

RINGNECK PHEASANTS
DAY-OLD CHICKS
DRESSED PHEASANTS
SMOKED PHEASANTS

PHEASANTS
FOR
LIBERATION
BREEDING
FOOD

MacFarlane

TELEPHONE 608-757-7881
800-345-8348
FAX 608-757-7884

9:00 A.M.-5:00 P.M.
Monday-Friday



Pheasant Farm, Inc.

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September 5, 1997

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

9009 '97 SEP -8 A10:25

Dear Sir,

This letter is in response to your "Request for Comments on Development of Options to Encourage Animal Drug Approvals for Minor Species and for Minor Uses" - as listed in Federal Register Volume 62, No. 120, pages 33781-33783 - Docket Number 97N-0217.

I chair the committee for the North American Gamebird Association (NAGA) that is involved in the feed medication issue. Also I am the Vice-President of the NAGA and will become the President in January 1998. We appreciate the FDA efforts to assist those of us who are in the business of raising minor species.

Feed medication is imperative for commercial gamebird farms to maintain their flocks and their livelihood. The NAGA has joined in the Minor Species Animal Health Coalition to strive to find a solution to the feed medication issue. We support the Minor Species Animal Health Coalition plan as submitted in response to your request for comment. In addition we add the following comments:

Amending AMDUCA to permit extra-label use of feed medication seems to be the easiest fix. But it seems likely that another solution will need to be found.

Drug companies have limited incentives to clear their medications for minor species. We all would welcome legislation that would either streamline the approval process or provide incentives for drug companies to clear feed medications for minor species use. If drug companies can be induced to get the needed drugs approved - that is a solution. But I believe another solution will need to be found.

Most feed medications that gamebird raisers want are currently approved for use in the commercial poultry industry. Much of the approval research has already been completed for the major species (chickens and turkeys). If gamebird producer groups can coordinate efficacy studies - that would be an excellent mechanism to garner the info needed for approval. Perhaps CVM standards that would require only limited gamebird efficacy studies can be implemented. Of course each species of gamebird would require separate efficacy studies. Efficacy studies seem to me to be one of the best options available.

Sincerely,

Bill MacFarlane

97N-0217

C10


NEXT DAY AIR

LETTER

Place parcel register tape or stamp UPS shipper number

Place your address label below



NEXT DAY AIR TRACKING LABEL

Enter
Pounds

Print or Type
UPS Shipper
Number

N _____

Tracking No. 1414 8159 675

**Shipper
Instructions**

1. Enter weight & shipper number
2. Remove backing
3. Affix to carton directly left of the address label
4. Attach receipt below to your shipping record



TIME:

RECEIVER'S NAME (PLEASE PRINT):

REMARKS:

FOR
UPS
DRIVER
USE

1414 8159 675

EXTREMELY URGENT

A1109 R5/86 75MM 5 86
UNITED PARCEL SERVICE CO
LOUISVILLE KY

MAC FARLANE PHEASANT FARM, INC

2821 So. U.S. HWY 51
Janesville, WI 53546
(608) 757-7881

TO:

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

This section tends to imply a stricter interpretation of electronic identification than is required in the regulations for paper-based systems, where signatures are not required. Is the intent to describe log-in security as opposed to electronic signature?

V.A.1.: Entry of electronic signatures should be linked to a “commit” action rather than the entry of the data on the screen.

V.A.2.: This is appropriate if the intent is to cover login security only. Otherwise, this seems superfluous in a true electronic signature system, because a user should not be able to commit a record with his authorization code for a session under an other’s login ID.

V.A.5.: This is appropriate if V.A. applies to login security. However, 21 CFR Part 11 requires 2 levels of security if a screen-saver lockout occurs. This may be overly restrictive.

SECTION V.B.

V.B.1.a. There is a level of insecurity regarding system clocks on stand-alone workstations.

V.B.2. Suggest changing to “Audit trails should not be permitted to be altered.”

V.B.5. Time stamping for the audit trail should be *in* the audit trail file, not *on* the audit trail file. It should be acceptable to update an audit trail file as long as the time stamping of each actual change record in the file is secure.

SECTION V.C.

The final paragraph in section V.C 3 should be the first in the section, preceding section V.C.1.

V.C.3. The time zone should be included in the time stamp.

VI. System Design:

SECTION VI.A.

Subparts 1 and 2 are too specific and should be deleted, or listed as examples

SECTION VI.C.

The statement “and as necessary for record retrieval and review.” is in contravention to statements in Part 11, e.g. as cited in response to comments 30 and 69.

VII. Security:

SECTION VII.A.

In Paragraph VII.A.5. “Lock and key” may be too specific. “External safeguards should be sufficient to guarantee the integrity of the data and collection devices”

SECTION VII.B.

VII.B.2 & 3. This is too restrictive. A given computerized system can support more than one trial and therefore should not be restricted to one. Also, can we not validate our study SW in a more complex environment if it makes business sense?

VII.B.3. Agree with the intention here, however recommend to reword the last sentence to make it clear that change management SOPs need to be in place.

VIII. System Dependability

SECTION VIII.C.

VIII.C.1. SW developers *can not* perform validation. At most they can perform a limited part of the qualification testing and supply documents required to support parts of the validation. Some testing must be carried out in the production environment.

The second paragraph needs to be reworded. It currently implies that companies are expected to collect evidence of testing for products like Lotus 1-2-3 and Microsoft Excel. What should be done is some sort of qualification testing of the applications built in such SW packages.

VIII.C.2.b. Remove reference to structural analysis - delete "including both structural".

SECTION D:

VIII.D.2. All changes to the system, regardless of the relation to original design specifications, should be handled according to established change management procedures. This includes evaluation of the extent of testing.

IX. System Controls

SECTION C:

IX.C.2. The location of back-up records should not be specified, merely that they be separate from the originals.

XI. Records Inspection

SECTION A:

XI.A. Do companies need to provide licenses to FDA to view copies of electronic data which uses SW not owned by the agency? Is it sufficient to provide them with the use of the software at company's facility?

SECTION B:

XI.B. This is contrary to other sections of this document which state that certified copies of electronic data are acceptable source documents. In other words, at the close of a study, if all records, including audit trails are printed and certified and the hardware removed from the site to be used elsewhere, the certified copies should be sufficient for inspection. It is not efficient to leave equipment at the investigators site after the close of a trial if he or she will not continue to require the equipment. It is also not efficient to reinstall equipment or to leave the equipment at the site unused, on the chance that an inspection will be scheduled for that particular site.

