

## **FREEDOM OF INFORMATION SUMMARY**

### **I. GENERAL INFORMATION**

#### **A. File Number**

ANADA 200-108

#### **B. Sponsor**

Phoenix Pharmaceuticals, Inc.  
4621 Easton Road  
P. O. Box 6457-Fairleigh Station  
St. Joseph, Missouri 64506-0457

#### **C. Proprietary Name**

Dexamethasone Solution

#### **D. Established Name**

Dexamethasone

### **II. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS**

Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an in vivo bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, April 1990).

Based upon the formulation characteristics of the generic product, Phoenix Pharmaceutical, Inc. was granted a waiver from conducting an in vivo bioequivalence study for DEXAMETHASONE SOLUTION. The generic and pioneer products contain the same active and inactive ingredients and are administered as injectable solutions.

### **III. HUMAN FOOD SAFETY**

There is no withdrawal period associated with this or the pioneer product; therefore, no human safety data pertaining to residues in food was required. A 24 hour expiry is assigned to this generic product.

#### **IV. AGENCY CONCLUSIONS**

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that DEXAMETHASONE SOLUTION when used under the proposed conditions of use, is safe and effective for its labeled indications.

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.