Oregon Prescription Drug Affordability Board

Manufacturer feedback submission

Drug under review	Humulin R U-500 concentrated (insulin regular)
Manufacturer	Eli Lilly

Publication note: The information below was submitted by the manufacturer through the Oregon Prescription Drug Affordability Board manufacturer feedback form. Responses are presented as submitted, with minor formatting changes. Blank survey fields are identified as "No response provided." Contact and other form fields identified as not for public posting have been omitted. Manufacturer-submitted statements have not been independently verified unless otherwise stated in the drug review packet.

Manufacturer Responses

Question 1. Select the name of the drug.

Humulin R U-500 concentrated (insulin regular)

Question 2. FDA approval pathway (select all that apply)

No response provided.

Question 3. Year of the first FDA approval

No response provided.

Question 4. Is the drug currently marketed in Oregon?

No

Question 5. Number of FDA-approved therapeutic alternatives for the primary indication

No response provided.

Question 6. Are generic or biosimilar versions FDA-approved?

No response provided.

Question 7. Is the drug considered first-in-class for its primary indication?

No response provided.

Question 8. Does the drug currently have FDA recognized market exclusivity?

No response provided.

Question 9. Type of exclusivity (select all that apply)

No response provided.

Question 10. Earliest known expiration of exclusivity or patent protection

No response provided.

Question 11. Does the drug have orphan drug designation from the FDA to prevent, diagnose or treat a rare disease or condition?

No response provided.

Question 12. Does the drug have FDA approval to prevent, diagnose or treat diseases or conditions that are not considered rare diseases?

No response provided.

Question 13. Does the manufacturer provide price concessions (rebates, discounts, etc.) for the drug in the U.S. market?

No response provided.

Question 14. Types of price concessions offered (select all that apply):

No response provided.

Question 15. Primary entities that receive price concessions (select all that apply):

No response provided.

Question 16. Does the manufacturer offer patient financial assistance programs related to this drug?

No response provided.

Question 17. Types of patient assistant offered (select all that apply):

No response provided.

Question 18. Are patients with public coverage (Medicare, Medicaid) eligible for any assistance?

No response provided.

Question 19. Are patients without public or private insurance eligible for any assistance?

No response provided.

Question 20. Is the drug commonly subject to utilization management (e.g., prior authorization or step therapy)?

No response provided.

Question 21. Which factors most influence the drug's list price over time? (select up to two)

No response provided.

Question 22. Does the manufacturer believe the drug's current pricing aligns with its clinical value?

No response provided.

Question 23. Any additional information the manufacturer chooses to provide.

Humulin RU-500 NDC 00002-8501-01 is not currently marketed in the US. The Humulin RU-500 Kwikpen is marketed in the US and information was submitted via a separate form.