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UNITED STATES DEPARTMENT OF COMMERCE  
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Washington, D.C. 20231

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In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,145,863

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,145,863, which claims a method of using the human drug product PHOTOFRIN® (porfimer sodium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 916. U.S. Patent No. 5,145,863 has an original expiration date of June 12, 2007, subject to the provisions of 35 U.S.C. § 41(b). Accordingly, extension of the patent for 916 days will result in an extended expiration date of December 14, 2009.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 916 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of April 4, 1997 (62 Fed. Reg. 16,163). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (3,441 - 2,858) + 624 \\ &= 916 \text{ days} \end{aligned}$$

Since the regulatory review period began November 11, 1984, before the patent issued (September 8, 1992), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From November 11, 1984 to September 8, 1992 is 2,858 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(e)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

|                              |   |                                          |
|------------------------------|---|------------------------------------------|
| U.S. Patent No.              | : | 5,145,863                                |
| Granted                      | : | September 8, 1992                        |
| Original Expiration Date     | : | June 12, 2007                            |
| Applicant                    | : | Thomas J. Dougherty et al.               |
| Owner of Record              | : | Health Research, Inc.                    |
| Title                        | : | Method to Destroy of Impair Target Cells |
| Classification               | : | 514/410                                  |
| Product Trade Name           | : | PHOTOFRIN® (porfimer sodium)             |
| Term Extended                | : | 916 days                                 |
| Expiration Date of Extension | : | December 14, 2009.                       |

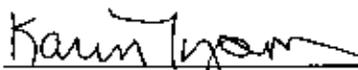
Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703) 308-6916  
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520  
2011 Crystal Drive  
Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



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Karin Tyson  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HPY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

RE: PHOTOFRIN® (porfimer sodium)  
FDA Docket No.: 96E-0509