# FINDING OF NO SIGNIFICANT IMPACT

and

# ENVIRONMENTAL ASSESSMENT

for

## PROPOSAL TO REVOKE SANCTIONS FOR GENTIAN VIOLET IN POULTRY FEEDS

and

## DECLARATION THAT ALL USES OF GENTIAN VIOLET IN ANIMAL FEEDS ARE UNAPPROVED FOOD ADDITIVE AND NEW ANIMAL DRUG USES

FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

AUGUST 1987

# FINDING OF NO SIGNIFICANT IMPACT

## Gentian Violet Proposed Rule

The Center for Veterinary Medicine (Center) of the Food and Drug Administration (FDA) has carefully considered the potential environmental impacts of its proposed rule to declare that gentian violet, when added to animal feeds, is an unapproved food additive and a new animal drug. This proposal would revoke FDA's interim policy that sanctions the use of gentian violet at up to 8 parts per million (ppm) as a mold inhibitor in poultry feed. There are currently no approved uses of gentian violet in animal feed. Therefore, in effect, the proposal would prohibit the use of gentian violet in animal feed until such time as a petitioner or applicant can meet the requirements necessary to file and receive an approved food additive petition or new animal drug application.

The Center has determined that substitute, generally recognized as safe, mold inhibitor compounds are readily available which would be expected to be used in poultry feed in lieu of gentian violet. Propionic acid and/or combinations of similar organic acids (or their salts) are used as active ingredients in such products. These products are in prevalent use in animal feeds, including poultry feeds. An analysis of the environmental properties of propionic acid and benzoic acid demonstrates that these organic acids are relatively innocuous, naturally-occurring compounds which are commonly present throughout the environment.

Gentian violet is a xenobiotic dye that is a possible occupational exposure hazard. While this action will probably not significantly affect the overall production of gentian violet, some occupational exposures to the product in the feed industry will be avoided.

Accordingly, the Center concludes that the proposed action is not expected to result in a significant impact on the human environment and therefore, that an environmental impact statement will not be prepared. The evidence supporting this finding is contained in the attached environmental assessment which was prepared under 21 CFR 25.22(a)(19) and 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).

8-19-87
Date

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8-19-87
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12/23/87
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Attachment (1)