DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 15 2006

Nancy Thompson-Brown
Senior Regulatory Compliance Specialist
Schering-Plough Animal Health Corporation
1095 Morris Avenue
Union, NJ 07083-1982

RE: NADA 141-206 Nuflor® (florfenicol) 2.3% Concentrate Solution
Direct to Consumer Advertising

Dear Ms. Thompson-Brown,

The Center for Veterinary Medicine (CVM) has reviewed a magazine advertisement (SPAH-NWDC-24) with brief summary for Nuflor® (florfenicol) 2.3% Concentrate Solution, NADA 141-206. The advertisement was published in Pork magazine, Vol.26, No. 5, May 2006. This advertisement is false and misleading because it fails to reveal any risk information in the body of the advertisement. Therefore, the drug is misbranded under sections 201(n) and 502(n) [21 U.S.C. §§ 321(n) and 352(n)] of the Federal Food, Drug and Cosmetic Act (the Act).

Background

Nuflor® 2.3% Concentrate Solution is a synthetic broad-spectrum antibiotic indicated for the treatment of swine respiratory disease associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella cholerasuis*, and *Streptococcus suis* Type 2 in swine.

The FDA-approved labeling for Nuflor® contains the following statements:

in the **Residue Warnings** section:

> *Swine intended for human consumption must not be slaughtered within 16 days of the last treatment. Use of this product in a manner other than indicated or with dosages in excess of those included on this label may result in illegal drug residues in edible tissues.*

in the **Warning** section:

> *This product contains material that can be irritating to skin and eyes. Avoid direct contact with skin, eyes, and clothes.*

and, in the **Precaution** section:

> *The effects of Nuflor® 2.3% Concentrate Solution on the reproductive function of treated swine have not been determined. Do not use in swine intended for breeding.*

Omission of Risk Information

Although this advertisement presents several effectiveness claims for Nuflor®, it fails to include any of the risk information in the body of the advertisement. As noted above, improper use of Nuflor® or excessive doses may result in illegal drug residues in edible tissues; the product is irritating to skin and eyes and direct contact should be avoided; and use of Nuflor® in swine intended for breeding should be avoided. These are important facts that producers should be aware of, and the absence of a brief statement regarding these risks may lead to the unsafe use of Nuflor®. The advertisement therefore causes the drug to be misbranded. See 21 C.F.R. 202.1(e)(5)(iii).

Conclusion and Requested Action

As discussed above, the advertisement omits important risk information from the body of the advertisement. Accordingly, the drug is misbranded under sections 201(n) and 502(n) [21 U.S.C. §§ 321(n) and 352(a)] of the Act.

The Division of Surveillance requests that Schering-Plough Animal Health immediately cease dissemination of the Nuflor® advertisement described above. Future promotional materials should adequately address risk information. Please submit a written response within 30 days of receipt of this letter describing your intent to comply with this request. Please direct your response to me at the Food and Drug Administration, Center for Veterinary Medicine, Division of Surveillance, HFV-216, 7519 Standish Place, Rockville, MD 20855. We remind you that only written communications are official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to see that your promotional materials for Nuflor®, as well as other Schering-Plough Animal Health products, comply with the requirements of the Act and its implementing regulations.

Sincerely yours,

Mohammad I. Sharar, DVM, M.Sc.
Team Leader, Post-approval Regulatory
Review Team, HFV-216
Division of Surveillance
Center for Veterinary Medicine