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AMERICAN ASSOCIATION OF AVIAN PATHOLOGISTS

Robert J. Eckroade, Secretary-Treasurer of AAAP

382 West Street Road, Kennett Square, PA 19348

Phone (610) 444-4282; Fax (610) 444-5387

E-mail AAAP@vet.upenn.edu

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August 22, 1997

RE: Docket No. 97N-0217

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Dear Sir/Madam:

The American Association of Avian Pathologists, Drugs and Therapeutics Committee, submits the following comments on Docket Number 97N-0217, regarding minor uses and minor species.

We suggest that primary and multiplier breeder hens (including leghorns, broiler breeders, and turkey breeders), cockerels, and toms prior to sexual maturity be classified as minor species with regard to effectiveness, animal safety, and human safety data collection.

These classes of livestock exist in relatively small numbers. For example, an inventory of less than 290,000 broiler breeder hens in lay will supply the hatching egg requirements of a broiler complex slaughtering 1,000,000 head per week. The average turkey breeder hen will produce about 100 poults. From the standpoint of numbers, these are truly a minor class of livestock.

Because of major differences in management, these breeder birds tend to have fewer health problems, and to a certain extent their diseases tend to be different from those in the layers, broilers, or market turkeys. For example, broiler breeder pullets occasionally experience fowl cholera (caused by *Pasteurella multocida*), which rarely occurs in broilers, and for which there are few effective approved drugs. Recently, broiler breeder pullets have experienced blackhead (caused by *Histomonas meleagridis*), which almost never occurs in broilers, and for which there are currently no approved drugs since the removal of the imidazole compounds. From the standpoint of frequency of occurrence and availability of approved drugs, these uses would indeed be minor uses.

These classes of birds are long-lived birds which are not intended for immediate human consumption. They produce fertile eggs which are hatched for the production of commercial layers, broilers, or turkey poults. In the case of broiler breeders, these birds are kept in lay for approximately 35 to 40 weeks or longer, leghorns may be kept in lay for 12-14 months, and turkey breeders for 6 months. These spent breeder layers may be slaughtered for human consumption. However, if these minor uses are restricted to birds prior to sexual maturity, then withdrawal

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periods of 6-12 months (depending on species) are ensured prior to human consumption of these birds, due to standard management practices. Fertile eggs not suitable for hatching may also be sold for human consumption. This is a minor concern, and it would be agreeable to the industry to exclude such eggs from treated flocks from human consumption for prolonged periods (up to and including the life of the flock if necessary) in order to be able to use certain drugs.

We further recommend that certain medicated feeds be considered for minor uses in these classes of birds under AMDUCA, for the same reasons cited above.

The effectiveness and animal safety data generated in the related classes of birds (layers, broilers, or commercial turkeys) should be directly applicable to these minor classes. The only exception might be the effects of broiler or commercial turkey drugs on egg production in the breeders, and in most cases the minor uses proposed involve mortality and production losses which far exceed any concerns with drug-induced effects on egg production or fertility. Likewise, human safety data should be directly applicable, particularly with the ease of achieving compliance with extremely long withdrawal periods in these classes of birds.

In summary, we recommend that breeder hens and turkeys, cockerels, and toms prior to sexual maturity (i.e., prior to egg production) be classified as minor species, and that certain drug uses be considered minor uses in these classes of birds, due to their limited numbers, the limited incidence of disease in these classes of birds, the unique nature of many of their diseases, the lack of effective treatments for many of these diseases, and the unique ability to exclude these birds and their products from human food channels for extremely prolonged periods.

Sincerely,

A handwritten signature in black ink, appearing to read "G. Thomas Holder", with a long, sweeping flourish extending to the right.

G. Thomas Holder DVM
Chairman, AAAP Drugs and Therapeutics Committee

AMERICAN ASSOCIATION OF AVIAN PATHOLOGISTS
UNIVERSITY OF PENNSYLVANIA
New Bolton Center
Kennett Square, Pa. 19348—1692



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Security - Logical:

B1: An audit trail does not restrict access to the database - it only records who made changes. It typically does not audit who made queries or browsed data.

B1: "the protective system software" seems to imply a single protective system package when in fact there may be many layers of protection using different systems.

B2: While this is desirable, it is not easy for a sponsor to control.

B3: What is meant by "reevaluate" and what is required to document the results?

System dependability

B: Sponsor has little ability to impose our standards on investigative sites - it would be difficult for the site to meet all the standards of X number of pharmaceutical companies with whom they are doing business.

C: It is unclear what is meant by "validation" in this context. The guidance needs to distinguish between the responsibilities of the investigator and sponsor under the two following circumstances:

- Site originates and/or modifies software and/or hardware
- Sponsor provides hardware and/or software to investigator

C1: Most OTS companies will not provide design level validation documentation to the sponsor, although they may allow you to audit it at their offices. Would an audit report of this nature be considered adequate documentation of the design level validation?

C1(4): It sounds as if any time anyone uses an Excel spreadsheet to enter clinical data, that we must have the design level validation of Excel from Microsoft.

This section uses the terms "design level validation", "validation" and "software validation". Are these terms interchangeable or do they each refer to something different?

C2a: Validation is generally based upon adherence to requirements specifications. Does the guidance mean that design documents are acceptable in place of requirements specifications?

C2c: Unclear as to what the "predetermined criteria" are. The design specs?

System controls:

C2: Delete reference to "specified in SOP". If secure location of backups is changed this will require a rewrite of the SOP.

Training of personnel:

A2: Computer skills are not a core competency we require of our CRAs, though they should know enough to identify problems that may affect the integrity of the data.

Records inspection

No comment.

Certification of electronic signatures

No comment.

Sincerely,

A handwritten signature in cursive script that reads "Elizabeth Beaty".

Elizabeth Beaty
Regulatory Affairs Specialist