EXHIBIT G

TO THE THIRD DECLARATION OF JENNIFER A. SORENSON

U.S. Food & Drug Administration

Animal & Veterinary

Update: FDA's Proposed Withdrawal of Approval of Poultry Flouroquinolones

What did FDA's CVM propose?

FDA's Center for Veterinary Medicine (CVM) proposed to withdraw approval of the new animal drug application for use of the fluoroquinolone antimicrobial drug enrofloxacin in poultry. If the approval is withdrawn, this drug would no longer be legally marketed for this indication. Other approved uses of fluoroquinolones in cattle, dogs, and cats would not be affected by this withdrawal.

What drug is involved and which company is the sponsor?

The drug subject of this proposed withdrawal is New Animal Drug Application (NADA) 140-828, Baytril® 3.23% Concentrate Antimicrobial Solution -- enrofloxacin -- approved 10/4/96. The sponsor is Bayer Corporation, Agriculture Division, Animal Health, Shawnee Mission, KS.

How did CVM propose this withdrawal?

On October 30, 2000, CVM published a Notice of Opportunity for Hearing (NOOH)[1] in the *Federal Register*. This NOOH is a notice to the sponsor of the NADA that CVM proposes to withdraw the approval of the drug. This action is based on sectior 512(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), in that new evidence not contained in the NADA or no available until after the application was approved, evaluated together with the evidence available when the application was approved, shows that enrofloxacin is not shown to be safe. The NOOH offers the sponsor an opportunity for a hearing to show why this drug approval should not be withdrawn.

If a sponsor decides to seek a hearing, it must file a written notice of appearance and request for a hearing and the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact to justify a hearing. The Bayer Corporation filed a request for a hearing and, the firm submitted data and analysis upon which they based their request for a hearing.

What is the status of the hearing?

FDA announced in the February 20, 2002[2], Federal Register, that a hearing would be held on the proposal to withdraw approval of NADA 140-828 for enrofloxacin. This notice of hearing (NOH) provides factual and legal information concernin CVM's proposal to withdraw the NADA, and identifies the factual issues that will be the subject of the evidentiary hearing. The NOH also stated that a pre-hearing conference would be held on April 8, 2002, and that Administrative Law Judge Daniel J. Davidson would preside.

On March 22, 2002, Judge Davidson issued a Notice and Order that canceled the pre-hearing conference that had been scheduled for April 8. The Judge's Notice and Order also stated that the parties were required to file a proposed schedule incorporating all of the pre-hearing requirements on or before April 5.

Judge Davidson issued another order on April 10, 2002[3], that set a schedule for due dates for the hearing.

From April 28 – May 7, 2003, cross-examination of the witnesses took place.

As ordered by Judge Davidson, CVM filed a post hearing brief in Support of its Proposal to Withdraw Approval of the New Animal Drug Application for Enrofloxacin (Baytril) on July 18, 2003[4].

On August 15, 2003, CVM filed replies to post-hearing briefs from the Animal Health Institute and Bayer on Withdrawal of Approval of New Animal Drug Application (NADA) 140-828 (Baytril) – (Animal Health Institute[5]) and (Bayer[6]).

The next step is for Judge Davidson to render his decision on the proposed withdrawal.

Why is CVM proposing to withdraw approval of this drug?

CVM set forth its rationale for proposing to withdraw the approval of enrofloxacin in poultry in the Notice of Opportunity fo a Hearing[7].

Specifically, CVM has determined that:

- The use of fluoroquinolones in poultry causes the development of fluoroquinolone-resistant *Campylobacter*, a

pathogen to humans, in poultry;

- This fluoroquinolone-resistant *Campylobacter* is transferred to humans and is a significant cause of the developmen of fluoroquinolone-resistant *Campylobacter* infections in humans; and
- Fluoroquinolone-resistant *Campylobacter* infections are a hazard to human health.

What is the legal basis for approving or withdrawing approvals for NADAs?
The requirement for approval of NADAs are set out in section 512 of the Federal Food, Drug, and Cosmetic Act (the Act). That section requires that a new animal drug must be shown to be safe and effective for its intended uses. In determining safety, CVM must consider the safety to humans of substances formed in or on food as a result of the use of the new animal drug.

Under Section 512(e)(1)(B) of the Act, the approval for a NADA must be withdrawn if:
"...new evidence not contained in [an approved] application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, show that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved...."

Where can interested parties obtain additional information about the NOH and the basis for CVM's proposed withdrawal?
Further information is included in the October 31, 2000[8] and the February 20, 2002[9], *Federal Register*).

Was enrofloxacin the only fluoroquinolone approved for use in poultry?
No, sarafloxacin hydrochloride was also approved for use in poultry. Abbott Laboratories, North Chicago, IL, is the sponso of two NADAs for sarafloxacin hydrochloride. NADA 141-017, Sara Flox WSP, was approved August 18, 1995, for the control of mortality in growing turkeys and broiler chickens associated with *E. coli* organisms. NADA 141-018, Sara Flox Injection, was approved October 12, 1995, for the control of early chick mortality associated with *E. coli* organisms in chickens and turkeys. Abbott Laboratories voluntarily requested withdrawal of these NADAs[10], and therefore, these NADAs are not covered by the NOH.

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2. http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-4082-filed
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U.S. Food and Drug Administration
10903 New Hampshire Avenue

Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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