FINDING OF NO SIGNIFICANT IMPACT
for

Terramycin (oxytetracycline) Premix
for Use in Lobster
(NADA 38-439 C027)

Pfizer Inc.
New York, NY

The Center for Veterinary Medicine (the Center) has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment and that an environmental impact statement therefore will not be prepared.

Pfizer Inc. has requested approval of a supplement to NADA 38-439 for the use of Terramycin (oxytetracycline) Premix in lobsters to control gaffkemia infections caused by Aerococuccus viridans. The product will be used at a dosage level of 2.2 mg oxytetracycline (OTC) per gram of feed and will be fed to lobsters for a total of five days.

In support of the approval of this supplement, Pfizer Inc. submitted an abbreviated environmental assessment (EA) dated April 3, 1987 (copy attached). The abbreviated EA provides environmental information concerning the manufacture of oxytetracycline (OTC) for use in the control of gaffkemia in lobsters. The Center has reviewed Pfizer's abbreviated EA and finds that it adequately addresses the environmental requirements for the manufacture of OTC for use in lobsters. The abbreviated EA indicates that the firm's facilities at Groton, Connecticut; Terre Haute, Indiana; and Lee's Summit, Missouri, are in compliance with Federal, State, and local environmental requirements.

The potential environmental impact from the use of OTC in lobsters was assessed in an EA dated November 26, 1984 (Public Master File Number 5-028), prepared by Dr. Stanley E. Katz, Rutgers University, for Interregional Research Project No. 4 (IR-4). A copy of the IR-4 EA is attached. In the IR-4 EA, Dr. Katz determined that the use of OTC in lobster at a dose of 2.2 mg OTC per gram of feed would probably have no impact on the environment. It is noted that Dr. Katz reached this conclusion based on a feeding regimen of five days of medicated feed, 10 days of non-medicated feed, followed by another five days of medicated feed; a dosage regimen twice that proposed under NADA 38-439, i.e., a single five-day treatment. The dosage regimen proposed under the current supplement would result in the environmental introduction of significantly less OTC than estimated in the IR-4 EA. Therefore, the potential impacts from the use proposed under the NADA would be expected to be significantly less than those considered in the IR-4 EA.

Based on the information contained in Pfizer's abbreviated EA and the IR-4 EA, the Center concludes that the manufacture and use of OTC in lobster for the control of gaffkemia is not expected to have a significant impact on the quality of the human environment.

4/9/87
Date

Preparer, HFV-152

4/13/87
Date

Primary Action Officer, HFV-133

4/10/87
Date

Chief, Environmental Staff, HFV-152

Attachments