

FINDING OF NO SIGNIFICANT IMPACT
AND
ENVIRONMENTAL ASSESSMENT
FOR
VITAMIN K ACTIVE SUBSTANCES (VKAS)

CENTER FOR VETERINARY MEDICINE
FOOD AND DRUG ADMINISTRATION
NOVEMBER 1990

FINDING OF NO SIGNIFICANT IMPACT

for

VITAMIN K ACTIVE SUBSTANCES (VKAS);

DECLARATORY ORDER


The Center for Veterinary Medicine (Center) of the Food and Drug Administration (FDA) has carefully considered the environmental impact of requiring that certain vitamin K active substances (VKAS) be marketed under provisions of a food additive regulation. The proposed action is being taken as required under 21 CFR 570.38. The effect of the action is that some VKAS products will, at least temporarily, no longer be permitted to be used in animal feeds.

The Center has determined that substitute compounds (including some VKAS) and animal feed ingredients are available that could be utilized for non-approved uses of VKAS. Additionally, food additive or GRAS affirmation petitions can be prepared and submitted to the FDA for any currently disallowed uses of VKAS.

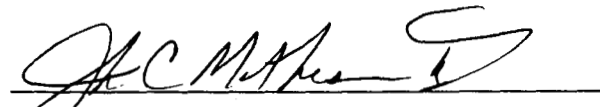
The Center has reviewed all available data relevant to an environmental assessment of the action and has been unable to identify any significant environmental effects that might be expected to occur following implementation of the action. Based on the limited available information, any impacts that might result from the increased production and use of the allowed VKAS are not expected to be greater than those from withdrawn VKAS.

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. Therefore, an environmental impact statement is not required. 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 (21 CFR Part 25) and the Council on Environmental Quality's regulations (40 CFR 1500-1508) implementing the National Environmental Policy Act.

11/16/90
Date


Raanan A. Bloom, Ph.D.
Preparer,
Environmental Sciences Staff

11/16/90
Date


John C. Matheson III
Preparer and Chief,
Environmental Sciences Staff

Date

Gerald B. Guest, DVM
Director,
Center for Veterinary Medicine

Attachment: Environmental Assessment, dated November 1990