

# FDA Home<sup>3</sup> Drug Databases<sup>4</sup> Orange Book<sup>5</sup>

# **Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations** Search results from the "OB\_Rx" table for query on "021462."

Active Ingredient:	PEMETREXED DISODIUM			
Dosage Form;Route:	INJECTABLE; IV (INFUSION)			
Proprietary Name:	ALIMTA			
Applicant:	LILLY			
Strength:	EQ 500MG BASE/VIAL			
Application Number:	N021462			
Product Number:	001			
Approval Date:	Feb 4, 2004			
Reference Listed Drug	Yes			
RX/OTC/DISCN:	RX			
TE Code:				
Patent and Exclusivity Info for this product: View				
Active Ingredient:	PEMETREXED DISODIUM			
Dosage Form;Route:	INJECTABLE; IV (INFUSION)			
Proprietary Name:	ALIMTA			
Applicant:	LILLY			
Strength:	EQ 100MG BASE/VIAL			
Application Number:	N021462			
Product Number:	002			
Approval Date:	Sep 7, 2007			
Reference Listed Drug	Yes			
RX/OTC/DISCN:	RX			
TE Code:				
	A 10 10 10 10			

Patent and Exclusivity Info for this product: View

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FDA/Center for Drug Evaluation and Research Office of Generic Drugs Division of Labeling and Program Support Update Frequency: Orange Book Data - **Monthly** Generic Drug Product Information & Patent Information - **Daily** Orange Book Data Updated Through October 2015 Patent and Generic Drug Product Data Last Updated December 11, 2015

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### Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations Patent and Exclusivity Search Results from query on Appl No 021462 Product 001 in the OB\_Rx list.

### Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N021462	001	5344932	Jul 24, 2016	Y	Y		
N021462	001	5344932*PED	Jan 24, 2017				
N021462	001	7772209	Nov 24, 2021			U - 1077	
N021462	001	7772209	Nov 24, 2021			U - 1296	
N021462	001	7772209*PED	May 24, 2022				

### **Exclusivity Data**

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration	
N021462	001	PED	Sep 17, 2014	
N021462	001	M - 122	Oct 17, 2015	

#### Additional information:

- 1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
- 2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.

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- 5. ../default.cfm
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