IMPACT ANALYSIS:
ZYDUS LIFESCIENCE, MORAIYA, AHMEDABAD

Half of Zydus' U.S. Sales at Stake, ~60% Without Backup

17th Oct 2026

RESEARCH DELTA

Impact Analysis: Zydus Lifescience, Moraiya

17th Oct 2026

Zydus Moraiya Facility Received 5 Form 483 Observations: Half of Zydus' U.S. Sales at Stake, ~60% Without Backup

Zydus Lifesciences' Moraiya manufacturing plant in Ahmedabad was inspected by the USFDA from October 5 to October 13, 2026, and the inspection concluded with five observations. Details of the observations have not been disclosed. The site is important because it generates of Zydus' total U.S. sales*

- **Facility Profile:** The plant has 89 products (87 ANDAs and 2 NDAs), mainly oral solids along with transdermal, injectable and other forms. The top 10 products contribute ~26% of Zydus' total U.S. sales*. Seven of the top 10 ( ) have backup manufacturing, so the largest products look relatively protected.
- 13 products have no backup, market share >20% and sales >$3 Mn, so they are the most likely to face shortages. Together they represent of Zydus' U.S. sales*:

  The is the largest product at the site and has only 3 competitors, so it is the most likely to create a market gap. Competitors should track supply and pricing in these products. *(More detail of this 13 Products given in **Table 1**)*
- The site has recovered from OAI before, moving from OAI (May 2019) to VAI (August 2022), which shows earlier remediation worked.
- However, the most recent classification was OAI (January 2023), so two of the last four inspections were OAI. Five observations at a site with this record carry a higher chance of escalation than at a clean site.
- **Conclusion:** This inspection matters more to Zydus than the observation count suggests. About of its U.S. sales* comes from this one site, and of its U.S. sales* has no alternate source. Given the OAI history, USFDA is likely to look closely at Zydus' response, so the quality of the corrective actions and any follow-up inspection will shape the final classification. Competitors should watch the and the other products with **no backup** facility first. For investors, the key question is whether the backup sites, which cover of total U.S. sales*, can take extra volume if needed. The 483 contents will show whether these are isolated lapses or repeats of the earlier OAI issues.

**Sales as per Medicaid Drug Rebate Program (12-month sales ended Q1-2026). Total U.S. sales of*

CHART 1: PRODUCT SALES FROM MORAIYA FACILITY BACKED UP VS NON-BACKED UP SALES

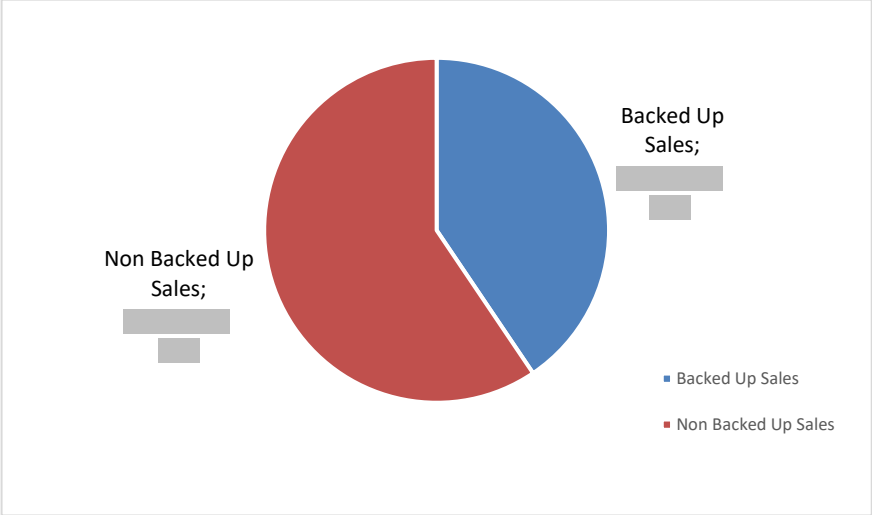


TABLE 1: PRODUCTS LIKELY EXPOSED TO SHORTAGE

Sr. No.	ApplNo	Generic Name	Brand Name	Dosage; Form	ANDA Owner	Other Gx competi -tors	Other Facility for same ANDA	Complexity	Sales* (IN USD MN)	% of US Sales*	Market Share
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
								Total			

Premium Content

Detailed Analyses

TABLE 2: ALL PRODUCTS

Sr. No.	ApplNo	Generic Name	Brand Name	Dosage; Form	ANDA Owner	Other Gx competi -tors	Other Facility for same ANDA	Complexity	Sales* (IN USD MN)	% of US Sales*	Market Share
1	214594	ETHINYL ESTRADIOL; NORELGESTROMIN	ORTHO EVRA	FILM ER; TRANSDERMAL	ZYDUS CADILA	3	-	Patch	**45.24**	**5.72%**	**27.83%**
2											
3											
4											
5											
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Premium Content

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79											
80											
81	Premium Content										
82											
83											
84											
85											
86											
87											
88											
89											
								Total			

Source: - GenUS, Research Delta Advisors | Market share based on total revenue of therapeutically equivalent NDA and ANDAs | ****Sales (IN USD MN):*** *Sales as per Medicaid Drug Rebate Program (12 Months sale ended in Q1-2026) | Total Zydus U.S. sales of ~$ | *Coloured text drugs are currently Discontinued according to FDA & *Coloured drugs are NDA/ RLD*

TABLE 3: INSPECTION HISTORY

Inspection End Date	Classification
05-03-2019	Official Action Indicated (OAI)
03-22-2019	No Action Indicated (NAI)
08-05-2022	Voluntary Action Indicated (VAI)
01-27-2023	Official Action Indicated (OAI)

--------End of the Report--------