



JUN -6 2001

Charles E. Van Horn, Esq.  
Finnegan Henderson Farabow Garrett & Dunner  
1300 I Street NW  
Washington DC 20005-3315

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,746,680

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,746,680, which claims the human drug product MERIDIA® (sibutramine hydrochloride monohydrate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

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 Director will issue a certificate of extension, under seal, for a period of five years.

The period of extension has been calculated using the Food and Drug Administration (FDA) determination of the length of the regulatory review period published in the Federal Register of December 28, 1998 (63 Fed. Reg. 71493). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (3,486 - 852) + 837 \\ &= 2,154 \text{ days (6 years)}\end{aligned}$$

Since the regulatory review period began January 23, 1986, before the patent issued May 24, 1988, 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 May 24, 1988 to January 23, 1986 is 852 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(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further 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.	4,746,680
Granted	May 24, 1988

U.S. Patent No.:

4,746,680

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Original Expiration Date<sup>1</sup> June 11, 2002  
Applicant James E. Jeffery et al.  
Owner of Record: Knoll Aktiengesellschaft  
Title: Therapeutic Agents  
Classification: 514/646  
Product Trade Name: MERIDIA® (sibutramine hydrochloride  
monohydrate)  
Term Extended: Five Years  
Expiration Date June , 2007

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

By mail: Assistant Commissioner for Patents      By FAX: (703) 872-9411  
Box Patent Ext.      Attn: Karin Tyson  
Washington, D.C. 20231

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



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

cc David T. Read      RE: MERIDIA®  
Acting Director Health Assessment Policy Staff, CDER      FDA Docket No. 98E-0755  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

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<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).