

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 140-921

B. Sponsor

Lloyd, Incorporated
604 W. Thomas Avenue, P. O. Box A
Shenandoah, Iowa 51601 U.S.A.

C. Proprietary Name

PrednisTab[®]

D. Established Name

prednisolone, USP

E. Dosage Form

Oral tablet

F. Route of Administration

Oral

G. Dosage Regimen

2.5 mg per 10 lb. (4.5 kg) body weight per day.
Average total daily oral doses for dogs are as follows:

to 20 lb. (2 to 9 kg) body weight.....1.25 to 5 mg

20 to 40 lb. (9 to 18 kg) body weight.....5 to 10 mg

40 to 80 lb. (18 to 36 kg) body weight.....10 to 20 mg

80 to 160 lb. (36 to 73 kg) body weight.....20 to 40 mg

H. Indication

See labeling

I. Effect of Supplement

Provides for a new 20 mg tablet size.

II. EFFECTIVENESS

Refer to the FOI for NADA 140-921 approved November 8, 1991

III. TARGET ANIMAL SAFETY

Refer to the FOI for the original approval for NADA 140-921 approved November 8, 1991.

IV. HUMAN FOOD SAFETY

Data on human food safety, pertaining to consumption of drug residues in food were not required for approval of this supplemental NADA, since the drug is labeled for use in a non-food animal species (dogs).

V. AGENCY CONCLUSIONS

The data submitted in support of this NADA comply with the requirements of Section 512 of the Act and Section 514.111 of the regulations. The data demonstrate that 20 mg PrednisTab® (prednisolone), is safe and effective when used according to the proposed conditions of use.

The drug is restricted to use by or on the order of a licensed veterinarian because a knowledge of veterinary medicine is needed for the accurate diagnosis of conditions for which the drug is indicated and for the determination of the appropriate dose, monitoring of treatment, and adverse reactions.

Under the Center's supplemental approval policy 21 CFR 514.106(b)(2), this is a category II change that did not require reevaluation of the safety or effectiveness data in the parent application.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.