HFV-152

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FINDING OF NO SIGNIFICANT IMPACT

for

Naxcel® (Ceftiofur Sodium) Sterile Powder for Acute Bovine Foot Rot

NADA 140-338 S0072

The Upjohn Company
Kalamazoo, MI

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for

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NADA 140-338 S0072

The Upjohn Company
Kalamazoo, MI

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 an environmental impact statement therefore 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 treatment of acute bovine interdigital necrobacillosis (foot rot) in beef and lactating dairy cattle. The product is to be administered by intramuscular injection to beef and dairy cattle at a dosage of 0.5 to 1.0 mg ceftiofur per pound of body weight repeated every 24 hours for three to five days as needed. The drug is to be used by or on the order of a licensed veterinarian. Naxcel® is approved under 21 CFR 522.313 for the treatment of bovine respiratory disease (BRD) in beef and dairy cattle.

The Upjohn Company has submitted the attached July 15, 1995, environmental assessment (EA) in support of the supplemental NADA.

The drug substance, ceftiofur sodium, will be produced at the Upjohn Company, Kalamazoo, Michigan. The drug product, ceftiofur sodium sterile powder, will be manufactured at SmithKline Beecham (SKB), Conshohocken, PA. The revised EA provides environmental information for the Kalamazoo, MI and the Conshohocken, PA facilities. The EA lists the chemical substances expected to be emitted and provides a discussion of the controls utilized to prevent adverse impacts on the environment during the production of bulk ceftiofur. The potential occupational effects have been addressed along with measures (material safety data sheet, safety equipment, and other safety requirements) to mitigate potential effects on employees at the production facilities. The bulk ceftiofur manufacturing facility in Kalamazoo, MI and the final formulation facility in Conshohocken, PA are stated to be in compliance with all applicable Federal, state, and local environmental (including occupational) requirements.

Approximately one percent of all beef and dairy cattle in U.S. develop acute bovine foot rot. Foot rot, if untreated, can lead to lameness. With the use of Naxcel® for the treatment of acute bovine foot rot, the dairy and beef production will be more efficient and less costly to producers because of the reduction in cattle suffering from acute foot rot. The use of ceftiofur sodium for the treatment of bovine foot rot would be expected to increase U.S. use of this product by about 2% over its current usage.

Any intact ceftiofur and bioactive metabolites excreted in bovine manure, are expected to degrade in a relatively short period. The degradation is expected to occur predominantly as

a result of hydrolysis and biodegradation. Degradation of ceftiofur in manure has been demonstrated to yield products which are inactive against sensitive indicator microorganisms. Ceftiofur has been shown to hydrolyze rapidly in water at pH 7. Biodegradation in three soils has been demonstrated to result in the rapid breakdown of ceftiofur to carbon dioxide (CO_2). Consequently, any parent ceftiofur and its metabolites which may be introduced into the environment, are expected to degrade rapidly and completely to biologically inactive products.

The information provided in the July 15, 1995, EA is adequate to conclude that the manufacture and use of Naxcel® for the treatment of acute bovine interdigital necrobacillosis (foot rot) in beef and lactating dairy cattle are not expected to have a significant impact on the environment.

8/11/95
Date

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Attachments: Environmental Assessment dated July 15, 1995