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JAN 31 2005

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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. 6,017,927 was filed on December 20, 2004, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, VESicare® (solifenacin succinate), 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

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

cc: Susan J. Mack
Sughrue Mion PLLC
2100 Pennsylvania Ave. NW
Washington DC 20037-3212

2005E-0235

LET 1

Proprietary Name Search Results from "OB_Rx" table for query on "VESicare."

Appl No	TE Code	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
<u>021518</u>		Yes	SOLIFENACIN SUCCINATE	TABLET; ORAL	10MG	VESICARE	YAMANOUCI
<u>021518</u>		No	SOLIFENACIN SUCCINATE	TABLET; ORAL	5MG	VESICARE	YAMANOUCI

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FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
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Patent Data Last Updated: January 28, 2005

Patent and Exclusivity Search Results from query on Appl No 021518 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
021518	001	6017927	DEC 27,2015	Y	Y	

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
021518	001	NCE	NOV 19,2009

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 submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor and are detailed in the above table.
 3. 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.
 4. *PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with *PED as was done prior to August 18, 2003. Patents with *PED added after August 18, 2003 will not contain any information relative to the patent itself other than the *PED extension. Information related specifically to the patent will be conveyed on the original patent only.
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