



JAN 10 1997

**CERTIFIED MAIL,**  
**RETURN RECEIPT REQUESTED**

Larry R. McDougald, Ph.D.  
Department of Poultry Science  
University of Georgia  
Athens, Georgia 30602

**WARNING LETTER**

Dear Dr. McDougald:

On June 18, 1993, representatives of the Food and Drug Administration visited Georgia Poultry Research, Inc., (GPR) and collected documents on clinical studies which you performed for the following clinical investigation:

We have evaluated these copies of study documents obtained at your facility and also have evaluated documents received from \_\_\_\_\_ in response to a request of May 23, 1991, and from \_\_\_\_\_ in response to a request of June 7, 1993. Based upon our evaluation, the Center for Veterinary Medicine believes that you have submitted false information to the sponsors of the referenced study and have repeatedly and deliberately violated regulations governing the proper conduct of clinical studies involving investigational-use new animal drugs, as published under Title 21, Code of Federal Regulations (CFR), Part 511 of which a copy is enclosed.

This letter provides written notice of the alleged violations. We propose that you be disqualified from receiving investigational-use new animal drugs as set forth under 21 CFR 511.1(c). You may respond to this matter, including any explanation of why you should remain eligible to receive investigational drugs and not be disqualified as a clinical investigator, in a written response or at an informal conference in my office. This procedure is provided for in Section 511.1(c)(1) of the investigational new animal drug regulations.

The following are the specific allegations of submission of false information:

In Study \_\_\_\_\_ the final weight entries on the raw data sheet for pens 24 (females), 33 (females) and 34 (males) and the Table 2 entries in the final report for the average female body weights for pens 24 and 33 were falsified in submissions to the sponsors.

You submitted the final report and raw data records to both \_\_\_\_\_ study monitors \_\_\_\_\_ (respectively) under a cover letter dated February 27, 1987. The final report included a Table 2 summary of average weight values for each pen \_\_\_\_\_ and the "Final Wt" raw data sheet dated 2/20/87, which is an original document of study observations and has handwritten entries recording the weight of the birds.

Additionally, a spreadsheet printout table summary of raw data from Study \_\_\_\_\_ was sent to both \_\_\_\_\_ study monitors under a cover letter dated February 22, 1987, signed by Dr. Mathis, General Manager, Georgia Poultry Research, Inc.

Discrepancies were noted for pens 24, 33, and 34 when comparing the original raw data sheet for "Final Wt" dated 2/20/87, the Table 2 final report data, and the spreadsheet data summary sent under the February 22 cover letter.

A. Discrepancies Between "Final Wt" Raw Data and Table 2 Final Report Data

Comparison of the "Final Wt" raw data sheet dated 2/20/97 sent to each firm reveals that the copies are not identical because different values for weights are entered for the females in pens 24 and 33 and the males in pen 34. Additionally, comparison of the Table 2 final report sent to each firm reveals that the copies are not identical, because different values for female average weights are entered in pens 24 and 33. Discrepancies noted for the raw data sheet and the Table 2 final report data submitted to both firms on 2/27/87 are presented in the following table:

Comparison of Raw Data and Table 2 Data

	Pen 24 Females	Pen 33 Females	Pen 34 Males
Final Wt. Raw Data	95.0 lb	97.9 lb	116.0 lb
Av. Wt. Table 2 Final Report	1.877 kg	1.934 kg	2.291 kg
Final Wt. Raw Data	90.5 lb	93 lb	106 lb
Av. Wt. Table 2 Final Report	1.787 kg	1.839 kg	2.291 kg

Study data indicates that there were 23 females in pen 24, 23 females in pen 33, and 23 males in pen 34. The "Final Wt" raw data values reported to \_\_\_\_\_ for the females in pens 24 and 33, and the males in pen 34 do not correspond to those values reported to \_\_\_\_\_ demonstrating that two different sets of raw data were generated for final bird weight and that these values for pens 24, 33, and 34 were

falsified. Additionally, the average female weight values for pens 24 and 33 listed in the Table 2 final report differ from the average female weight values for pens 24 and 33 listed in the Table 2 final report, demonstrating that two different sets of data were generated for average female bird weight in pens 24 and 33 and that these values were falsified.

Furthermore, the average female weight values for pens 24 and 33 listed in the Table 2 final report sent to each firm were consistent with the average female weight values derived from the "Final Wt" raw data sheet values sent to that firm, and the average male weight pen 34 Table 2 value sent to is consistent with the average male weight value derived from the "Final Wt" raw data values sent to for that pen. However, the average male weight value for pen 34 listed in the Table 2 final report sent to cannot be calculated from the "Final Wt" raw data value for males sent to or pen 34. Instead, the Table 2 value corresponds to the Table 2 value sent to

**B. Discrepancies Between "Final Wt" Raw Data Sheet and Spreadsheet Data**

The weight values for pens 24, 33, and 34 are identical on the spreadsheets sent to both firms under the February 22 cover letter. Discrepancies noted between the "Final Wt." raw data sheet dated 2/20/87 and the spreadsheet data summary submitted on 2/22/87 are presented in the following table:

Comparison of "Final Wt" Raw Data and 2/22/87 Spreadsheet Data

	Pen 24 Wt. Females	Pen 33 Wt. Females	Pen 34 Wt. Males
Final Wt. Raw Data	95.0 lb	97.9 lb	116.0 lb
Final Wt. Raw Data	90.5 lb	93 lb	106.0 lb
2/22/87 Data to	41.1 kg (90.6 lb)	42.3 kg (93.2 lb)	52.7 kg (116.2 lb)

The raw data values for final weight (rounded) for the females in pens 24 and 33 reported to are consistent with the figures previously submitted to both firms under the February 22 cover letter; however, the raw data value for the males in pen 34 is not consistent with the spreadsheet value. The raw data value for the males in pen 34 reported to is consistent with the figure previously reported under the February 22 cover letter; however, the values reported to for the females in pens 24 and 33 are not consistent with the spreadsheet values.

**C. Discrepancies Between Table 2 Final Report and Spreadsheet Data**

Discrepancies noted between the Table 2 final report data submitted on 2/27/87 and the spreadsheet data summary previously submitted to both firms on 2/22/87 are presented in the following table:

**Comparison of Table 2 Final Report Data and 2/22/87 Spreadsheet Data**

	Pen 24 Av. Wt. Females	Pen 33 Av. Wt. Females	Pen 34 Av. Wt. Males
Table 2	1.877	1.934	2.291
Table 2	1.787	1.839	2.291
2/22/87 Data to	1.786957	1.839130	2.291304

The average female body weights for pens 24 and 33 listed in the Table 2 final report sent to do not match the data for pens 24 and 33 in the spreadsheet printout sent to both firms under the 2/22/87 cover letter, although the data for the males in pen 34 is consistent. The average female body weights for pens 24 (Treatment Group 4) and 33 (Treatment Group 6) listed in the Table 2 final report and derived from the "Final Wt" raw data sheet were the lowest values for average female body weights in their treatment groups in the raw data and final report submitted to

In the final report submitted to the values (rounded) for the Table 2 average weights for the females in pens 24 and 33 and the males in pen 34 match the values reported in the spreadsheet printout sent to both firms under cover letter dated 2/22/87. As noted above, however, the average weight value for males in pen 34 listed in the Table 2 final report sent to does not correspond to the average weight value derived from the "Final Wt" raw data sheet values sent to

In summary, the submission to the sponsors of two different copies of a raw data sheet and Table 2 final report which should have been identical demonstrate that study results were manipulated and that the raw data for final weight in pens 24, 33, and 34 and the Table 2 average weights for pens 24 and 33 were deliberately falsified. Furthermore, the discrepancies between the raw data sheet and Table 2 final report submitted on February 27, 1987, and data spreadsheet submitted on February 22, 1987, also demonstrate that study results were manipulated.

This letter is not intended to be an all-inclusive list of deficiencies with your clinical studies of investigational drugs. It is your responsibility to ensure adherence to each requirement of the law and relevant regulations.

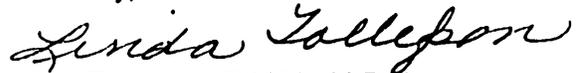
Within (15) working days of the receipt of this letter, write or call me at (301) 594-1761 to indicate your intent to request an informal conference or to respond directly in writing. If you choose to respond in writing and require additional time, state the reason for the delay and the time within which your response will be forthcoming. Your reply should be sent to Dr. Patricia E. Hasemann, HFV-234, Center for Veterinary Medicine, 7500 Standish Place, Rockville, Maryland 20855.

If you decide to request an informal conference, please be informed that a transcript of our discussions will be prepared. You may bring legal counsel with you to such a conference.

You may not wish to avail yourself of the opportunity for an informal conference or to make a written reply. Rather you may prefer to enter into a consent agreement with the agency regarding your future eligibility to receive investigational drugs. Such an agreement would terminate further administrative proceedings. If you wish to consider this option, we will forward an agreement for your review.

If we cannot come to terms on such an agreement, or if your written or oral responses to our allegations are unsatisfactory, you will be offered a regulatory hearing before the Food and Drug Administration, pursuant to part 16 (enclosed) and section 511.1(c) of the regulations. This hearing will determine whether or not you will remain eligible to receive investigational new animal drugs. You should be aware that neither entry into a consent agreement nor pursuit of a hearing precludes the possibility of a corollary judicial proceeding.

Sincerely,



Linda Tollefson, D.V.M., M.P.H.  
Director, Office of Surveillance  
and Compliance  
Center for Veterinary Medicine

Enclosures (2)