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July 10, 2012

The Honorable Margaret A. Hamburg, M.D.
Commissioner
C/o Division of Dockets Management (HFA–305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

ATTN: Comments on Draft Codified Language for Docket No. FDA-2010-N-0155;
Veterinary Feed Directive (VFD)

Dear Commissioner Hamburg:

On behalf of The Pew Charitable Trusts (Pew), I am writing to thank the U.S. Food and Drug Administration (FDA) for issuing draft codified language expanding the Veterinary Feed Directive (VFD). This proposed regulation represents a viable method for allowing antibiotics to be administered to large numbers of food animals at one time, in those instances when such action would be warranted. This draft language will place critically-important antibiotics already approved for over the counter sales under closer supervision by a veterinarian. We believe this is an important step to limit overuse of antibiotics in food animal production.

Although the language is a positive development, Pew wishes to raise concerns about potential weaknesses:

- The current regulations allow a Veterinary Feed Directive to be issued only within the confines of a valid veterinarian-client-patient relationship.[i] This is a necessity to ensure animal health and proper veterinary oversight of medication used in animals that enter our food supply. The proposed draft changes to the VFD, however, simply indicate that a VFD order must be issued by a licensed veterinarian in the course of a veterinarian's professional practice. Pew urges that language be inserted in §558.6(a)(1) of the draft such that it would state: "A feed containing a VFD drug (a VFD feed) shall be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian in the course of the veterinarian's professional practice and within the confines of a valid veterinary-client-patient relationship."

- Furthermore, the FDA should restate the current definition of what constitutes a valid veterinarian-client-patient relationship. This relationship is a basic principle of Guidance 209, to which the VFD is closely linked. A lack of clarity would allow a veterinarian with

no knowledge of a particular site to write a VFD order; this is a loophole that may not be adequately addressed in all state veterinary laws. The draft VFD should adopt the language in 21 CFR §530.3(i), which defines a valid veterinarian-client-patient relationship as one in which:

> (1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;
> (2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and
> (3) The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

- The new draft language states that feed mills and veterinarians must keep records for only one year from date of receipt and distribution. Pew recommends all involved parties should retain a copy of the VFD and any other required records for at least two years, as required in the existing regulation. Since the new language will greatly expand the use of electronic record keeping, maintenance of records for two years would not be an extra burden and would allow FDA a reasonable amount of time to have data available for inspection and verification as needed. Furthermore, feed mills and veterinarians should be required bi-annually to submit electronic or hard copies of each VFD to the Center for Veterinary Medicine for compilation, analysis and public reporting. This step is necessary to determine how drug use is changing and if further steps are needed.

- The new draft language in §558.6(b)(2)(x) requires veterinarians to enter the level of drug in the feed and the duration of its use, however there is no language limiting re-issuance of a VFD. We believe this ambiguity could allow use of antibiotics for overly long periods of time, such as throughout an animal's life. Pew recommends the language be amended to include a defined duration as follows: "(x) The level of drug in the feed and the duration of use, with duration not to exceed 21 days inclusive of reorders (refills)." This language is consistent with the current FDA Guidance 152, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern."

Pew urges FDA to modify and issue a Veterinary Feed Directive regulatory proposal expeditiously. With the improvements recommended above, we believe FDA can create a more robust regulation that provides veterinary oversight of vitally important antibiotics in order to better protect public health from impacts associated with overuse and misuse of these drugs on industrial farms.

Thank you for your consideration.

Sincerely,

Gail Hansen, MPH, DVM
Senior Officer, Pew Health Group

The Pew Charitable Trusts
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[i] See 21 CFR §530.3(i).