

Date: February 10, 2017
To: FDA Steven Elliott

From: Clinipak Ltd.

Subject: K106334 RTA Response number 26

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Response to number 26 – Shelf life.

Shelf life recommendation is 5 years.

Permeability tests were carried out on both Gorilla Bags and Dry Gorilla Bags.

The results were as below:

	<i>New sample</i>	<i>5 year old sample</i>
<i>Gorilla Bags</i>	1980 l/m ² /s	1690 l/m ² /s
<i>Gorilla Bags DRY</i>	920 l/m ² /s	940 l/m ² /s

We therefore from the data above can recommend a shelf life of 5 years as the permeability of this product is well in excess of the 500 l/m²/s recommended air permeability Clinipak's pass criteria.

Gorilla Bags are manufactured to the same specification in colours purple, red, yellow & orange. The pass rate above of 500 l/m²/s pass rate covers all Gorilla Bags in any of these colours as colour does not affect air permeability.



Summary

Air Permeability Pass criteria for Gorilla Bags/ Gorilla Bags DRY = 500 l/m²/s

This includes all products encompassed in the Gorilla Bags/ Gorilla Bags DRY family
in all colours

<i>Air permeability test</i>	
Gorilla Bags (5 YEAR OLD)	PASS
Gorilla Bags Dry (5 YEAR OLD)	PASS

Approved by Julian Gilbert (Quality Manager) Date 10th Feb 2017

