



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 8 2003

NADA 141-174

Randy Lynn, Director, Regulatory Affairs
IDEXX Pharmaceuticals, Inc.
4249-105 Piedmont Parkway
Greensboro, NC 27410

Dear Dr. Lynn:

This is in reference to your submission dated January 2003 for ACAREXX® (0.01% ivermectin) Otic Suspension for Cats and Kittens, NADA 141-174. The submission contains a "Dear Doctor" letter which accompanies a reference journal article that was published in *Veterinary Therapeutics* in the fall of 2001. A copy of the full prescribing information is included on the back of the letter, as required by 21 CFR 201.105 (d).

Promotional materials are misleading if they state or suggest that a drug is useful in a broader range of conditions than has been demonstrated by substantial evidence or substantial clinical experience. See 21 CFR § 202.1(e)(6)(i). Your letter is misleading because it presents claims for ACAREXX that are not supported by substantial evidence or substantial clinical experience. The approved product labeling specifically states that effectiveness against eggs and immature stages has not been proven.

The Dear Doctor letter transmits and describes "an *in vitro* study that proves **ACAREXX Otic Suspension is effective against eggs and immature stages of *Otodectes cynotis***" (emphasis in the original). This statement is misleading because it suggests that ACAREXX has been demonstrated to be useful for cats and kittens infested with eggs and other immature stages of mites, primarily by using the words "proves" and "is effective" and by bolding the phrase "ACAREXX Otic Suspension is effective against eggs and immature stages." The *in vitro* study does not constitute substantial evidence or substantial clinical experience to support claims promoting the use of ACEREXX in cats and kittens infested with eggs and other immature stages of mites. Specifically, since this study is not a clinical trial, it does not, by itself, support these claims.

Later in the paragraph, you state that the *in vitro* study results "indicate that the product is effective again the immature forms." This statement is potentially misleading. It could mean that the results *suggest* effectiveness against immature stages of mites when used in cats and kittens, especially since the statement notes that further studies are required

before the label may be revised. It could also mean that the results *show* effectiveness against immature stages of mites. This reading is bolstered by the earlier statement that the study proves the product is effective.

We request that you immediately stop dissemination of this and any other similar promotional pieces. Please inform us of your intentions within 30 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

Mohammad I. Sharar, D.V.M., M.Sc.
Team Leader, Marketed Product Scientific
and Regulatory Review Team II, HFV-216
Division of Surveillance
Center for Veterinary Medicine