



SEP 30 2005

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United States Patent and Trademark Office  
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Office of Regulatory Policy  
HFD - 13  
5600 Fishers Lane,  
Rockville, MD 20857

Attention: Claudia Grillo

Dear Ms. Axelrad:

The attached application for patent term extension of U.S. Patent No. 5,661,136 was filed on February 25, 2005, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, CLOLAR™ (clofarabine), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7744 (telephone) or (571)273-7744 (facsimile).

Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Anthony M. Insonga  
Jones Day  
222 East 41st Street  
New York, NY 10017

## Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code
<u>021673</u>	001	4918179	JUN 14,2005	Y		
<u>021673</u>	001	5384310	MAY 23,2009	Y	Y	
<u>021673</u>	001	5661136	AUG 26,2014			<u>U-626</u>

## Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
<u>021673</u>	001	<u>ODE</u>	DEC 28,2011
<u>021673</u>	001	<u>NCE</u>	DEC 28,2009
<u>021673</u>	001	<u>PED</u>	JUN 28,2010
<u>021673</u>	001	<u>PED</u>	JUN 28,2012

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- . 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).
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- . 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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FDA/Center for Drug Evaluation and Research

Office of Generic Drugs

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Orange Book Data Updated Through August, 2005

Patent and Generic Drug Product Data Last Updated: September 29, 2005