APR - 4 2000

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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Washington, D.C. 20231

David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 4,690,951 was filed on February 18, 2000, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, PAYLEAN™ (Ractopamine hydrochloride), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product, or the method of use of manufacturing such a product, which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Any correspondence, especially any change of address for the patent term extension application from applicant, with respect to this matter should be addressed as follows:

By mail:	Commissioner for Patents Box Patent Ext. Washington, D.C. 20231	By hand:	Crystal Plaza Four, Suite 3C23 2201 South Clark Place Arlington, VA 22202
By FAX:	(703) 308-6916 or (703)941-8711 Attn: Karin Tyson		

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

Karin Tyson, Senior Legal Advisor, Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Frederick D. Hunter
Eli Lilly and Company
Patent Division/FDH
Lilly Corporate Center
Indianapolis IN 46285

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