EXHIBIT L

TO DECLARATION OF
JENNIFER A. SORENSON

FDA Tentative Response to 2005 Petition (2005)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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October 4, 2005

Karen Florini, Senior Attorney
Environmental Defense
1875 Connecticut Avenue, NW
Suite 600
Washington, DC 20009

Re: Docket No. 05P-0139

Dear Ms. Florini:

Pursuant to the administrative regulations at 21 CFR 10.30(e)(2)(iii), this is a tentative response to the Citizen Petition (05P-0139/CP1) submitted by you on behalf of Environmental Defense, the American Academy of Pediatrics, the American Public Health Association, and the Union of Concerned Scientists.

The petition requests that FDA withdraw approvals for herdwide/flockwide uses of the following antimicrobial drugs in chicken, swine, and beef cattle for purposes of growth promotion (including weight gain and feed efficiency) and disease prevention and control (except for non-routine use where a bacterial infection has been diagnosed within a herd or flock): penicillins, tetracyclines, aminoglycosides, streptogramins, macrolides, lincomycin, and sulfonamides.

Your petition seeks withdrawal of these drugs based, in part, on the criteria listed in Guidance for Industry #152, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern." Guidance #152 outlines a qualitative risk assessment approach to evaluate the microbial food safety of certain drugs.

In order for the Agency to withdraw a new animal drug approval, two processes need to be completed. First, FDA's Center for Veterinary Medicine (Center or CVM) needs to determine whether to initiate formal withdrawal proceedings. Second, if the Center decides to initiate formal withdrawal proceedings, it must then undertake the formal withdrawal process required by statute. For legal, scientific and resource reasons, withdrawal actions for the petitioned drugs need to be considered on a drug by drug basis. Data and information will need to be reviewed and analyzed for each drug. Thus, the petitions can only be granted or denied on a drug by drug basis as reviews are completed and resources permit.

An approved new animal drug application can be withdrawn if, among other things, experience or scientific data show that the drug is unsafe (section 512(e)(l)(A)), or if the drug is not shown to be safe (section 512(e)(l)(B)). If the Center concludes that a drug's

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approval should be withdrawn, it is required by section 512(e)(l) to provide the drug's sponsor with notice and an opportunity for a formal administrative hearing (NOOH). A separate NOOH is ordinarily issued for each individual drug, because most of the relevant scientific evidence is likely to be unique to the individual drug, although actions involving chemically related drugs may be consolidated.[1]

Issuance of NOOHs and requests for a hearing are governed by the FDA's regulations regarding formal evidentiary public hearings (21 CFR Parts 12 and 514). A sponsor who requests a formal hearing is required to submit detailed data to justify the request. The request will be reviewed and, if the Commissioner determines that a hearing is justified, the Commissioner will issue a notice of hearing. A presiding officer will conduct a formal evidentiary hearing and render an initial decision, which can be appealed to the Commissioner. A sponsor may appeal the Commissioner's decision to withdraw an approval of a new animal drug to the U.S. Court of Appeals as specified in section 512(h).

The Agency's experience with contested, formal withdrawal proceedings is that the process can consume extensive periods of time and Agency resources. For example, the NOOH for withdrawal of the approval for enrofloxacin in poultry was issued in October 2000[2], but the final rule withdrawing the approval was not published until August 2005, with an effective date of September 12, 2005.[3]

The Agency recognizes the need to address concerns related to the role that antimicrobial drug use in food-producing animals plays in the emergence and selection of antimicrobial drug resistant bacteria. To address these public health concerns, the FDA has developed a regulatory strategy that includes Guidance #152 which describes a recommended process for evaluating the safety of antimicrobial drugs intended for use in food-producing animals. Guidance #152 is based on the Agency's current thinking on this topic and is primarily aimed at providing guidance to sponsors of antimicrobial new animal drug applications on evaluating the safety of their proposed product during the pre-approval process. As stated in Guidance #152, it contains non-binding recommendations. Like all FDA guidance documents, Guidance #152 does not establish legally enforceable responsibilities.

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[1] For example, separate NOOHs were issued for the proposed withdrawals of approval for nitrofurazone (36 FR 5927, March 31, 1971) and furazolidone (36 FR 14343, August 4, 1971), but the actions involving both nitrofurans were consolidated for hearing. See 56 FR 41902 (August 23,1991).

[2] See 65 FR 64954 (October 31, 2000)

[3] See 70 FR 44048 (August 1, 2005)

As explained above, the petition can only be granted or denied when the Agency makes a final decision on whether to withdraw any of the drug approvals listed in your petition. Therefore, at this time, it would be premature to grant or deny the petition, in whole or in part.

Sincerely yours,

Stephen F. Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine

cc: HFA-305 (Docket 05P-0139)