DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Deramaxx
Docket No.: 03E-0246

7991 '03 NOV -5 A9:11

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

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 5,521,207, filed by G. D. Searle L.L.C., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Deramaxx, the animal drug product claimed by the patent.

The total length of the regulatory review period for Deramaxx is 1,675 days. Of this time, 1,578 days occurred during the testing phase and 97 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: January 21, 1998.

   The applicant claims January 27, 1998, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the date of FDA's official acknowledgement letter assigning a number to the INAD was January 21, 1998, 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: May 17, 2002.

   FDA has verified the applicant's claim that the new animal drug application (NADA) for Deramaxx (NADA 141-203) was initially submitted on May 17, 2002.

3. The date the application was approved: August 21, 2002.

   FDA has verified the applicant's claim that NADA 141-203 was approved on August 21, 2002.

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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

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

cc: James W. Warner
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