



ANIMAL WELFARE INSTITUTE

P.O. Box 3650, Washington, D.C. 20007-0150

Telephone: (202) 337-2332 Fax: (202) 338-9478

email: awi@animalwelfare.com

April 2, 1999

TO: Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 98-D-1146 - Discussion Paper: "A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals."

FROM: Christine Stevens, President

On behalf of the Animal Welfare Institute, I wish to comment on the Food and Drug Administration's "Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals" (64 Fed. Reg. 887, Jan. 6, 1999).

The serious dangers to human health caused by subtherapeutic doses of antibiotics fed to animals raised for agricultural purposes should bring a prompt decision by FDA to eliminate all antibiotics used for medical purposes in humans from the feed for livestock. It is difficult at the present time for farmers even to obtain undoctored feed. Those who raise animals humanely in natural conditions do not require these antibiotic supplements. Antibiotics should be used only to treat sick human beings and sick animals. There is substantial scientific agreement on this subject, and many countries have stopped use of subtherapeutic antibiotics for food animals. The European Union has recently banned four specific antibiotics in order to protect public health in the EU. Sweden has banned all use of antibiotics as growth promoters.

It is the inhumane conditions in hog factories which drive the corporations who own them to dose all the occupants of their windowless buildings with antibiotics in order to cut the death rate, which is higher in hog factories than on family farms where sows and their piglets graze on pasture or occupy barns comfortably bedded with straw. It is obvious from the disastrous overproduction of pork, which is driving family farmers off the land, that there is no possible rational reason to continue the factory system which uses antibiotics as a crutch.

FDA should regulate antibiotic manufacturers vigorously and require all relevant drug sales information to be submitted to FDA. Antibiotic resistance is still growing, and this requirement would greatly enhance FDA's ability to prevent sickness and death of human beings in hospitals. This drug sales information should be made available to the public.

98 D-1146

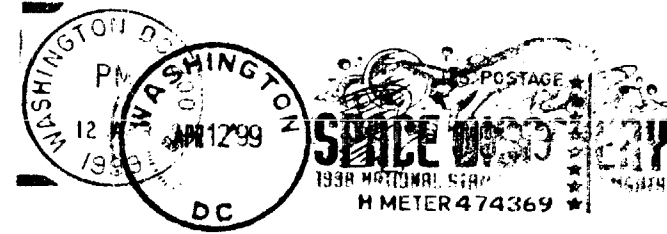
C45




ANIMAL WELFARE INSTITUTE

P.O. Box 3650

Washington, D.C. 20007



*Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852*

 Printed on recycled paper

20857 / 0002

