

Date of Index Listing: February 27, 2015

FREEDOM OF INFORMATION SUMMARY

ORIGINAL REQUEST FOR ADDITION TO THE INDEX OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL  
DRUGS FOR MINOR SPECIES

MIF 900-010

F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE

(benzalkonium chloride, polyhexanide and cypermethrin topical solution)

Raptors, Pet Birds, Captive Small Mammals, Captive Reptiles, and  
Captive Exotic/Zoo Mammals

"For use as a topical antiseptic for surface wounds, to repel flies, and to treat infestations due to fly strike in raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals."

Requested by:

Health and Hygiene (Pty) Ltd

**TABLE OF CONTENTS**

I. GENERAL INFORMATION: .....1

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY: .....2

    A. Findings of the Qualified Expert Panel: .....2

    B. Literature Considered by the Qualified Expert Panel: .....4

III. USER SAFETY: .....9

IV. AGENCY CONCLUSIONS: .....9

    A. Determination of Eligibility for Indexing: .....9

    B. Qualified Expert Panel: .....10

    C. Marketing Status: .....10

    D. Exclusivity: .....10

    E. Attachments: .....10

**I. GENERAL INFORMATION:**

- A. File Number:** MIF 900-010
- B. Requestor:** Health and Hygiene (Pty) Ltd  
P.O. Box 906  
Florida Hills, 1716, South Africa
- U.S. Agent:  
Kristen V. Khanna, PhD, MBA  
Animal Clinical Investigation, LLC  
4926 Wisconsin Ave, NW  
Washington, D.C. 20016
- C. Proprietary Name(s):** F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE
- D. Established Name(s):** Benzalkonium chloride, polyhexanide and cypermethrin topical solution
- E. Pharmacological Category:** Antimicrobial and Insecticide
- F. Dosage Form(s):** Topical solution
- G. Amount of Active Ingredient(s):** 0.405 g benzalkonium chloride and 0.03 g polyhexanide/100 mL and 0.25 g cypermethrin/100 g
- H. How Supplied:** 100 mL and 500 mL bottles
- I. How Dispensed:** Over-the-Counter (OTC)
- J. Dosage(s):** Applied topically to wound site
- K. Route(s) of Administration:** Topical
- L. Species/Class(es):** Raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals (use is prohibited in food-producing species such as rabbits, deer, ducks, pigeons, and turtles)
- M. Indication(s):** For use as a topical antiseptic for surface wounds, to repel flies, and to treat infestations due to fly strike in raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals.

## II. EFFECTIVENESS AND TARGET ANIMAL SAFETY:

In accordance with 21 CFR part 516, a qualified expert panel evaluated the target animal safety and effectiveness of F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE, for use as a topical antiseptic for surface wounds, to repel flies, and to treat infestations due to fly strike in raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals, to determine whether the benefits of using F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE for the proposed uses outweigh its risks to the target animals. The members of the qualified expert panel were:

David Sanchez-Migallon Guzman, LV, MS, Diplomate ECZM (Avian), Diplomate ACZM;

Neil A. Forbes, BVetMed, Diplomate ECZM (Avian), FRCVS;

Michelle Barrow, BSc, BVMS ZooMed (Avian), PF Cert Conservation Medicine MRCVS;

Michael Stanford, BVSc, FRCVS; and

Jaime Samour, MVZ, PhD, Diplomate ECZM (Avian).

### A. FINDINGS OF THE QUALIFIED EXPERT PANEL:

Based on a thorough review of the literature, data from laboratory studies, and their own personal experience, the qualified expert panel concluded that F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE is both effective and safe for the following uses:

For use as a topical antiseptic for surface wounds, to repel flies, and to treat infestations due to fly strike in raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals.

Benzalkonium chloride is a nitrogenous cationic surface-acting agent belonging to the quaternary ammonium group. Polyhexanide, also known as PHMB and hexamethylene biguanide, is a cationic biocide. Benzalkonium chloride and polyhexanide are used in a number of common household products such as face and hand washes and as an all-purpose cleaner and disinfectant, respectively.

Cypermethrin is a synthetic pyrethroid insecticide used for control of agricultural insect pests, as spot treatment to control insect pests in houses, and as an insect repellent for animals.

In order to assess the safety F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE, the qualified expert panel performed a review of six laboratory toxicology studies, available literature, and their own experience using the drug. Laboratory studies reviewed by the expert panel included: acute oral toxicity in rats, acute dermal toxicity in rats, acute dermal irritation in guinea pigs, acute sensitization in guinea pigs, acute inhalation toxicity in rats, and acute eye irritation in rabbits.

The LD50 after oral dosing in rats was between 2000 and 5000 mg/kg, which the panel calculated to be a dose of 4-10 L of F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE per kg bodyweight.

In the acute inhalation toxicity study, rats were dosed with >2 mg/L air for 4 hours. Mild respiratory distress was seen initially but resolved after the first hour of dosing, and no gross findings were found at necropsy.

In the acute dermal irritation study, a 6 cm<sup>2</sup> area of skin was shaved on three guinea pigs. The drug was applied to the shaved area and remained in contact with the skin for 4 hours. Two of the three study animals had mild erythema at the application site at the end of the dosing period. The erythema resolved in both animals within 24 hours after dosing without treatment.

The acute eye irritation study was conducted in three New Zealand white rabbits. The drug was applied to the right eye of each rabbit. After one hour of contact, mild swelling and eversion of the eyelids was noted in the treated eyes. These signs decreased within 24 hours after dosing and resolved in all animals within 72 hours after dosing without treatment.

Results of the acute dermal toxicity and acute sensitization studies were negative. Additionally, the expert panel stated in their report that they have used F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE extensively in practice without adverse reactions.

To determine the effectiveness of F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE for the proposed intended uses, the expert panel performed a review of available literature, in vitro laboratory studies, and their own personal experience administering the drug. The antimicrobial mechanism of action of F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE is disruption of the cell membrane causing loss of essential cell components. As part of their determination of effectiveness, the expert panel considered the need for both of the antimicrobial active ingredients (benzalkonium chloride and polyhexanide) in the drug formulation. The panel states that studies have shown that benzalkonium chloride and polyhexanide function more efficiently in different environments. The two active ingredients are more effective and have a larger spectrum of activity when administered in combination rather than individually (Brown, 2008; Wattanaphansak et al., 2010).

Laboratory studies reviewed by the expert panel include in vitro bactericidal, fungicidal, virucidal, and sporicidal tests to support antimicrobial activity and in vitro studies with adult, larval, and the ova of *Lucilia cuprina*, commonly known as the Australian sheep blowfly, to support insecticidal activity. The in vitro antimicrobial studies were conducted with a separate product marketed by the requestor which contains only benzalkonium chloride and polyhexanide as the active ingredients in solution form. The tests were conducted to support registration of this product by the U.S. Environmental Protection Agency (EPA). An acceptable reduction in microbial counts was achieved in all tests and the product is registered by the EPA as a disinfectant at a concentration of 0.0216% benzalkonium chloride and 0.0016% polyhexanide.

The in vitro insecticidal studies reviewed by the panel were a South African Bureau of Standards (SABS) knockdown study with adult *L. cuprina* and two additional studies to determine the effectiveness of F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE against the larvae and ova of *L. cuprina*. In the knockdown study, 100% mortality was achieved against adult flies within 24 hours after exposure to the drug. In the study using *L. cuprina* larvae, 89.2% mortality was achieved, with the remaining 10.8% of larvae considered moribund, within 24 hours after exposure to the drug. There was 100% mortality in the treated larvae 120 hours after exposure to the drug. In the study using *L. cuprina* ova, no treated eggs hatched after exposure to the drug.

The report contains multiple examples of successful uses of the drug either provided in literature or when administered by the expert panel members themselves. They list a multitude of species which have received topical application of the drug to treat dermal wounds, abrasions, puncture wounds, maggot infestations, and fly strike wounds (myiasis). Some of the species listed are non-domestic felids, elephants, antelope, hyena, non-human primates, rodents, raptors, ostriches, tortoises, snakes, and lizards.

The expert panel states that F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE is of particular benefit when treating non-domesticated zoological and wildlife patients who tend to live in outdoor enclosures where flies can come in contact the wound site. In addition, daily wound management is generally dangerous and impractical with these animals. Panel members have found the drug to be effective in controlling infection and myiasis which may arise when dart puncture wounds and open wounds are left, by necessity, to heal by second intention.

#### **B. LITERATURE CONSIDERED BY THE QUALIFIED EXPERT PANEL:**

1. Bailey, T.A. & Sullivan, T. (2001). Aerosol therapy in birds using a novel disinfectant. *Exotic DVM*, 3.4.
2. Bailey, T.A. (2002). Aspergillosis: Therapy and prevention in zoo animals with emphasis on raptors. *Falco*, 20, 18-22.
3. Bailey, T.A. (2008). Raptors: Respiratory problems. In J. Chitty & M. Lierz (Eds.), *BSAVA Manual of raptors, pigeons and passerine birds* (pp. 223-234). Gloucester, UK: British Small Animal Veterinary Association.
4. Bailey, T.A. & Lloyd, C. (2008). Raptors: Disorders of the feet. In J. Chitty & M. Lierz (Eds.), *BSAVA Manual of raptors, pigeons and passerine birds* (pp. 176-189). Gloucester, UK: British Small Animal Veterinary Association.
5. Bailey, T.A. (2008). Disease of and medical management of Houbara bustards and other *Otididae*. Commissioned by Environmental Agency Abu Dhabi.
6. Barrows, M. (2007). F10, A novel product range most suited to zoological medicine. *The Facts*, 6. Retrieved from [www.healthandhygiene.co.za](http://www.healthandhygiene.co.za).
7. Brown, W.E. (1996, revised 2008). Clean and mean: Effective targeting for disinfectants and disinfectant combinations. Alberta Agricultural and Rural Development. [www1.agric.gov.ab.ca/\\$department/deptdocs.nsf/all/pou3653](http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/pou3653).

8. Chitty, J. (2002). "A Novel Disinfectant in Psittacine Respiratory Disease." *23<sup>rd</sup> Ann. Conf. Expo. Assoc. Avian Vet*, (pp.25-28).
9. Chitty, J. (2005). Respiratory disease in exotics and small mammals. *Veterinary Times*, 35(38).
10. Chitty, J. (2006). The injured bird of prey Part 2. *UK Vet*, 11(4).
11. Chitty, J. (2010). Birds of prey. In A. Meredith & C. Johnson Delaney (Eds.), *BSAVA Manual of Exotic Pets* (p. 210). Gloucester, UK: British Small Animal Veterinary Association.
12. Copper, J.E. (2002). *Birds of prey: Health and diseases*, 3<sup>rd</sup> Ed. Wiley-Blackwell.
13. Davies, R.R. (2003). Respiratory disease in psittacine birds. *UK Vet*, 8(8).
14. Drake, G., Koepfel, K. & Barrows, M. (2010). Disinfectant (F10SC) nebulisation in the treatment of 'red leg syndrome' in amphibians. *Vet Rec*, 166(19).
15. Elliot, D. (2007). Some experiences in the use of F10 in the treatment of reptiles. *The Facts*, 7. Retrieved from [www.healthandhygiene.co.za](http://www.healthandhygiene.co.za)
16. Forbes, N.A. (2001). Aspergillosis in raptors. *International Falconer*, May, 44-47.
17. Forbes, N.A. (2004). Emergencies and first aid: A course for rehabilitators and falconers. (course notes).
18. Forbes, N.A., Lloyd, E. & Temperley, J.P. (2005). "Macro-broth Minimum Inhibitory Concentration (MIC) and Agar Disc-Diffusion Zone of Inhibition Determination on F10SC Disinfectant." *BVZS Autumn Conference*, (pp. 98-101).
19. Forbes, N.A. (2005). "Biosecurity of the Avian Hospital Facility by Design, Protocols and Procedures." *Conference of the European Association of Avian Vets*. Arles, FR.
20. Forbes, N.A. (2005). Hunting with birds of prey guidelines. Association of Masters of Foxhounds. UK.
21. Forbes, N.A. (2006). Raptor management for health and longevity. *Vets Now*. Swindon, UK. (training course notes).
22. Forbes, N.A. (2006). Pet parrots day course. Great Western Referrals. Swindon, UK. (course notes).
23. Forbes, N.A. (2006). Zoo bird staff training course. Great Western Referrals. Swindon, UK. (course notes).
24. Forbes, N.A. (2006). Management of risks associated with pigeon racing in the case of avian influenza disease outbreak. Consultancy Report for the Royal Pigeon Racing Association. UK.
25. Forbes, N.A., Flamank, M. (2007). Balai Surveillance Programme for Importation of a collection of >200 raptors from USA to UK.
26. Forbes, N.A. (2007). Handling and diagnostic approach to the sick bird. Proveto. Amsterdam, Netherlands. (post graduate training course notes).

27. Forbes, N.A. (2007). Bird room environmental management. *Parrots Magazine*.
28. Forbes, N.A. & Rodriguez Barbon, R. (2007). Clinical case, Avian. *Consulta Difus Vet*, 139, 73-74.
29. Forbes, N.A. (2008). Raptors: parasitic disease. In J. Chitty & M. Lierz (Eds.), *BSAVA Manual of raptors, pigeons and passerine birds*. Gloucester, UK: British Small Animal Veterinary Association.
30. Forbes, N.A. & Redrobe, S. (2008). Endoscopy of birds and reptiles. Great Western Referrals. Swindon, UK. (course notes).
31. Forbes, N.A. (2008). Falconry centre staff training course. (course notes).
32. Forbes, N.A. (2008). "The Production of a Nucleus Colony of Health Status Ensured Greater Flamingos *Phoenicopterus ruber roseus* in UK for Exportation to New Zealand." *BVZS Spring Conference*.
33. Forbes, N.A. (2008). Avian module. Cert GP Exotic. Improve International. (course notes).
34. Forbes, N.A. (2008). Bumblefoot, arthritis, musculo-skeletal problems in birds. MSC Wild Animal Health. Royal Veterinary College, Zoological Institute of London. (course notes).
35. Forbes, N.A. (2008). Respiratory diseases of birds. Bristol University Vet School. (undergraduate training course notes).
36. Forbes, N.A. (2008). Avian orthopaedic and soft tissue surgery. Wet Lab Training Course. Improve International. (course notes).
37. Forbes, N.A. (2009). Endoscopy of birds. Improve International. (course notes).
38. Forbes, N.A. (2009). National bird control training course. (course notes).
39. Forbes, N.A. (2009). LANTRA falconry training course for assessors. (course notes).
40. Forbes, N.A. (2010). Aspergillosis in raptors. *Falconers and Raptor Conservation Magazine*.
41. Forbes, N.A. (2010). Avoiding trauma and stress in the initial training of falconry birds. British Falconers Club. (presentation).
42. Forbes, N.A. (2010). Common diseases of birds. Improve International. (lecture notes).
43. Forbes, N.A. & Kubiak, M. (2011). Avian practice: Veterinarians care of raptors – Part 1. *In Practice*, 33, 28-32.
44. Forbes, N.A. (2011). Managing exotic animal emergency and critical care patients. Vets Now 'Cutting Edge' Training Program. (lecture notes).
45. Forbes, N.A. (2011). "Common Diseases of Birds." *World Veterinary Association Conference*.
46. Forbes, N.A. (2011). "Parasitic Diseases of Birds." *World Veterinary Association Conference*.



47. Forbes, N.A. (2011). "Psittacine Medicine." *Hellenic Veterinary Association Conference*.
48. Forbes, N.A. (2011). Common diseases of birds of prey. Vets Now. Exeter, UK. (course notes).
49. Forbes, N.A. (2011). Orthopaedics and endoscopy. Vets Now. Swindon, UK. (course notes).
50. Forbes, N.A. (2011). "Avian Round Table Case Discussions". *BVZS Conference*.
51. Forbes, N.A. (2011). Update on rabbit and ferret medicine. (Excel Lecture course notes).
52. Forbes, N.A. (2012). Pbfd recognition and control in veterinary practice. *British Vet Nursing Association Congress Times*.
53. Forbes, N.A. (2012). Standard operating procedure: Poultry seizure and biosecurity control for the Royal Society of Protection of Cruelty to Animals. (personal communication).
54. Forbes, N.A. (2012). Aspergillosis how to avoid (or survive it). *World of Falconry*.
55. Forbes, N.A. (2012). Treating bumblefoot in birds. *World of Falconry*.
56. Forbes, N.A. (2012). Managing psittacine respiratory disease in practice, Vets Now. Swindon, UK. (course notes).
57. Forbes, N.A. (2012). "Pet Parrots: Welfare and Behavioral Needs of Parrots." *Think Parrots Conference*.
58. Forbes, N.A. (2012). "Exotics Case Discussion Workshop". *Crieff Vets Now Conference*.
59. Gardner, B. & Le Rochais, C. (2009). F10 used to treat abscesses in two African Elephants. *The Facts*, 13. Retrieved from [www.healthandhygeine.co.za](http://www.healthandhygeine.co.za).
60. Lampen, F., Bailey, T.A., & Combreau, O. (2005). Medical rehabilitation and quarantine of illegally traded Macqueen's Bustard (*Chalmydotis macqueenii*) in the UAE. *Journal of Avian Medicine and Surgery*, 19(1), 35-45.
61. Le Roux F.E. (2004). "An Alternative Localised Therapy with Extended Clinical Application." *BSAVA Conference 2004*.
62. Monks, D., Zsivanovits, P., Cooper, J.E. & Forbes, N.A. (2006). Successful treatment of tracheal xanthogranulomatosis in red-tailed hawk (*Buteo jamaicensis*) by tracheal anastomosis. *Journal of Avian Medicine and Surgery*, December 2006.
63. Mouton, J.W. (1999). Combination therapy as a tool to prevent emergence of bacterial resistance. *Infection*, 27(2), 24-28.
64. Redrobe, S. (2004). "Treatment of Respiratory Disease in Birds." *29<sup>th</sup> World Small Animal Congress*.
65. Rodriguez Barbon, A. & Forbes, N.A. (2007). Use of paromomycin in the treatment of a cryptosporidium infection in two falcons. *Falco*, 30.

66. Samour, J.H., Naldo, J.L., Werner, U. & Beer, M. (2007). Highly pathogenic avian influenza H5N1 phenotype infection in a Saker falcon (*Falco cherrug*). *Falco*, 30.
67. Slabber, M. (2008). Some experiences and success with F10 products in equine practice. *The Facts*, 10. Retrieved from [www.healthandhygiene.co.za](http://www.healthandhygiene.co.za).
68. Stanford, M. (2001). Use of F10 in psittacines. *Exotic DVM*, 3.4.
69. Samour, J. (2006). Management of raptors. In G. Harrison & T. Lightfoot (Eds.) *Clinical Avian Medicine* (Vol. 2, pp. 915-956). Palm Beach, FL: Spix Publishing.
70. Samour, J. & Naldo, J. (2010). The use of F10 in falcon medicine: practical applications. *Falco*, 35, 21.
71. Smith, S. & Forbes, N.A. (2006). "Treatment of Pyotraumatic Dermatitis Infected with Methicillin-Resistant *Staphylococcus aureus* in Three Pet Psittacines." *European Association and Avian Vets Conference*.
72. Stanford, M. (2002). Use of F10 on a grey parrot with confirmed aspergillosis. Retrieved from [Birdmed@numbat.murdoch.edu.au](mailto:Birdmed@numbat.murdoch.edu.au).
73. Stanford, M. (2003). "Recombinant Omega Interferon in Combination with F10 Nebulisation for the Treatment and Prevention of Circovirus Infection in African Grey Parrots." *International Conference on Exotics*.
74. Stanford, M. (2004). Interferon treatment of circovirus infection in grey parrots (*Psittacus erithacus*). *Veterinary Record*, 154(14), 435-436.
75. Stanford, M. (2006). "Use and Safety of F10 in Exotics." *BVZS Spring Meeting*. Whippsnade, UK. May 13-14, 2006.
76. Stanford, M. (2009). "Management of Raptors", *BVZS Satellite Day BSAVA Conference*. April 1, 2009.
77. Stanford, M. (2009). Infectious disease. In J. Chitty & M. Lierz (Eds.), *BSAVA Manual of Raptors, Pigeons and Passerine Birds* (pp. 212-222). Gloucester, UK: British Small Animal Veterinary Association.
78. Stanford, M. (2010). Cage and aviary birds. In A. Meredith & C. Johnson-Delaney (Eds.), *BSAVA Manual of Exotic Pets* (pp. 177-186). Gloucester, UK: British Small Animal Veterinary Association.
79. Stanford, M., Verwoerd, D.J., & Temperley, J.P. (2005). Determination of disinfectant residues in tissue after oral supplementation of drinking water with F10SC disinfectant. *The Facts*, 4. Retrieved from [www.f10products.co.za](http://www.f10products.co.za).
80. Van der Spuy, S. (2002). "Aspergillosis in the Pet Bird" *SAVA Veterinary and Paraveterinary Congress*.
81. Van Wyk, W. (2002). The use of F10 in treating avian respiratory disease. (personal communication in Bird and Exotic Animal Clinic).
82. Verwoerd, D.J. (2000). Aerosol use of a novel disinfectant as part of an integrated approach to preventing and treating aspergillosis in falcons in the UAE. *Falco*, 17, 15-17.

83. Verwoerd, D.J. (2001). "F10: Clinical Uses in an Avian Model with Individual Aspergillosis in Gyr Falcons and Fungal and Bacterial Air Sacculitis in Ostriches/ Case Studies." *BVZS Conference*. Edinburgh, Scotland.
84. Verwoerd, D.J. & Temperley, J. (2003). F10: Some applications in biosecurity, preventative health and treatment of clinical cases relative to raptor veterinary medicine. *Falco*, 22.
85. Verwoerd, D.J. & Bailey, T.A. (2011). "Novel Therapeutic Agents and Treatment Modalities for Falcons." *3<sup>rd</sup> Falconry Festival*, UAE.
86. Wattanaphansak, S., Singer, R.S. & Gebhart, C.J. (2010). Evaluation of in vitro bactericidal activity of commercial disinfectants against *Lawsonia intracellularis*. *Journal of Swine Health and Production*, 18(1), 11-17.
87. Zsivanovits, P., Forbes, N.A., Saunders, R. & Higston, S. (2004). Suggestions for optimising recovery and minimising disease risks in raptor rehabilitation facilities. *Journal of Wildlife Diseases*, 44, 427-433.

### III. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE:

"Not for use in humans. Keep out of reach of children. Do not contaminate food, water, eating utensils, or food contact surfaces. Wash hands before eating or drinking. If accidentally ingested, contact a Poison Control Center or a doctor. Do not induce vomiting unless advised by the Poison Control Center or a doctor. If accidental eye contact, hold eye open and rinse with water for 10 minutes. Seek medical help if necessary. Avoid breathing of spray mist."

### IV. AGENCY CONCLUSIONS:

The information submitted in support of this request for F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE for addition to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (Index) for use as a topical antiseptic for surface wounds, to repel flies, and to treat infestations due to fly strike in raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals satisfies the requirements of section 572 of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 516.

#### A. DETERMINATION OF ELIGIBILITY FOR INDEXING:

As part of the determination of eligibility for inclusion in the Index, FDA determined that the drug for these intended uses was safe to the user, did not individually or cumulatively have a significant effect on the human environment, and that the description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new animal drug was sufficient to demonstrate that the requestor has established appropriate specifications for the manufacture of the new animal drug. Additionally, the requestor has committed to manufacture the drug in accordance with current good manufacturing practices (cGMP).

The Index is only available for new animal drugs intended for use in minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals and for new animal drugs intended for use only in a hatchery, tank, pond, or other similar contained man-made structure in an early, non-food life stage of a food-producing minor species, where safety for humans is demonstrated in accordance with the standard of section 512(d) of the act. Because this new animal drug is not intended for use in food-producing animals, FDA did not require data pertaining to drug residues in food (i.e., human food safety) for granting this request for addition to the Index.

Due to the broad range of species included in the intended uses, FDA determined that labeling language was necessary to prevent potential use in major species and in food-producing species. The following two statements were added to the labeling:

"Use of this product is prohibited in dogs, cats, and horses and in food-producing species such as cattle, pigs, chickens, turkeys, rabbits, deer, ducks, pigeons, and turtles."

"Use only when there is a reasonable certainty that the treated animal will not be consumed by humans or food-producing animals."

**B. QUALIFIED EXPERT PANEL:**

The qualified expert panel for F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE met the selection criteria listed in 21 CFR 516.141(b). The panel satisfactorily completed its responsibilities in accordance with 21 CFR part 516 in determining the target animal safety and effectiveness of F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE for use as a topical antiseptic for surface wounds, to repel flies, and to treat infestations due to fly strike in raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals.

**C. MARKETING STATUS:**

F10 brand ANTISEPTIC WOUND SPRAY WITH INSECTICIDE will be marketed over-the-counter.

**D. EXCLUSIVITY:**

Products listed in the Index do not qualify for exclusive marketing rights.

**E. ATTACHMENTS:**

Facsimile Labeling:

100 mL bottle and 500 mL bottle