FINDING OF NO SIGNIFICANT IMPACT

for

Naxcel® (Ceftiofur Sodium) Sterile Powder
for Turkey Poults

NADA 140-338

The Upjohn Company
Kalamazoo, MI

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The Center for Veterinary Medicine 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, therefore, an environmental impact statement will not be prepared.

The Upjohn Company is requesting approval of a supplement to NADA 140-338 for the use of Naxcel® (ceftiofur sodium) sterile powder for the control of colibacillosis in day-old turkey poults. The product is administered by subcutaneous injection in the neck at 0.17 to 0.5 mg ceftiofur/poult. The drug is to be used by or on the order of a licensed veterinarian. Ceftiofur sodium is approved under 21 CFR 522.313 for the treatment of bovine and swine respiratory disease, and for the control of colibacillosis in day-old chickens.

The Upjohn Company has submitted the attached August 24, 1995, environmental assessment (EA) in support of the supplemental NADA. The submitted EA describes the impact on the environment of ceftiofur sodium due to the additional use in turkey poults. Information is provided on environmental introductions due to manufacturing and use of the product. The fate and effects of ceftiofur sodium from its use in turkeys will be similar to that resulting from its use in chickens, cattle, and swine. Expected environmental concentrations are in the low ppb range and ceftiofur is expected to degrade in the environment. Based on maximum treatment rates and market penetration, it is estimated that approximately 70 kg of ceftiofur sodium will be used per year for the treatment of colibacillosis in turkey poults. This amount is small compared to the amount of ceftiofur sodium marketed for other purposes.

The drug substance, ceftiofur sodium, will be produced at The Upjohn Company manufacturing complex in Portage, Michigan. The drug product, Naxcel®· Sterile Powder, will be manufactured at SmithKline Beecham (SKB), Conshohocken, PA. The EA lists the chemical substances expected to be emitted and provides a discussion of the controls utilized to minimize emissions during the production of bulk ceftiofur. Potential occupational effects have been addressed alcng with measures to mitigate any effects to employees at the production facilities (material safety data sheet, safety equipment, and other safety requirements) . The Portage facility is stated to be in compliance with all applicable Federal, state, and local environmental (including occupational) requirements. The final formulation facility in Conshohocken, PA, is certified to be in compliance with all applicable Federal, state, and local emissions and occupational requirements.

The information provided in the October 18, 1995, EA, is adequate to conclude that the manufacture and use of Naxcel® for the control of colibacillosis in day-old turkey poults are not expected to have a significant impact on the environment.

5/22/96
Date

L. C. Livingston
Director, Office of New Animal Drug Evaluation, HFV-100

Attachments: Environmental Assessment dated August 24, 1995