DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Neutersol
Docket Nos. 03E-0405
03E-0452

The Honorable James E. Rogan
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

MAY 18 2003

Dear Director Rogan:

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. The animal drug product claimed by the patents is Neutersol (zinc gluconate), which was assigned NADA No. 141-217.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990).

The NADA was approved on March 17, 2003, which makes the submission of both patent term extension applications on May 14, 2003, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patents are eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

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

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Grace J. Fishel
Suite 220
11970 Borman Drive
St. Louis, MO 63146

03E-0452

LET 3