

Date of Approval: NOV 6 2001

## **FREEDOM OF INFORMATION SUMMARY**

### **ANADA 200-301**

Indication for use: Privasan™ Antiseptic Ointment is used as a topical antiseptic ointment for surface wounds on dogs, cats, and horses.

Sponsored by:

First Priority, Inc.  
1585 Todd Farm Drive  
Elgin, Illinois 60123

## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION:

ANADA:	200-301
Sponsor:	First Priority, Inc. 1585 Todd Farm Drive Elgin, Illinois 60123
Generic Name:	Chlorhexidine Antiseptic Ointment
Trade Name:	Privasan™ Antiseptic Ointment
Dosage Form:	Topical ointment
How Supplied:	1 oz (28 g) tubes, 7 oz (198 g) jars & 16 oz (453 g) jars
How Dispensed:	OTC
Amount of Active Ingredients:	1 % chlorhexidine acetate in a hydrophilic ointment
Route of Administration:	Topical
Species:	Dogs, cats and horses
Pharmacological Category:	Antiseptic
Labeled Dosage & Indications for Use:	Use as a topical antiseptic ointment for surface wounds on dogs, cats and horses.
Pioneer Product/ “Listed Product:	Nolvasan® Antiseptic Ointment NADA 09-782 (Fort Dodge Animal Health)

### 2. TARGET ANIMAL SAFETY and DRUG EFFECTIVENESS

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the 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 is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. 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, October, 2000).

Based upon the formulation characteristics of the generic product, First Priority, Inc. was granted a waiver on June 17, 1999, from conducting an *in vivo* bioequivalence study for Privasan Antiseptic Ointment. The generic and pioneer products are topical ointments, which contain the same active ingredients in the same concentrations as the pioneer, and similar inactive ingredients in a hydrophilic ointment base. The pioneer product, Nolvasan® Antiseptic Ointment, Fort Dodge Animal Health, NADA 9-782, was approved on March 22, 1955.

3. HUMAN SAFETY:

Chlorhexidine diacetate ointment is intended for use only in dogs, cats and horses, which are nonfood animals.

Human Warnings are provided on the product label as follows:

“For Animal use only.

Keep Out of Reach of Children.

Not for use in horses intended for food.”

Human Safety Relative to Possession, Handling, and Administration: Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed under section 512(b) of the Federal, Food, Drug and Cosmetic (FFD&C) Act satisfies the requirements of section 512(n) of the Act and demonstrates that Privasan™ Antiseptic Ointment when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. LABELING:

Attachments:

**Pioneer Labeling:**

1 oz (28 g) tube  
7 oz (198 g) jar  
16 oz (453 g) jar

**Generic Labeling:**

1 oz (28 g) tube  
7 oz (198 g) jar  
16 oz (453 g) jar

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration  
Freedom of Information Staff (HFI-35)  
5600 Fishers Lane  
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6500.