



U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

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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:

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FDA/Center for Drug Evaluation and Research

Office of Generic Drugs

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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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