FINDING OF NO SIGNIFICANT IMPACT

and

ENVIRONMENTAL ASSESSMENT

for

THE PROPOSAL TO WITHDRAW THE APPROVALS OF THE NADA'S FOR DIMETRIDAZOLE

FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

NOVEMBER 1986

FINDING OF NO SIGNIFICANT IMPACT
FOR THE PROPOSAL TO WITHDRAW
APPROVALS OF NADA's FOR DIMETRIDAZOLE

The Center for Veterinary Medicine (Center) of the Food and Drug Administration (FDA) has carefully considered the potential environmental impacts of its proposal to withdraw approval of the new animal drug applications (NADA's) for the use of dimetridazole in turkeys (1) for the treatment and prevention and as an aid in the control of histomoniasis, (2) for growth promotion, and (3) for improved feed efficiency. The Center has also considered the potential environmental impacts of its proposal as it relates to the misuse of dimetridazole in swine dysentery. The proposed action is being taken as required under Section 512(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360b(e)(1)(B). Given the seriousness of the questions surrounding the safety of dimetridazole and the residues that may result from its use, including the questions of the carcinogenicity of dimetridazole and its metabolites, no reasonable alternatives to the proposed action could be identified.

The Center has determined that substitute drug products are available which could be utilized for all of the approved uses of dimetridazole. Many substitute drug products also exist for the prevention, control, or treatment of swine dysentery, a disease for which dimetridazole is not approved, but for which the drug is misused.

The Center has reviewed all available data relevant to an environmental assessment of the proposed action and has been unable to identify any significant environmental effects which might be expected to occur following implementation of the proposal. Some toxicity to microorganisms in aquatic ecosystems, and to plants in aquatic and terrestrial ecosystems might occur with the use of turkey waste containing dimetridazole or its most likely substitute, ipronidazole, but data supporting this possibility are limited and any effects are expected to be limited to organisms exposed to fresh turkey waste.

Increases in the manufacture of substitute products for the uses of dimetridazole in turkeys and its misuse in swine are not expected to result in significant adverse impacts on the environment at the sites of manufacture of the drug products. Some impacts might result from the increased production of ipronidazole, but any such impacts would depend upon the effluent treatment utilized at the manufacturing facility and subsequent amounts of parent compound and production by-products in the wastes from the manufacturing facility. Any impacts which might occur would be expected to be equivalent for both dimetridazole and ipronidazole. Increases in the production of substitutes for dimetridazole's misuse in swine are expected to be distributed among a significant number of approved products and are not anticipated to be substantial for any one product.

Accordingly, the Center concludes that the proposed action is not expected to result in a significant impact on the human environment and that an environmental impact statement will, therefore, not be prepared. The evidence supporting this finding is contained in the attached environmental assessment which was prepared under 21 CFR 25.31b of FDA's environmental regulations and the Council on Environmental Quality's regulations implementing the National Environmental Policy Act (40 CFR 1500-1508).

11/24/86
Date

Charles E. Eirkson III
Preparer and Environmental Biologist
Environmental Staff
Center for Veterinary Medicine

11/24/86
Date

John C. Matheson III, Chief
Environmental Staff
Center for Veterinary Medicine

12/4/86
Date

Gerald B. Guest, DVM
Director
Center for Veterinary Medicine

Attachment (1)