DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

July 29, 2002

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Counsel:

I have reviewed the record of the regulatory hearing involving Carey L. Quarles, Ph.D., the summary decision of the Presiding Officer, the parties' summary decision memoranda with attachments, and the parties' submissions requesting review of the summary decision. Based upon my review, I have concluded that Dr. Quarles repeatedly violated 21 CFR Part 511 in connection with investigational new animal drug studies of Cygro. Consistent with 21 CFR § 511.1(c)(2), I have determined that Dr. Quarles is no longer entitled to receive investigational use new animal drugs. The reasons for my decision are set forth in the enclosed decision.

Dr. Quarles may seek to have his eligibility to receive investigational use new animal drugs reinstated pursuant to 21 CFR § 511.1(c)(6) upon presentation of adequate assurances that the investigator will employ investigational use new animal drugs solely in compliance with the provisions of 21 CFR Parts 50, 56, and 511.

Sincerely,

Lester M Crawford

Lester Crawford, D.V.M., Ph.D.
Deputy Commissioner

Enclosure

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submitting false information to a study sponsor. Therefore, I am disqualifying Dr. Quarles from receiving investigational use new animal drug products The reasons for my decision follow

I. PROCEDURAL BACKGROUND

The charges in this proceeding are based on studies conducted by Dr. Quarles for the sponsor, American Cyanamid Company (ACC), at his research facility, Colorado Quality Research, Inc. (CQR), Fort Collins, Colorado, where Dr. Quarles served as President and Chief Executive Officer during the time in question. Dr. Quarles conducted the studies to determine whether Cygro, in combination with bacitracin zinc and other antibiotics, promoted growth and improved feed efficiency in pen-reared turkeys

From October 1988 through March 1989, Dr. Quarles conducted twelve studies involving Cygro. In September 1990 and November 1991, investigators from CVM inspected Dr. Quarles' facility and reviewed his studies. Around this same time, CVM conducted a criminal investigation of ACC and Dr. David Sharkey (Dr. Sharkey), ACC's principal study monitor for all Cygro studies In February and April 1994, Dr. Sharkey and ACC each pleaded guilty to a violation of 21 U.S.C. § § 331(e) and 333(a)(1) - the

failure to establish and maintain records required to be kept under the Federal Food, Drug, and Cosmetic Act, relating to the investigational use of Cygro. Dr. Quarles was not implicated in either of these plea agreements

In September 1995, CVM issued a Warning Letter to Dr Quarles for four of his twelve Cygro studies, alleging that Dr. Quarles submitted false data to ACC and violated regulations governing the proper conduct of studies. In January 1996, Dr Quarles offered his written response to the Warning Letter. On August 13, 1998, FDA issued a Notice of Opportunity for Hearing (NOOH) to Dr Quarles, alleging that Dr. Quarles submitted false data to the study sponsor in connection with Study A-88-29, Study A-88-37, Study A-88-41, and Study A-89-8

Subsequent to the issuance of the NOOH, Dr. Quarles and CVM participated in informal settlement negotiations and mediation, but the parties were unable to reach an agreement. On June 16, 2000, CVM charged Dr. Quarles with falsification under 21 CFR § 511.1(c)(2) and filed a request for summary decision, alleging that Dr. Quarles had repeatedly or deliberately:

falsified feed preparation records and drug inventory records, by claiming that he mixed two batches of 7000 pounds of feed for two treatment groups when in actuality he only mixed 4000 pounds each for the two groups, on January 1989 in study A-88-29, and submitted these false data to study sponsor;

falsified feed preparation records on January 11, 1989 and on February 7, 1989 in study A-88-37 to report that he mixed a large batch of feed on one day, when he actually mixed smaller batches over the course of several days, to conceal the fact that he had obtained an assay for only the first of these smaller batches of feed, and submitted these false data to the study sponsor;

falsified feed preparation records on November 9 1988 and on February 28, 1989 in study A-88-37 by falsely reporting that four batches of feed were "mixed but not used," when in fact Dr. Quarles actually used this feed but reported it as discarded to conceal his

failure to obtain assays for these batches, and submitted these false data to the sponsor;

(4) falsified feed preparation records on January 11, 1989 and on February 7, 1989 in study A-88-41 to report that he mixed a large batch of feed on one day, when he actually mixed smaller batches over the course of several days, to conceal the fact that he had obtained an assay for only the first of these smaller batches of feed, and submitted these false data to the study sponsor;

(5) falsified feed preparation records on November 9, 1988 and on February 28, 1989 in study A-88-41 by falsely reporting that four batches of feed were "mixed but not used," when in fact Dr. Quarles actually used this feed but reported it as discarded to conceal his failure to obtain assays for these batches and submitted these false data to the sponsor;

(6) submitted false feed retention samples for assay in study A-89-8; and

falsified data for weighback amounts for pens 8, 13 and 27 for two kinds of feed and submitted these false data to the sponsor in study A-89-8.

On June 16, 2000, Dr. Quarles filed a request for summary decision, contending that CVM had not raised genuine and substantial issues of fact that could support disqualification and that the proceeding should be dismissed on the following procedural grounds: (1 FDA did not act within a reasonable time frame, thus prejudicing Dr. Quarles' ability to respond; (2) FDA's action for disqualification was taken for punitive rather than remedial purposes; (3 FDA cannot meet its burden of proving repeated or deliberate conduct; and (4) given CVM's delay in issuing the NOOH, it is fundamentally unfair for FDA to pursue this action further.

Under 21 CFR § 16.26(b), the presiding officer may issue a summary decision on any issue when there is no genuine and substantial issue of fact respecting that issue Based upon the evidence presented in, and attached to, CVM's Initial Request for Summary Decision, Dr Quarles Initial Request for Summary

Decision and Response to CVM's Request, and CVM's Opposition to Dr. Quarles' Initial Request, P.O. Dr. Startzman issued a summary decision on three of the charges in favor of CVM on October 23, 2001. Specifically, P.O. Dr. Startzman concluded that summary decision was warranted on the following three allegations: (1 that Dr. Quarles falsely reported to the study sponsor that he discarded feed mixed on November 9, 1988 in study A-88-37; (2) that Dr. Quarles falsely reported to the sponsor that he discarded feed mixed on November 9, 1988 in study A-88-41; and (3) that Dr. Quarles submitted to the sponsor falsified data for weighback amounts for pens 8, 12, 13, and 27 for grower 3 feed and withdrawal feed in study A-89-8. On the remaining charges, P.O. Dr. Startzman found that a determination could not be made without further evidence, and therefore denied CVM's Initial Request for Summary Decision on those grounds. Based upon these findings, P.O. Dr. Startzman concluded that Dr. Quarles' actions were done "repeatedly" within the meaning of 21 CFR § 511.1(c and therefore recommended that I disqualify Dr. Quarles from being eligible to receive investigational use new animal drugs.

However, P.O. Dr. Startzman did note that [ ] [ ] warranted some consideration in my decision.[1]

Quarles and CVM requested review of P.O. Dr. Startzman's decision on several bases. Specifically, Dr. Quarles argues that the record does not support a summary decision against him because genuine and substantial issues of fact have been raised that warrant a hearing in this case; and alternatively, that even if the record did support summary decision for CVM, no useful regulatory purpose would be served by this disqualification and that I should thus find that the exigent circumstances in this case mitigate against disqualification.

CVM requests review of P.O. Dr. Startzman's decision with respect to two issues, arguing that: (1 P.O. Dr. Startzman misunderstood the nature of the records for study A-88-29, and, upon review, I should find that the amount of Cygro used in study A-88-29 was falsified on either the form filed in study A-88-29 or on the form filed in study A-89-1 and that the question of which form contained the false information is immaterial; and (2)

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[1]Specifically, P.O. Dr. Startzman stated that [ ] [ ] should play a role in evaluating the need for disqualification ":

." P.O. Dr. Startzman's Decision at 31

Dr. Quarles' age and health status are inappropriate factors for me to consider.

II. DECISION

In order to conclude that a clinical investigator is no longer eligible to receive investigational use new animal drugs, I must find that the investigator repeatedly or deliberately failed to comply with the conditions of the applicable regulations or repeatedly or deliberately submitted false information to FDA or to the study sponsor. Section 511.1(c)(2) of Title 21 of the Code of Federal Regulations provides

> If, after evaluating all available information, including any explanation presented by the investigator, the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the conditions of the exempting regulations in this section or has repeatedly or deliberately submitted false information to the sponsor of an investigation, the Commissioner will notify the investigator and the sponsor of any investigation in which he has been named as a participant that the investigator is not entitled to receive investigational use new animal drugs with a statement of the basis for such determination.

Therefore, a determination that an investigator either repeatedly or deliberately submitted false information is a sufficient basis for disqualification.

In this proceeding, Dr. Quarles is charged with repeatedly or deliberately submitting false information to the sponsor in four studies I will, as P.O. Dr. Startzman did in his summary decision, separately address each of the studies and the charges involved therein

A. The Four Studies at Issue

1. Study A-88-29

In study A-88-29, CVM alleged that Dr. Quarles falsified feed preparation records and drug inventory records by reporting that he mixed two batches of 7000 pounds of feed each for Treatment Groups 1 and 2 on January 19, 1989, when in fact he mixed two batches of 4000 pounds each for the two treatment groups, and submitted false records regarding these batches to the sponsor with the final report of the study. To support this allegation, CVM compared Dr. Quarles handwritten drug inventory records from study A-88-29 with his drug inventory records for study A-89-1

Both parties agreed that the information on the handwritten drug inventory records for study A-89-1 were supposed to have carried over the inventory data of drugs used during study A-88-29 on January 19, 1989, as reflected in the record contained in

the file for study A-88-29. The problem was that the inventory records for study A-88-29 were inconsistent with those for study A-89-1. Specifically, the drug inventory records for study A-88-29 report that more Cygro and bacitracin methylene disalicyclate (BMD-50) were used on January 19, 1989 in study A-88-29 than is reflected in the carry-over data reported in the drug inventory records for study A-89-1. The amount of Cygro reported in the records for study A-88-29 on that date is sufficient for the mixing of two batches of feed weighing 7000 pounds each and is consistent with the amount of Cygro reported in Dr. Quarles' feed preparation records for study A-88-29. By contrast, the amount of Cygro reflected in the carry-over data reported in the records for study A-89-1 is sufficient only for the mixing of two batches of feed weighing 4000 pounds each. Comparable discrepancies were found in the amount of BMD-50 recorded in the drug inventory records for these two studies. Additionally, CVM presented evidence that Dr. Quarles' mixer only had a mixing capacity of 4000 pounds; accordingly, CVM argued that Dr. Quarles could not have mixed batches of 7000 pounds.

In response, Dr. Quarles admitted that the records for the two studies are inconsistent, but submitted an affidavit from

member of his staff, [ ], indicating that the inconsistencies merely reflected a subscription error in transferring data and not an intentional falsification. With respect to the mixer capacity, Dr. Quarles noted that he had a California Pellet Mill, which enabled him to make a continuous mix for production of a variety of batch sizes exceeding 4000 pounds.

P.O. Dr. Startzman reviewed the records and concluded that there were indeed actual discrepancies between the records for two studies. Although, P.O Dr Startzman noted that "it is undisputed that the records for one of the two studies contains false information," P.O. Dr. Startzman concluded that he could grant CVM's Request for Summary Decision on this issue because a genuine and substantial issue of fact remained as to whether it was the records from study A-88-29 or from study A-89-1 that were incorrect.[2]

After reviewing the administrative record, I reject P.O. Dr. Startzman's finding that genuine and substantial issues of fact

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[2]P.O. Dr. Startzman also noted that, based on the evidence before him, he could not resolve the issue of whether Dr. Quarles could have mixed batches of feed larger than 4000 pounds.

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2. Study A-88-37

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of allegations: (1 that Dr. Quarles falsified feed preparation records to report that he mixed a large batch of feed on one day, when he actually mixed smaller batches over the course of several days, and (2) that Dr. Quarles falsely reported in his feed preparation records that four batches of feed (two batches of starter feed prepared on November 9, 1988 and two batches of grower 1 feed prepared on February 28, 1989) were "mixed but not used." To substantiate these allegations, CVM offered copies of Dr. Quarles feed preparation records and compared them to a handwritten chart prepared by Dr. Sharkey, which P.O. Dr Startzman characterized as a compilation of the feed preparation information for study A-88-37

With respect to the first set of allegations, P.O. Dr. Startzman concluded that summary decision was unwarranted, because, although CVM argued that Dr. Sharkey's chart demonstrated that Dr Quarles mixed batches of feed over several days, Dr. Quarles' explanation that the chart was merely Dr. Sharkey's mixing plan - a plan that was not followed by Dr Quarles - was equally plausible. I agree with P.O. Dr Startzman's finding that genuine and substantial issues of fact remain and thus deny summary decision with respect to the charge

that, in study A-88-37, Dr. Quarles falsified feed preparation records to report that he mixed a large batch of feed on one day, when he actually mixed smaller batches over the course of several days

With regard to the second set of allegations, P.O. Dr. Startzman concluded that CVM had established that Dr Quarles falsely reported in his feed preparation records that the feed mixed on November 9, 1988 was discarded. The feed preparation records contain a notation at the bottom of the page that these batches were "mixed but not used"; consistent with this notation the word "toss" is written next to the entries for these batches of feed on Dr. Sharkey's chart. CVM argued that if Dr. Quarles had discarded the feed as he claims he did, he would not have had enough feed to distribute to the turkeys in Treatment Groups 1 and 2. According to P.O Dr. Startzman, Dr. Quarles did not dispute that the amount of feed distributed to Treatment Groups 1 and 2 exceeded the amount of feed mixed for that phase of the study, and Dr. Quarles did not have a credible explanation for this discrepancy;[3] therefore, P.O Dr. Startzman concluded that

[3]Dr. Quarles did submit an affidavit from [ ] who offered three reasons why these batches might have been discarded: (1) the feed was mixed incorrectly, (2) extra feed was

summary decision was warranted on this claim. After reviewing administrative record, I affirm P.O. Dr. Startzman's finding summary decision was appropriate on the charge that Dr Quarles falsely reported in his feed preparation records in study A-88-37 that the feed mixed on November 9 1988 was discarded However, regarding the feed prepared on February 28, 1989, Dr. Startzman found that genuine and substantial issues of fact remained, because, unlike the feed mixed on November 9, the mixed on February 28 did not raise the question of an apparent shortage of feed for the study, nor did CVM make such an allegation. Because I agree with P.O. Dr. Startzman that it is possible that the feed mixed on February 28 could have been discarded while the study continued, as Dr Quarles described in final report, I sustain his finding that summary decision on this issue is inappropriate

3. Study A-88-41

CVM alleged that Dr. Quarles failed to obtain assays for some batches of feed and tried to conceal this failure by falsely

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made at ACC's request as backup feed in case the first batch proved to be out of compliance by assay, or (3) feed was mixed in excess of what was needed to feed the birds in the study. However, as P.O. Dr. Startzman noted, none of these reasons explains the discrepancies between the feed preparation records and the pen cards.

as Dr. Quarles claimed, there were only 1,000 pounds of feed available for distribution to Treatment Group 1 Similarly, for Treatment Group 2, the evidence showed that 2,445.3 pounds of starter feed was distributed for Treatment Group 2, but that excluding the feed mixed on November 9, only 2,000 pounds of starter feed was mixed for this time period. Therefore, P.O. Dr Startzman found that summary decision was warranted as to CVM's allegation that Dr Quarles falsified data in study A-88-41 by reporting in a feed preparation record that starter feed for two different treatment groups was discarded on November 9, 1988. After reviewing the administrative record, I affirm P.O. Dr Startzman's findings that summary decision for CVM is warranted for this charge.

As for the feed reported to have been discarded for study A-88-41 on February 28, 1989, P.O Dr. Startzman found that genuine and substantial issues of fact remained because, as with the feed reported to have been discarded on that date in connection with study A-88-37, this feed could have been discarded while study continued, as described in Dr. Quarles' final report. I affirm P.O Dr. Startzman's finding that summary decision is not

appropriate for this charge, because genuine and substantial issues of fact remain.

4. Study A-89-8

CVM presents two allegations with respect to study A-89-8: (1) that Dr. Quarles submitted false feed samples for assay; and (2) that Dr. Quarles falsified data for weighback amounts for pens 8, 12, 13, and 27 for grower three feed and withdrawal feed and submitted these falsified data to the study sponsor

With respect to the first allegation, CVM points out that some of the assay records obtained from Dr. Sharkey's files indicate that three feed samples were found to be subpotent or at the low end of the acceptable assay range for bacitracin zinc; according to CVM, to correct these poor assay results, Dr. Quarles mixed 500 pounds of feed at the end of the study, sent samples from this batch of feed to the analytical laboratory on January 16, 1990, and represented these samples as retention samples from the batches of feed for which there were poor assay results. To supports its allegations, CVM relied on an unsigned, handwritten note found in Dr. Sharkey's files, listing three of the feed assays for bacitracin zinc that tested as subpotent; CVM maintained that Dr. Sharkey wrote this note. At the bottom of

note was a comment that according to CVM, read, "Will mix 500 lbs for 3 bac zn assays." CVM argued that this notation demonstrated that Dr. Quarles mixed new feed for additional assays of bacitracin zinc at the request of Dr. Sharkey

In response, Dr. Quarles denied that he mixed additional feed samples. According to Dr. Quarles, Dr Sharkey consistently asked for additional feed samples for analysis during the studies he oversaw, so Dr. Quarles issued a standard order to his staff to take large amounts of feed samples to satisfy Dr. Sharkey's repeated requests.[4] Dr Quarles claimed to have no knowledge of why Dr. Sharkey requested that multiple feed samples be sent for analysis, but Dr. Quarles speculated that either Dr Sharkey or the assaying laboratory lost the originally submitted samples and that repeated samples were needed because the assaying procedure

bacitracin and Cygro was difficult to conduct and reproducible assay results were difficult to obtain due to the fatty composition of turkey feed. Dr. Quarles further stated that, although he was responsible for submitting all feed samples

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[4]This statement was corroborated by an affidavit from [ ] which stated that Dr. Sharkey frequently asked for multiple retention samples and that it became standard practice during the study to take a large sample of each mixed batch to have sufficient retention samples for repeated submissions of samples for assay.

for assay to the independent laboratory, the assay results from the laboratory did not go to him but were sent directly to Dr. Sharkey. Moreover, Dr. Quarles claimed no independent information from which he could explain the comment at the bottom of Dr. Sharkey's handwritten note and could only disagree with CVM's conclusions drawn from that comment. Finally, Dr. Quarles argued that Dr. Sharkey's note was not part of the data submitted by Dr. Quarles to the sponsor and thus could not constitute a basis for charging him with falsification

Based upon his review of the evidence, P.O. Dr. Startzman found that Dr. Quarles raised genuine and substantial issues of fact and thus that summary decision was unwarranted. After reviewing the administrative record, I affirm P.O. Dr. Startzman's findings with respect to this charge. As CVM conceded, feed mixing records from Dr. Quarles' file did not show the use of any additional bacitracin zinc beyond what was needed for the study. Moreover, although CVM noted that Dr. Quarles could have bought bacitracin zinc over the counter, there was no evidence to support this allegation. Finally, like P.O. Dr. Startzman, I find [ ] affidavit denying that new feed samples were mixed after the fact to be sufficient to raise a

genuine and substantial issue of fact, thereby precluding summary decision.

With respect to the allegation that Dr Quarles falsified data for weighback amounts for four pens and for two kinds of feed, CVM argued that a comparison between Dr. Quarles' study files and a facsimile sent by Dr. Sharkey to [ ], one of the staff members who worked with Dr Quarles, shows that Dr. Quarles falsified data for pens 8, 12, 13, and 27. Dr Sharkey's facsimile, which was dated March 1, 1990 and thus appeared to been written after Dr. Quarles completed his final report study A-89-8, listed the final feed weighbacks for pens 8, 13, and 27 and showed Dr Sharkey's calculations; the last page also contained the notation, "Will talk to CQ." CVM interprets "CQ" to be "Carey Quarles." As further evidence, CVM offered a letter written by [ ] and dated March 30, 1990, which contained responses to the several questions and corrections identified by Dr. Sharkey in his facsimile. Regarding final feed weighback data, [ ] wrote, "Pens 8, 12, 13, and 27 -- feed weighback before withdrawal feed added were incorrect. Figures corrected." Relying on this evidence, CVM asserted that Dr Quarles made two types of changes to the study data: (1 that Dr

Quarles crossed out final feed weighback data for these four pens on the "Weight Data Sheets"[5] and wrote new data above the original data; and (2) that Dr. Quarles changed grower 3 feed weighback data on the pen cards by erasing the original entries and writing new entries in their place. CVM argued that Quarles made these alterations to ensure that the originally reported amount of total feed consumed by pens 8, 12, 13, and 27 remained unchanged and that this alteration of data was favorable to the study results

Dr Quarles responded by admitting that he made the changes described by CVM, but suggesting that errors in the raw data occurred when leftover feed from the grower 3 phase was mistakenly recorded as leftover feed from the withdrawal phase According to Dr. Quarles, this error made it appear that the turkeys ate a lot of grower 3 feed but an insufficient amount of withdrawal feed to sustain them Dr Quarles stated that original data could not have been correct because if the turkeys had eaten so little feed during the withdrawal phase, they would most likely have died or at least become very sick, which Dr

[5]The "Weight Data Sheets" are the records reporting the total amount of feed used in each pen.

Quarles claimed did not comport with the fact that the turkeys in these pens were healthy and of similar size and weight to the turkeys in the other pens.[6] Dr. Quarles stated that when this apparent error in the weight data sheets was brought to his attention, he corrected the data consistent with the good health of the turkeys. To make this correction Dr Quarles stated that he used a feed guide to determine how much grower 3 and withdrawal feed the birds in pens 8, 12, 13, and 27 would have eaten at the relevant stages of development Dr. Quarles argued that his alteration of the data was not a falsification, because he was attempting to present a reasonable approximation of the amount of feed consumed by the turkeys in the pens at issue.

P.O Dr. Startzman pointed out that there is no dispute that an error occurred and that Dr. Quarles explanation does not change the facts that (1) he used a standardized feed chart to calculate the amount of feed that the turkeys should have eaten and, (2) he changed the data accordingly and submitted them to the sponsor as the true study data. Accordingly, P.O. Dr. Startzman concluded that Dr. Quarles use of the feed chart was

[6]CVM agreed that the original raw data were inconsistent with the good health of the turkeys and that it was likely that an error occurred in collecting and recording the raw data.

more than a correction; it was "simply inventing data to suit the desired outcome of a study." P.O. Dr. Startzman's Decision at 27. Moreover, P.O. Dr. Startzman pointed out that the data submitted to the sponsor do not contain an accompanying explanation or any indication - other than cross-outs and eraser marks - that the numbers reported were not the raw data from the study. Therefore, P.O. Dr. Startzman concluded that regardless of Dr. Quarles' underlying motivation and regardless of whether the sponsor was aware of the alterations to the raw data made by Dr. Quarles, Dr. Quarles failure to document these alterations rendered the submission of data "false information" under 21 CFR § 511.1 and compromised the integrity of the study and thus summary decision was warranted with respect to this allegation

After reviewing the administrative record, I affirm P.O Dr Startzman's findings that summary decision for CVM is warranted on the charge that Dr. Quarles falsified data for weighback amounts for four pens and for two kinds of feed in study A-89-8. There is no dispute that Dr. Quarles used a standardized feed chart to change the final feed weighback data for these four pens and that these alterations were submitted as the actual raw data from the study. Accordingly, there is no question that Dr

Quarles submitted to the sponsor "false information," under 21 § 511.1.

B. Equitable Considerations

Both before P.O. Dr. Startzman and in his appeal to me, Dr Quarles requested consideration of three equitable factors in this case: (1) the time delay between completion of the studies in 1989, the FDA's issuance of the NOOH in 1998, and today; (2) his age; and (3) his health condition

With respect to the time delay, although P.O. Dr. Startzman stated that a "disturbing length of time" had passed since the completion of the studies and the FDA's issuance of the NOOH,

Dr. Startzman correctly noted that there are no time limitations in the regulations for disqualification proceedings, and that Dr. Quarles admits that he altered feed weighback data

times in study A-89-8. On this basis alone, Dr. Quarles is subject to disqualification under 21 CFR § 511.1(c)(2) Moreover, the submission of false data to the sponsor of a clinical investigation is an extremely serious violation, because

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[7]In his Initial Request for Summary Decision, Dr. Quarles also contended that FDA's purpose in pursuing this disqualification was punitive. Although this argument was not raised in Dr. Quarles' Request for Commissioner's Review, I note for the record that I agree with P.O. Dr. Startzman that there is no evidence in the record to support such an allegation.

FDA necessarily relies upon the validity of this information in approving the use of new animal (and new human) drugs Therefore, I do not find that the mere passage of time is a basis for excusing Dr. Quarles from facing responsibility for his actions.[8]

However, P.O. Dr. Startzman did suggest that I take into account [ ] in resolving this disqualification proceeding, to the extent that these factors might "prevent Dr. Quarles from participation in scientific studies in the future." P.O. Dr Startzman's Decision at 31. Although 21 CFR § 511.1(c does not on its face give me any discretion to consider equitable factors,[9] the agency has established in the preamble to its clinical investigator disqualification regulation that I have discretion to refuse to disqualify an investigator "if the violations are insignificant, or if lesser sanctions would be adequate." 52 F.R. 8798, at 8826. The preamble and the applicable caselaw also make clear

[8]There is no statute of limitations in these matters.

[9]The regulation states that if "the Commissioner determines that the investigator has . . . repeatedly or deliberately submitted false information to the sponsor . . ., the Commissioner will notify the investigator and the sponsor . . . that the investigator is not entitled to receive investigational use new animal drugs . . ." 21 C.F.R. § 511.1(c)(2) (emphasis added).

however, that this discretion should be exercised only in extraordinary circumstances (e.g., where the violations are truly insignificant, or where disqualification would be truly unjust or would accomplish nothing). Id.; see also In the Matter of Huibert M. Vriesendorp, M.D. (2001 at 37; In the Matter of James A. Halikas, M.D. (2001 at 28.

Based on the evidence in the record, I find that Dr. Quarles' [ ] alone do not guarantee that he would not participate in any future investigational-use drug studies and thus that disqualification would be unnecessary. Dr Quarles is [ ] which in today's world is not remarkably old; there are many people his age who are still working and who continue to work for many years. Moreover, Dr. Quarles' non-binding representations to CVM that he is now retired cannot be relied upon, because (1 they are not legally enforceable, and (2) Dr. Quarles has in the past told CVM that he was retiring but has then returned to work, so there is reason to believe that he might do so again. See Quarles' Initial Request for Summary Decision at 8.

With respect to Dr. Quarles [ ] there is no evidence that [ ] would prevent him from returning to

work. In fact, the evidence points to the contrary Far from saying that he will never return to work, [ ] [ ] [ ] See Quarles' Ex. 11 (March 15, 2000 [ ] [ ]). Therefore, I find that there is no basis for assuming that [ ] alone would prevent him from participating in investigational-use animal drug studies in the future. Accordingly, these equitable considerations do warrant a finding against disqualification in Dr. Quarles' case.

C. Summary of Findings

Based upon the above analysis, I conclude that there is no genuine and substantial issue of fact with regard to whether Dr. Quarles failed to fulfill the responsibilities of an investigator by (1 submitting false information to the study sponsor with respect to the amount of Cygro used in study A-88-29;(2) falsely reporting to the study sponsor that he discarded feed mixed on November 9, 1988 in study A-88-37; (3) falsely reporting to the study sponsor that he discarded feed mixed on November 9, 1988 in study A-88-41; and (4) falsifying data for weighback amounts for

pens 8, 12, 13, and 27 for grower 3 and withdrawal feed in study A-89-8 and submitting this false information to the study sponsor. Under 21 CFR § 511.1(c)(2), my findings on these four charges are sufficient to disqualify Dr. Quarles for repeatedly submitting false information to the sponsor. Moreover, I find that these violations are sufficiently serious and numerous so as to require disqualification.

III. CONCLUSION

Therefore, I conclude that Dr. Quarles is no longer entitled to receive investigational-use new animal drugs. Dr. Quarles may seek to have his eligibility to receive investigational-use new animal drugs reinstated pursuant to 21 CFR § 511.1(c)(6)

Lester Crawford, D.V.M., Ph.D
Deputy Commissioner

Dated: 7/29/02