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1300 I Street, N.W.  
Washington, D.C. 20005-3315

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,670,455

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,670,455, which claims the method of use of the animal drug product DOMITOR® (medetomidine hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156, if elected. The period of extension has been determined to be three years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent and a statement of election 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.

The period of extension has been calculated using the FDA November 29, 1996 (61 Fed. Reg. 60,709). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,294 - 755) + 1,706 \\ &= 2,476 \text{ days} \end{aligned}$$

Since the regulatory review period began April 8, 1985, before the patent issued (June 2, 1987), 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 April 8, 1985 to June 2, 1987 is 755 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:  $2,294 - 755 = 1,539$  days.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The three year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation because the patent was issued and an action described in 35 U.S.C. § 156(g)(6)(B) was taken before the date of enactment of 35 U.S.C. § 156 (November 16, 1988, see 35 U.S.C. § 156(f)(8)). Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed three years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for three 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.

Applicant has also filed an application for patent term extension of U.S. Patent No. 4,544,664 based upon the regulatory review of the product DOMITOR® (medetomidine hydrochloride). No more than one patent may be extended for a single regulatory review period of a product. 35 U.S.C. 156(c)(4). When applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. 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 denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted. (A certificate of extension will be issued to U.S. Patent No. 4,544,664.) However, if U.S. Patent No. 4,670,455 is elected, the Commissioner will issue a certificate of extension, under seal, for a period of three years for the above-identified patent.

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

U.S. Patent No.:	4,670,455
Granted:	June 2, 1987
Original Expiration Date:	December 3, 2005
Applicant:	Raimo E. Virtanen et al.
Owner of Record:	Orzon-Yhtymä Oy
Title:	Method of Bringing About Sedation and/or Analgesia in a Mammal
Classification:	514/396
Product Trade Name:	DOMITOR® (medetomidine hydrochloride)
Term Extended:	Three years
Expiration Date of Extension:	December 3, 2008

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.

  
Karin Tyson  
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 (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

RE: DOMITOR®  
FDA Docket No.: 96E-0194