FINDING OF NO SIGNIFICANT IMPACT

AND

ENVIRONMENTAL ASSESSMENT

FOR

THE PROHIBITION OF USE OF THREE NITROFURAN COMPOUNDS IN FOOD-PRODUCING ANIMALS

CENTER FOR VETERINARY MEDICINE

FOOD AND DRUG ADMINISTRATION

MARCH 1984

FINDING OF NO SIGNIFICANT IMPACT

The Center for Veterinary Medicine (formerly the Bureau of Veterinary Medicine) of the Food and Drug Administration has carefully considered the potential environmental effects of its proposed actions to withdraw approval of New Animal Drug Applications (NADA's) for the use of furazolidone (NF-180), nitrofurazone (NF-7), and furaltadone (NF-260) in food-producing animals. Three regulatory alternatives have also been considered: (1) no action; (2) controlled use of furazolidone for uses not completely covered by alternate drugs; and (3) the proposed actions plus mitigative measures. All the relevant data available have been thoroughly examined, including, but not limited to, the information contained in the original environmental assessment of May 4, 1976, comments received thereon, and data, studies, and reports developed or published since 1976.

The Center has been unable to identify any significant potential environmental effects likely to follow implementation of the proposed actions. Based on a review of the available data, the Center has determined that there exist alternate drugs and animal management practices sufficient to completely cover all but two of the many approved prevention and treatment claims of furazolidone, nitrofurazone, and furaltadone.*

*Withdrawal of the NADA's for furazolidone might hamper the ability of turkey and chicken flock managers to prevent paratyphoid (pp. 58-62 of the attached environmental assessment) and may occasionally reduce the ability of turkey and chicken flock managers to treat chronic respiratory disease, when it is complicated by drug-resistant E. coli (pp. 62-69 of the attached environmental assessment).

The Center also finds that the volume of manufacture and use of nitrofurazone and furaltadone is insubstantial, thereby precluding any significant adverse environmental effects as a result of a prohibition on the use of these compounds in food-producing animals.

Regulatory Alternative 3, the proposed actions plus mitigative measures, would minimize the adverse effects associated with the only two claims for which adequate alternate drugs and animal management practices may not be available under the proposed actions. Consequently, Regulatory Alternative 3 is the environmentally preferred alternative. Regulatory Alternative 1, "No Action" would require Congressional amendment of the Delaney Clause of the Food, Drug and Cosmetic Act, 21 U.S.C. 360b(d)(1)(H). No action would result in continuing exposures to carcinogenic compounds in the edible tissue of food-producing animals. Regulatory Alternative 2, the controlled use of furazolidone for the two claims not covered by alternative drugs, would accomplish the same ends as Alternative 3 but does not appear feasible legally and economically.

Accordingly, the Center has concluded that the proposed actions and the regulatory alternatives will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The evidence supporting this finding is

contained in the attached environmental assessment, which was prepared under proposed 21 CFR 25.31 (44 FR 71742; December 11, 1979) and the Council on Environmental Quality's regulations implementing the National Environmental Policy Act (40 CFR 1500-1508).

3/25/84
Date

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3/28/84
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