

Exhibit VII

Letter Transmitting NADA to fDA

NEW ANIMAL DRUG APPLICATION
(Drugs for Animal Use)
(Title 21, CFR 514)

Form Approved: OMB No. 0910-0032
Expiration Date: December 31, 1986

NADA _____

GENERIC NAME:

Ractopamine Hydrochloride

PROPRIETARY NAME

PAYLEAN™

TYPE OF SUBMISSION (Check one)

- ORIGINAL APPLICATION (CFR 514.1(a))
 AMENDMENT TO AN UNAPPROVED ORIGINAL APPLICATION (CFR 514.6)
 SUPPLEMENT TO AN APPROVED APPLICATION (CFR 514.8(a))
 AMENDMENT TO AN UNAPPROVED SUPPLEMENT TO AN APPROVED APPLICATION (CFR 514.6)
 SPECIAL SUPPLEMENT TO AN APPROVED APPLICATION - CHANGES BEING EFFECTED (CFR 514.8(a))

NAME OF APPLICANT

Elanco Products Company
Division of Eli Lilly and Company

ADDRESS (Street Number, City, and Zip Code)

Lilly Corporate Center
Indianapolis, IN 46285

No new animal drug application may be processed unless a completed application form has been received (21 CFR 514.1)

INSTRUCTIONS FOR PREPARING AND SUBMITTING THE NEW ANIMAL DRUG APPLICATION

- i. Assemble and bind three identical copies of the submission.
- ii. Identify each front cover with the name of the applicant, the proprietary name, if available, the name of the new animal drug and the dosage form.
- iii. Use separate pages for each numbered heading consistent with subparagraph (1) through (12) of this application form. Number the pages of the new animal drug application. Each copy should bear the same page numbering.
- iv. Each copy of an original new animal drug application shall contain three complete sets of labeling.

v. Submit separate applications for each different dosage form of the drug proposed.

Repeating in each application basic information pertinent to all dosage forms is unnecessary if reference is made to the application containing such information. Such references should be made by volume and page. Include in each application information applicable to the specific dosage form, such as, labeling, composition, stability data, efficacy data, method of manufacture and investigational new animal drug application number.

- vi. Forward amendments, supplements, reports and other correspondence submitted after the original application in the above format. Identify the submission with the assigned NADA number. If the submission is a supplemental application, full information shall be provided on each proposed change concerning any statement made in the approved application.

[NOTE: Only this front page need be submitted with additional or supplemental information.]

vii. Submit to: Food and Drug Administration
Center for Veterinary Medicine
(HFV-16)
5600 Fishers Lane
Rockville, MD 20857

The undersigned official submits this application for a new animal drug pursuant to section 512(b) of the Federal Food, Drug, and Cosmetic Act. It is understood that the labeling and advertising for the new animal drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling which is part of this application and if the article is a prescription new animal drug, it is understood that any labeling which furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for use of the new animal drug will also contain, in the same language and emphasis, information for its use including indications, effects, dosages, routes, methods, and frequency and duration of administration, any relevant hazards, contraindications,

side effects, and precautions contained in the labeling which is part of this application in accordance with 21 CFR 201.105. It is understood that all representations in this application apply to the drug produced until changes are made in conformity with 21 CFR 514.8. It is further understood that new animal drugs as defined in 21 CFR 510.3, intended for use in the manufacture of animal feeds in any State will be shipped only to persons who may receive such drugs in accordance with 21 CFR 510.7.

The official agent by signing below certifies, that the methods, facilities, and controls described under item 5 of this application conform to the appropriate section of the current good manufacturing practice regulations in 21 CFR PART 200.

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, sec. 1001.)

SIGNATURE OF RESPONSIBLE OFFICIAL OR AUTHORIZED AGENT

Stanley E. Tol

DATE RECEIVED:

TITLE OF AUTHORITY

Product Registration Manager

DATE OF APPLICATION

August 27, 1987

FOR FDA USE ONLY

NOTE: This application must be signed by the applicant or by an authorized attorney, agent, or official. If the applicant does not have a place of business within the United States, the application must also provide the name and address of and be countersigned by an authorized agent or official residing or maintaining a place of business within the United States

1. IDENTIFICATION

DATE: August 27, 1987

ORIGINAL APPLICATION:

21 CFR 514
Subpart A, §514.1

NAME OF APPLICANT:

Elanco Products Company
Division Eli Lilly and Company

ADDRESS:

Lilly Corporate Center
Indianapolis, IN 46285

CHEMICAL NAME:

DL-4-hydroxy-•[[[3-(4-hydroxyphenyl)-1-methylpropyl]amino]
methyl]benzenemethanol, hydrochloride

GENERIC NAME:

Ractopamine Hydrochloride

PROPRIETARY NAME:

Paylean™