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APR 17 2001

David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 5,514,650, was filed on March 23, 2001, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, CANCIDAS® (caspofungin acetate), 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 sixty days 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, 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.

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

cc: Valerie J. Camara
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01E-0225

LETI

PATENT TERM EXTENSION AND NEW PATENTS - April 6, 2001
DOCKET NUMBER *95S-0117
*PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL USE EXPIRES	EXCLUS CODE	EXCLUS EXPIRES
021205 001	ABACAVIR SULFATE;TRIZIVIR	6180639	JAN 30, 2018	U-248	
021082 001	ACETAMINOPHEN;TAVIST ALLERGY/SINUS			NC	MAR 01, 2004
020760 001	ALATROPLOXACIN MESYLATE;TROVAN PRESERVATIVE	6194429	JUL 23, 2018		
020760 002	ALATROPLOXACIN MESYLATE;TROVAN PRESERVATIVE	6194429	JUL 23, 2018	NCE	DEC 18, 2002
020560 001	ALENDRONATE SODIUM;FOSAMAX	6194004	DEC 02, 2012		
021107 001	ALOSETRON HYDROCHLORIDE;LOTRONEX	5360800	FEB 02, 2010		
021078 001	ATOVAQUONE;MALARONE	6166046	NOV 25, 2013	NC	JUL 14, 2003
		5053432	OCT 01, 2008		
021078 002	ATOVAQUONE;MALARONE PEDIATRIC	5053432	OCT 01, 2008	NC	JUL 14, 2003
018874 001	CALCITRIOL;CALCIJEX	4308264	JAN 28, 2001		
		6051567	AUG 02, 2019		
		4308264*PED	JUL 28, 2001		
		6051567*PED	FEB 02, 2020		
018874 002	CALCITRIOL;CALCIJEX	4308264	JAN 28, 2001		
		6051567	AUG 02, 2019		
		4308264*PED	JUL 28, 2001		
		6051567*PED	FEB 02, 2020		
>ADD> 021227 001	CASPOFUNGIN ACETATE;CANCIDAS	5952300	MAR 28, 2017	NCE	JAN 26, 2006
>ADD>		5378804	MAR 16, 2013		
>ADD>		5514650	MAR 16, 2013		
>ADD>		5792746	MAR 16, 2013		
>ADD> 021227 002	CASPOFUNGIN ACETATE;CANCIDAS	5952300	MAR 28, 2017	NCE	JAN 26, 2006
>ADD>		5378804	MAR 16, 2013		
>ADD>		5514650	MAR 16, 2013		
>ADD>		5792746	MAR 16, 2013		
>ADD> 019111 001	CHLORPHENIRAMINE POLISTIREX;TUSSIONEX	4762709	AUG 09, 2005		
>ADD> 021022 001	CICLOPIROX;PENLAC	4957730	SEP 18, 2007	U-379	
021005 001	DICLOFENAC SODIUM;SOLARAZE			NP	OCT 16, 2003
>ADD> 020623 001	DOLASETRON MESYLATE MONOHYDRATE;ANZEMET	4906755	JUL 02, 2011		
>ADD> 020623 002	DOLASETRON MESYLATE MONOHYDRATE;ANZEMET	4906755	JUL 02, 2011		
>ADD> 020624 001	DOLASETRON MESYLATE MONOHYDRATE;ANZEMET	4906755	JUL 02, 2011		
020164 002	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122	
		4692435	DEC 24, 2004	U-123	
		5389618	FEB 14, 2012		
020164 003	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122	
		4692435	DEC 24, 2004	U-123	
		5389618	FEB 14, 2012		
020164 004	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122	
		4692435	DEC 24, 2004	U-123	
		5389618	FEB 14, 2012		
020164 005	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122	
		4692435	DEC 24, 2004	U-123	
		5389618	FEB 14, 2012		
020164 006	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-123	
		4692435	DEC 24, 2004		
		5389618	FEB 14, 2012		