PEER
Public Employees for Environmental Responsibility
2000 P Street, NW • Suite 240 • Washington, D.C. 20036 • 202-265-PEER(7337) • fax: 202-265-4192
e-mail: info@peer.org • website: www.peer.org

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

Re: Docket # FDA-2010-D-0094; 75 FR 37450 (June 10, 2010)

To Whom It May Concern:

Thank you for the opportunity to provide comments on the Food and Drug Administration's (FDA) June 28, 2010 Draft Guidance entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (hereinafter "Draft Guidance"). Public Employees for Environmental Responsibility (PEER) is a Washington D.C.-based non-profit, non-partisan public interest organization concerned with honest and open government. Specifically, PEER serves and protects public employees working on environmental issues. PEER represents thousands of local, state and federal government employees nationwide.

PEER has four primary concerns about the Draft Guidance. The specifics of these concerns are set forth below.

I. The FDA should be issuing regulations as opposed to discretionary guidance.

PEER is extremely concerned that Guidance does not establish any legally enforceable responsibilities. The Draft Guidance proposed by the FDA states that the misuse or overuse of antimicrobial drugs can lead to development of resistance to the drugs, ultimately posing a serious public health threat. Given the widespread use of antimicrobial drugs in food-producing animals, together with an increasing number of drug resistant illnesses, voluntary guidance is simply not enough to protect human health and the environment. The Center for Disease Control (CDC) estimates that in the United States, there are roughly 1.7 million hospital-associated bacterial infections, which cause or contribute to 99,000 deaths each year.[1] Although the CDC does not know how many of these infections are caused by antibiotic resistant bacteria, it could be as high as two-thirds.[2]

The Draft Guidance states that the FDA "considers an antimicrobial new animal drug to be 'safe' if the agency concludes that there is 'reasonable certainty of no harm to human health' from the proposed use of the drug in food-producing animals."[3] If a drug is found to not be safe before its initial approval, it cannot be approved. If, however, safety issues arrive after approval of a drug,

[1] *See* http://www.nytimes.com/2010/02/27/business/27germ.html.
[2] *Id.*
[3] Draft Guidance at 13.

the FDA can withdraw approval of new animal drug applications. In the case at hand, there is clear evidence that overuse of certain antimicrobials already approved are posing a serious and global health risk; therefore, the FDA must take action that goes beyond discretionary guidance. Specifically, PEER urges the FDA to withdraw approval of these antimicrobials for food-producing animals unless the animals in question require the drug to fight a disease they have contracted.

II. The definition of "nontherapeutic uses" should be expanded to include not only growth promotion, but also "routine disease prevention" in the absence of any indication of disease.

The Draft Guidance defines "nontherapeutic" as "growth enhancing".[4] However, antimicrobial drugs are often overused for routine disease prevention. In order to minimize the use of antimicrobial drugs, and therefore minimize the risks to humans and the environment, such drug use should be limited to instances where animals need the antimicrobial to treat an identified disease that has already been contracted. Prophylactic use of antimicrobials should be considered injudicious.

The Draft Guidance recommends two principles regarding the judicious use of medically important antimicrobial drugs in food-producing animals. The first of these two principles is: "[t]he use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health. The FDA states clearly that the use of these medically important antimicrobial drugs in food-producing animals for the purpose of promoting growth or to improve feeding efficiency "represents an injudicious use of these important drugs."[5] Therefore, it seems that an appropriate action in this case would be for the FDA to mandate that this injudicious use of antimicrobials for the purpose of growth enhancement and/or feeding efficiency be prohibited.

The second principle set forth by the FDA is: "[t]he use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation." PEER does not believe that the involvement of a veterinarian necessarily ensures that the use of a drug will be judicious. For example, a particular animal producer can have a veterinarian working for that animal producer who will not be making unbiased decisions; rather, s/he may be making decisions that are monetarily beneficial to the company. Therefore, rather than merely suggesting veterinary oversight or consultation before using a medically important antimicrobial drug, PEER suggests mandating the diagnosis of a specific disease requiring such a drug by a veterinarian prior to the use of such drugs.

Accordingly, given the risks associated with injudicious use of these drugs, together with the widespread nontherapeutic uses of antimicrobial drugs, the FDA should be proposing that both these principles be mandatory duties of food-producing animal facilities.

III. The scope of the Draft Guidance is too narrow, and should include the fate and ecological impacts of the antimicrobials.

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[4] *Id.* at 4.
[5] *Id.* at 16.

There is a plethora of evidence suggesting that the antimicrobials given to animals in food production ends up in the environment.[6] Not only is livestock manure often turned into fertilizer that is then used in the soil, but the antimicrobials used in livestock can also end up in the local water supply, creating several potential environmental concerns. The first is the impending toxic dangers of the compounds found in antimicrobials to fish, plants and other aquatic organisms – as well as to humans through drinking water – because water treatment plants generally cannot remove all such compounds. In addition, there is the potential that animal antibiotics may contribute to the emergence of strains of disease-causing bacteria that are resistant to even high doses of drugs.

As such, because the injudicious use of antimicrobial drugs poses a threat to environmental health, in addition to human health, the FDA should examine the environmental impacts of the injudicious use of these drugs, and include that analysis in any decisions on this Guidance or future regulations.

IV. An Environmental Impact Statement is required for the use of antimicrobial drugs in food-producing animals.

A. The National Environmental Policy Act

The National Environmental Policy Act (NEPA) was enacted in 1969 to compel federal agencies to "assess the environmental consequences of federal projects by following certain procedures during the decision-making process."[7] NEPA places upon an agency the obligation to consider every significant aspect of the environmental impact of a proposed action,[8] while ensuring that the agency will inform the public that it has indeed considered environmental concerns in its decisionmaking process.[9] Accordingly, NEPA requires that all federal agencies "include in every recommendation or report on proposals for legislation and other major federal actions significantly *affecting the quality of the human environment*, a detailed statement . . . on the environmental impact of the proposed action."[10]

For major federal actions, agencies must either: prepare an Environmental Impact Statement ("EIS"), designed to comprehensively examine the environmental impact of the proposed action; an Environmental Assessment ("EA"); or claim that the action falls within a Categorical Exclusion ("CE"), "a category of actions which do not individually or cumulatively have a

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[6] *See*, e.g., http://www.buffalo.edu/news/fast-execute.cgi/article-page.html?article=61110009; http://www.sciencedaily.com/releases/2004/10/041025120141.htm; and http://www.springerlink.com/content/c11ku50478l1670/.

[7] *City of Alexandria, Va. v. Slater*, 198 F.3d 862, 866 (D.C. Cir. 1999).

[8] *Vermont Yankee*, 98 S.Ct. 1197, 1216 (1973).

[9] *Baltimore Gas & Elec. Co.*, 103 S.Ct. 2246, 2252 (1983).

[10] National Environmental Policy Act of 1969, 42 U.S.C. § 4332(2)(c)(i)(emphasis added). "Major federal action," as defined in the Code of Federal Regulations, includes actions such as "[a]doption of official policy . . . [a]doption of formal plans . . . [a]doption of programs ... [and][a]pproval of specific projects." 40 C.F.R. § 1508.18(b)(1-4) (1999). However, the courts have defined the term federal "action" broadly, to include projects carried out by federal agencies and agency rule making, but also state and local programs funded by federal assistance, and private development authorized by federal permits. *See* Daniel R. Mendelker, *NEPA Law and Litigation, 2d*, § 1:1.

significant effect on the human environment . . . and for which, therefore, neither an [EA] nor an [EIS] is required."[11] In deciding whether to grant a categorical exclusion, an agency must define "cumulative impact" as "the impact on the environment that results from the incremental impact of the action when added to other past, present and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions."[12] Further, "cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time."[13] Thus, an agency should require submission of an EA and/or EIS if the impact of a given action will cumulatively result in a significant effect on the human environment.

B. FDA Regulation Pursuant to NEPA

The FDA routinely grants categorical exclusions for antimicrobial drugs used in food producing animals. FDA's decision to issue such categorical exclusions without consideration of their cumulative impact on the environment is arbitrary and capricious.

> In either the case of action or inaction, the "governing substantive statute" is the NEPA mandate that FDA "insure that presently unquantified environmental amenities and values may be given appropriate consideration in decision-making along with economic and technical considerations."[14] This provision of NEPA requires that environmental considerations be made in addition to the traditional scope of FDA's inquiry when approving a drug. When a petitioner is seeking review of the agency's failure to appropriately consider the significance of recent developments in data on the fate of drugs in the environment, the law to apply is clear: there is a Congressional mandate that such data be part of the record on which action is based. The claim crystallizes into an allegation that the agency has not taken all of the congressionally mandated factors into account and has therefore acted arbitrarily.[15]

The recent Draft Guidance acknowledges serious potential environmental impacts from some of the very same drugs that are subject to the categorical exclusions. Among other things, the Draft Guidance admits that antimicrobial misuses and overuse can result in a "serious public health threat" of "global significance."[16] This threat has long been known as scientists have found "clear evidence of adverse human health consequences due to resistant organisms resulting from non-human usage of antimicrobials."[17] In fact, antimicrobials are shown to have effects in studies conducted with earthworms, microorganisms, and plants at a concentration as low as 100 ppb.

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[11] 40 C.F.R. §§ 1508,3, 1508.4, 1508.9, 1508.11. It bears noting that "[a]n agency's interpretation of the meaning of its categorical exclusion "must be given controlling weight unless it is plainly erroneous or inconsistent with" the terms used in the regulation." *California ex rel. Lockyer v. U.S. Dept. of Agriculture*, 459 F. Supp. 2d 874, 900 (N.D. Cal., 2006).
[12] *Id.* at § 1508.7.
[13] *Id.*
[14] 42 U.S.C. § 4332(b).
[15] Nidel, *supra* note 5, at 96.
[16] Draft Guidance at 4.
[17] *Id.* at 10.

Thus, the FDA, in continuing to uphold categorical exclusions for animal drugs, has failed to adequately consider recent scientific developments (admitted by the FDA in the Draft Guidance) which indicate that these drugs have the potential to significantly affect the quality of the human environment in levels previously thought to be safe. Because the data for many active animal drug compounds suggest that there is a potential for significantly "affecting the quality of the human environment", the preparation of a full Environmental Impact Statement considering the impact of animal drugs is mandated by NEPA.

V. **Conclusion**

In 2007, 27.8 million pounds of major antibiotics were sold for animal use.[18] Studies conducted over the past 40 years show that the injudicious use of antimicrobials in food-producing animals poses a serious global threat to human health. Therefore, it is unconscionable that the FDA would only consider issuing voluntary recommendations on future use of these drugs. PEER urges the FDA to reconsider mandating severely restricted uses of medically important antimicrobials for the food-producing animal industry.

Thank you for the opportunity to comment.

Sincerely,

Christine Erickson, Staff Attorney
Public Employees for Environmental Responsibility (PEER)
2000 P Street, NW Suite 240
Washington, D.C. 20036
202-265-7337

Kyla Bennett, Director
New England PEER
P.O. Box 574
North Easton, MA 02356
508-230-9933

[18] *See* "Dosed Without Prescription: Preventing Pharmaceutical Contamination Of Our Nation's Drinking Water," NRDC White Paper, December 2009, p.10.