

Food and Drug Administration  
Rockville MD 20857Re: Neutersol  
Docket Nos.: 03E-0405 and 03E-0452

The Honorable Jon Dudas  
Acting Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office  
Box Pat. Ext.  
P.O. Box 1450  
Alexandria, VA 22313-1450

23 2004

Dear Acting Director Dudas:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,070,808 and 4,937,234, filed by Technology Transfer, Inc., under 35 U.S.C. § 156 *et seq.* We have reviewed the dates contained in the applications and have determined the regulatory review period for Neutersol, the animal drug product claimed by the patents.

The total length of the regulatory review period for Neutersol is 4,222 days. Of this time, 4,188 days occurred during the testing phase and 34 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 512(j) of the Federal Food, Drug, and Cosmetic Act involving this animal drug product became effective: August 27, 1991.

The applicant claims November 14, 1991, as the date the investigational new animal drug application (INAD) became effective. The applicant relied on this date based on a letter sent to the applicant by the document room on November 14, 1991 which provided the INAD number to the applicant. However, this letter was not intended to serve as an official acknowledgment of the INAD filing. FDA records indicate that the filing of a notice of claimed investigational exemption was August 27, 1991, which is considered to be the effective date for the INAD.

2. The date the application was initially submitted with respect to the animal drug product under subsection 512(b) of the Federal Food, Drug, and Cosmetic Act: February 12, 2003.

The applicant claims February 10, 2003, as the date the new animal drug application (NADA) for Neutersol (NADA 141-217) was initially submitted. However, FDA records reveals that NADA 141-217 was submitted on February 12, 2003.

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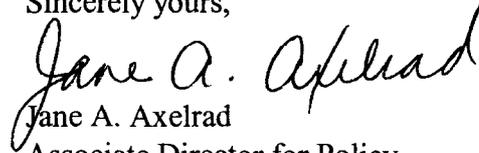
3. The date the application was approved: March 17, 2003.

FDA has verified the applicant's claim that NADA 141-217 was approved on March 17, 2003.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,



Jane A. Axelrad

Associate Director for Policy

Center for Drug Evaluation and Research

cc: Grace J. Fishel  
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