022]$. 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.

$a = [1, \ldots, A_{i,Y}]$. 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 $a = [1, \ldots, 12]$.

$b_{i,Y}^{a} = [-m, \ldots, -1]$. 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:

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