Approval Date: December 15, 2005

FREEDOM OF INFORMATION SUMMARY

Supplemental New Animal Drug Application

NADA 140-883

LEGEND Multi Dose (hyaluronate sodium)
Injectable Solution

LEGEND Multi Dose Injectable Solution is indicated for the treatment of joint dysfunction of the carpus or fetlock in horses due to non-infectious synovitis associated with equine osteoarthritis

Sponsored by:

Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201

1. GENERAL INFORMATION:

a. File Number:	NADA 140-883
b. Sponsor:	Bayer HealthCare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201 Drug Labeler Code: 000859
c. Established Name:	Hyaluronate sodium
d. Proprietary Name:	LEGEND Multi Dose Injectable Solution
e. Dosage Form:	Injectable Solution
f. How Supplied:	20 mL vials
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	10 mg/mL
i. Route of Administration:	Intravenous
j. Species/Class:	Equine
k. Recommended Dosage:	4 mL (40 mg) injected intravenously. Treatment repeated at weekly intervals for a total of three treatments.
l. Pharmacological Category:	Anti-inflammatory
m. Indications:	LEGEND Multi Dose Injectable Solution is indicated for the treatment of joint dysfunction of the carpus or fetlock in horses due to non-infectious synovitis associated with equine osteoarthritis.

n. Effect of Supplement: Approval of the supplement will add a multiple-dose vial containing the preservative benzyl alcohol.

2. EFFECTIVENESS:

This supplemental NADA does not require re-evaluation of effectiveness data. The effectiveness of LEGEND Multi Dose is based upon the existing LEGEND single dose approval. Please refer to the original NADA 140-883 Freedom of Information (FOI) summary dated September 12, 1991.

3. TARGET ANIMAL SAFETY:

This supplemental NADA does not require re-evaluation of target animal safety data. The safety of LEGEND Multi Dose is based upon the existing LEGEND single dose approval. Please refer to the original NADA 140-883 Freedom of Information (FOI) summary dated September 12, 1991.

4. HUMAN SAFETY:

This drug is intended for use in horses, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this supplemental NADA. Human Warnings are provided on the product label as follows: "Do not use in horses intended for human consumption. Not for use in humans. Keep this and all other drugs out of the reach of children."

5. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that LEGEND Multi Dose when used under the labeled conditions of use is safe and effective for the treatment of joint dysfunction of the carpus or fetlock in horses due to non-infectious synovitis associated with equine osteoarthritis.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise is needed to make a diagnosis of equine osteoarthritis.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

According to the Center's supplemental approval policy (21 CFR 514.106), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

LEGEND Multi Dose is under the following U.S. patent numbers:

U.S. Patent Number	Date of Expiration
4,808,576	April 28, 2006

6. *ATTACHMENTS:*

Facsimile labeling is attached as indicated below:
Vial Label – 20 mL vial
Carton Label – 20 mL vial
Package Insert