



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 23 1999

NADA 140-338
NADA 141-036

Thomas R. Schriemer, Manager
Worldwide Animal Health Regulatory Affairs
Pharmacia & Upjohn Company
7000 Portage Road (9691-190-43)
Kalamazoo, MI 49001-0199

Dear Mr. Schriemer:

We refer to your Drug Experience Reports dated July 1, 1999, for Naxcel® Sterile Powder, **NADA 140-338** and Pirsue™ Aqueous Gel, **NADA 141-036**. The submissions include two promotional pieces which are deemed to be violative (1).

In the Naxcel Prewean Folder (1), ceftiofur is compared with enrofloxacin, danofloxacin, orbifloxacin, florfenicol, kanamycin, and oxytetracycline in a study for meat quality. We deem the comparison to be misleading. It is a misleading comparison because ceftiofur and oxytetracycline are the only two antibiotics (used in the study and) approved to treat bacterial pneumonia in swine in the United States. Therefore, to suggest that the use of ceftiofur results in less tissue damage at an injection site than the other antibiotics is misleading. In order for the comparisons to be valid, all products must be approved in the United States for the same indication(s), in the same dosage form, and the same route of administration.

Additionally, your advertisement for Pirsue™ Aqueous Gel is deemed to be unsatisfactory and in violation of 21 CFR §202.1(e)(7)(viii). Your brief summary fails to present information with a prominence and readability reasonably comparable with the presentation of information in the body of the advertisement, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, etc.

Furthermore, we have no record that your firm submitted the following promotional pieces at the time of their initial dissemination/publication: 1) the free audiocassette

1. NADA 140-338, Naxcel Prewean Folder (V99213C), insert for Naxcel Sets The Standard For Meat Quality. NADA 141-036, Make More Milk With Pirsue™ (V-77207A).

"Maximizing Prewean Pig Performance"; 2) the advertisement "Make More Milk With Pirsue"; 3) the advertisement "Don't go Bear Hunting with a stick"; 4) the advertisement "Anything else is all hat and no cattle"; and 5) the advertisement "This is Your Milk." We remind you to submit your promotional pieces at the time of their initial dissemination/publication, as required under 21 CFR §510.300(b)(3).

Please inform us of your intentions within 15 days of receipt of this letter. If you have any additional questions, you may contact us at (301)827-6642.

Sincerely yours/

Vitolis Vengris, D.V.M., Ph.D.
Marketed Product Scientific and
Regulatory Review, Team 1
Division of Surveillance
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