



Z-900010-D-0002

NOV 17 2011

Kristen V. Khanna, PhD, MBA  
President  
Animal Clinical Investigations, LLC  
4926 Wisconsin Ave., N.W.  
Washington, DC 20016

re: Revised Request for Eligibility for Indexing

Dear Dr. Khanna:

We grant your request on behalf of Health and Hygiene (Pty) Ltd for determination of eligibility for indexing F10 Germicidal Wound Spray (alkyl dimethyl benzyl ammonium chloride and poly [hexamethylene biguanide] hydrochloride) with Insecticide (cypermethrin and piperonyl butoxide) for the prevention and treatment of myiasis on wounds in multiple non-food-producing minor species. We find that the information you provided in your request dated August 10, 2011, as amended on October 31, 2011, for F10 Germicidal Wound Spray with Insecticide meets the criteria required in 21 CFR 516.129.

You proposed to use your product for the prevention and treatment of myiasis on wounds in the following minor species: Felidae, excluding the domestic cat; captive non-food-producing minor species hoof stock; non-human primates; captive Ursidae; raptors; elephants; hippopotamuses; hyenas; and captive tortoises. Please keep in mind that the qualified expert panel will need to ensure that the safety and effectiveness information supports use in all species to be included on the labeling. The actual wording of the intended use for this product will not be determined until after our review of the qualified expert panel's recommendations.

We have determined that your product is eligible for indexing for the intended uses stated above in addition to our original determination that F10 Germicidal Wound Spray with Insecticide is eligible for indexing for use as a topical antiseptic for surface wounds, dart puncture wounds, and primary closure sites in multiple non-food-producing minor species (CVM letter dated June 8, 2011, Z-900010-A-0000). Please note that the qualified expert panel should consider the uses for myiasis and the use as a topical antiseptic for surface wounds separately within the written report.

We would like to let you know that because this product includes more than one active ingredient, the report of the qualified expert panel should include a statement explaining the contribution made by each of the active ingredients to the effectiveness (or safety) of the drug combination. In other words, the panel should state their opinion of why the product needs to contain all four active ingredients (alkyl dimethyl benzyl ammonium chloride, poly [hexamethylene biguanide] hydrochloride, cypermethrin, and piperonyl butoxide).

In your submission, you claimed a categorical exclusion under 21 CFR 25.33(d)(1) for the indexing of F10 Germicidal Wound Spray with Insecticide for the prevention

and treatment of myiasis on wounds in multiple minor species. Furthermore, you stated that to your knowledge, no extraordinary circumstances exist that may significantly affect the human environment. We agree that the proposed indexing of F10 Germicidal Wound Spray with Insecticide for these uses falls within the categorical exclusion under 21 CFR 25.33(d)(1) and we are not aware of any extraordinary circumstances. Therefore, neither an environmental assessment nor an environmental impact statement is required.

If there are changes in the product (e.g., intended use, dosage, or duration of use) before you submit your request to add the drug product to the Index, please contact us immediately to determine if the categorical exclusion remains appropriate for the action.

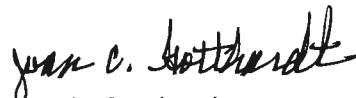
Our determination of eligibility for the indexing of this product is based on the information in your submission. Should we become aware of information that does not support this determination, we will need to re-evaluate the eligibility of your product for the Index.

We very much appreciate that your request for determination of eligibility for indexing was well organized. Your next step should be to submit a list of the members of your proposed qualified expert panel for our determination of whether the panel meets the selection criteria contained in 21 CFR 516.141.

Future correspondence regarding this submission should refer to the date of this correspondence and to file number Z-900010-D-0002. The letter should be addressed to Dr. Joan Gotthardt, Office of Minor Use & Minor Species Animal Drug Development (OMUMS), HFV-50, Center for Veterinary Medicine, 7500 Standish Place, Rockville, Maryland, 20855. However, the envelope containing the letter should be mailed to the FDA/CVM Document Control Unit, HFV-199, 7500 Standish Place, Rockville, Maryland 20855.

Please feel free to contact me at (240) 276-9331, or Dr. Meg Oeller at (240) 276-9005 if you have any questions.

Sincerely,



Joan C. Gotthardt, D.V.M.  
Director of Indexing  
Office of Minor Use & Minor Species  
Animal Drug Development  
Center for Veterinary Medicine