



MAY 31 2000

OLSON & HIERL, LTD
20 NORTH WACKER DRIVE
36TH FLOOR
CHICAGO IL 60606

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,949,718

NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 4,949,718, which claims the medical device ThermaChoice™ Uterine Balloon Therapy System, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 605 days.

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. Applicant is required to elect a single patent to be extended under 35 U.S.C. § 156 within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to these time periods. In the absence of such request for reconsideration or election of U.S. Patent No. 5,105,808, the Commissioner will issue a certificate of extension, under seal, for a period of 605 days for U.S. Patent No. 4,949,718.

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 May 28, 1999 (64 Fed. Reg. 29046). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (852) + 179 \\ &= 605 \text{ days} \end{aligned}$$

Since the regulatory review period began February 17, 1995, after the patent issue date (August 21, 1990), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(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.

It is noted that applicant has also filed an application for patent term extension of U.S. Patent No. 5,105,808 based upon the regulatory review of ThermaChoice™ Uterine Balloon Therapy System. No more than one patent may be extended for a regulatory review period of a single product. 35 U.S.C. § 156(c)(4). When applications are filed for extension of the terms of different eligible patents based upon the same regulatory review period for a product, the certificate of extension is issued to the eligible patent having the earliest date of issuance unless applicant elects a different eligible patent. Therefore, only one of above-identified patent and U.S. Patent No. 5,105,808 can be extended based upon the regulatory review period of ThermaChoice™ Uterine Balloon Therapy System and applicant should elect the patent to be extended. In the absence of an election by applicant within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in the above-identified patent will be granted based upon the regulatory review period of ThermaChoice™ Uterine Balloon Therapy System. Extension of time under 37 CFR 1.136(a) is NOT permitted.

If the above-identified patent is extended, the following information will be published in the Official Gazette:

U.S. Patent No.	4,949,718
Granted	August 21, 1990
Original Expiration Date	September 9, 2008
Applicant	Robert S. Neuwirth, et al.
Owner of Record	Gynelab Products
Title	Intrauterine Cauterizing Apparatus
Classification	128/401
Product Trade Name	ThermaChoice™ Uterine Balloon Therapy System
Term Extended	605 days
Expiration Date of Extension :	May 7, 2010

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 or (703)872-9411
Attn: Karin Tyson

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

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



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

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

RE: ThermaChoice™
FDA Docket No.: 98E-0850