Consumers Union
Center for Science in the Public Interest
Food Animal Concerns Trust

August 20, 2013

Sharon Lauritsen
Assistant U.S. Trade Representative for Agricultural Affairs and Commodity Policy
Office of the United States Trade Representative
600 17th Street NW
Washington, D.C. 20508

Brian Ronholm
Deputy Under Secretary for Food Safety
United States Department of Agriculture
1400 Independence Avenue SW, Room 227-E
Washington, DC 20250-0121

Michael Taylor
Deputy Commissioner for Foods and Veterinary Medicine
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Assistant U.S. Trade Representative Lauritsen, Deputy Under Secretary Ronholm, and Deputy Commissioner Taylor,

Re: U.S. position at CCRVDF on Veterinary Drugs including DES banned for use in the United States

The Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) is meeting in Minneapolis, Minnesota, from August 26-30, 2013. We are writing to ask that the U.S. support language that would urge countries to prohibit the use of nine veterinary drugs, that in the US have been removed from, or not allowed on, the market due to human health concerns, particularly carcinogenicity and mutagenicity (Option A).

One of the items on the CCRVDF agenda concerns what recommendations to make for veterinary drugs for which Codex's scientific body, the Joint Expert Committee on Food Additives (JECFA), has not been able to identify an acceptable level because of human health concerns, particularly cancer-causing potential and mutagenicity. There are ten veterinary drugs on this list: carbadox, two nitrofurans (nitrofural and furazolidone), chlorpromazine (thorazine), stilbenes (e.g. diethylstilbestrol, DES), olaquindox and the four nitroimidazoles (dimetridazole, ipronidazole, metronidazole and ronidazole). With the exception of carbadox, all these drugs have been banned for use in the U.S. due to

human health concerns (e.g. carcinogenicity and mutagenicity) or not allowed on the market. Indeed, all ten of these veterinary drugs are banned in the European Union and other countries, due to human health concerns.

One of the drugs on this list is well known for the hazard it poses. The stilbenes includes diethylstilbestrol, DES, an estrogen analogue that was prescribed to pregnant women and also used as a growth promoting feed additive in poultry, beef, swine and sheep production, starting in the late 1940s. DES was shown to cause cancer not only in the women who took it, but, more importantly, also in their children, both male and female. In 1971, a study was published which linked a rare vaginal cancer to the daughters of women given DES during pregnancy; consequently, the FDA told physicians to stop prescribing DES to pregnant women.[1] In terms of food use, DES was banned in poultry use in 1959, and as a feed additive for cattle and sheep in 1979.[2]

Another of the drugs is chlorpromazine, also known as thorazine. Thorazine is a drug used to treat schizophrenia. Its use in food producing animals is also not allowed in the U.S.

Given the potential toxicity of these drugs, the fact that they are banned in the U.S., and JECFA's determination that it could not identify a safe residue level for these drugs, we feel that CCRVDF should recommend that these drugs be banned from use in food producing animals. However, the U.S. delegation to CCRVDF has so far taken a much weaker position, urging that countries should be allowed to use these veterinary drugs as long as they do not leave "residues of toxicological concern" (Option B).

We believe that the current U.S. position potentially puts American consumers at risk. If a drug has been banned for use in the U.S. because it has been determined that there is no safe level of the drug residue in food (as DES has been), then the U.S. should also argue that that drug should be banned in other countries as well, otherwise American consumers may be exposed to food containing residues of that drug in food imports from countries that still allow the drug to be used, or when they eat meat while traveling or living in other countries. Thus, we urge the U.S. to support language that recommends that countries not allow the use of these veterinary drugs.

More specifically, we urge the U.S. to support the language of Option A: "In the view of the JECFA conclusions on the available scientific information, there is no safe level of residues of (indicate the substance's name) or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of (include the substance's name) in food. This can be accomplished by not using this drug in food producing animals." We urge the U.S. to oppose Option B which would open the door to use of the veterinary drug in food producing animals, particularly in developing countries. It contains the same wording as Option A, followed by the

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[1] http://www.cdc.gov/des/consumers/about/history.html

[2] Raun AP and RL Preston. 2002. History of diethylstilbestrol in cattle. https://www.asas.org/docs/publications/raunhist.pdf?sfvrsn=0

wording "or ensuring that use of the drug does not result in residues of toxicological concern."
Although we feel that carbadox should not be allowed on the market due to carcinogenicity and teratogenicity concerns, we realize that the U.S. does still allow use of carbadox in pig production. Thus, at the least, we urge U.S. to support Option A for the following nine veterinary drugs: the two nitrofurans (nitrofural and furazolidone), chlorpromazine (thorazine), stilbenes (including diethylstilbestrol, DES), olaquindox and the four nitroimidazoles (dimetridazole, ipronidazole, metronidazole and ronidazole).

Thank you for your consideration.

Sincerely,

Michael Hansen, Ph.D.
Senior Scientist
Consumers Union

Caroline Smith-DeWaal
Food Safety Director
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Steven Roach
Public Health Program Director
Food Animal Concerns Trust

Cc: Dr. Kevin Greenlees, FDA/CVM