I. BACKGROUND

A. Studies

After reviewing the documents submitted in connection with the Motions for Summary Decision submitted by the Center for Veterinary Medicine (CVM or the Center), Dr. Davidson as well as the documents submitted in connection with Dr. Davidson’s Motion to Dismiss, it is recommended that the Commissioner grant Dr. Davidson’s Motion to Dismiss. Each parties’ Motions for Summary Decision will be discussed before discussing the recommendation of dismissal.
The basis of this disqualification is data alleged by CVM to be false submitted in four studies conducted by Dr. Davidson between 1986 and 1989: studies [ ] . Dr. Davidson submitted these data to American Cyanamid Company (ACC), the sponsor of a New Animal Drug Application (NADA) for maduramicin ammonium (Cygro). Because CVM requests summary decision only on charges stemming from studies [ ] , the discussion in this recommendation will be limited to those two studies.\(^1\)

At the time of the studies, Dr. Davidson was president of Health Management Services (HMS), a contract research organization in Tulare California that conducts animal studies for veterinary drug manufacturers. The studies were intended to investigate whether Cygro, in combination with bacitracin zinc and other antibiotics, promoted growth and improved feed efficacy in pen-reared chickens. Dr. Davidson submitted these studies to ACC; ACC submitted the studies to FDA in support of its NADA for Cygro. CVM charges that these studies contained falsified raw data and final reports.

Study [ ] comprised [ ] Each pen had a pen card on which Dr. Davidson recorded raw study data by hand, including feed weight values and average bird weights at different points in the study. Chickens were weighed at the beginning of the studies; surviving birds were also weighed at the end of the studies. For those birds that died

\(^1\) In his Motion for Summary Decision, Dr. Davidson responds to CVM’s allegations concerning all four studies. By limiting its request for summary decision to studies [ ] , CVM apparently concedes the need for an oral hearing on its allegations related to studies [ ] . Were there any question of holding a hearing on this matter, this report would include preliminary findings on the charges stemming from those studies. No hearing is necessary for the reasons discussed in this report.
during the course of the studies, the “mortality weight” was taken upon death. Thus, the pen
cards reflected the chickens’ beginning weight as well as their end or mortality weight.

Each of the studies had a starter stage, a grower stage, and a withdrawal stage during
which the chickens were given different feeds. At the beginning of each stage, the feed was
weighed before it was put in the pen, yielding the “weigh-in” value. Leftover feed was removed
and weighed at the end of each stage, yielding the feed “weigh-back” value. The weigh-in and
weigh-back values were recorded on the pen cards for each of the three study stages.

Upon each study’s completion, the “adjusted feed efficiency” value was calculated for
each pen and recorded on the pen card. This value reflects the total feed consumed in a pen
divided by the total body weight of all chickens in a pen, including those that have died. Low
adjusted feed efficiency values support a finding of treatment efficacy because they show high
values for bird weight relative to feed consumed.

In addition to studies [redacted], which were submitted to FDA as part of the
Cygro NADA, Dr. Davidson has conducted numerous other studies relied upon by FDA in its
approval of NADAs. Between the years 1992 and 1999, FDA approved sixteen new animal
drugs for which Dr. Davidson conducted the pivotal studies.2

B. Regulatory Basis for Disqualification

In the two studies in question, hand-written data on pen cards, including values for
average body weight, mean body weight, mortality weight, feed weigh-in, feed weigh-back, and
adjusted feed efficiency, were changed. In some instances, numbers were crossed out and new
numbers were written in; in other instances new numbers were written over the initial entries. In

2 See Davidson Motion to Dismiss at 6-7 and 11-12. According to Davidson’s Motion to Dismiss, CVM sent
investigators to monitor six of those studies, but did not require a Bioresearch Monitoring inspection of the other ten
studies, as the Center did for the studies at issue in this case. All of those inspections were conducted before the
warning letter of 1995 issued. Id.
addition, Dr. Davidson wrote and submitted to ACC two final reports containing inconsistent data. CVM argues that Dr. Davidson made changes to the pen cards and altered final report values to manipulate the data in favor of approval of ACC’s NADA. Dr. Davidson responds that he corrected inaccurate data in some instances; in other instances he denies data were changed at all. In any case, Dr. Davidson denies an attempt to manipulate the data and attributes any inaccuracies in data submitted to carelessness.

Based on these changes to data submitted to ACC, CVM seeks disqualification under 21 C.F.R. § 511.1(c)(2), which provides:

Whenever the Food and Drug Administration has information indicating that an investigator has repeatedly or deliberately . . . submitted false information either to the sponsor of the investigation or in any required report, the Center for Veterinary Medicine will furnish the investigator written notice of the matter complained of in general terms and offer him an opportunity to explain the matter in an informal conference and/or in writing. If an explanation is offered but not accepted by the Center for Veterinary Medicine, the investigator shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Part 16 of the chapter on the question of whether the investigator is entitled to receive investigational new animal drugs.

CVM argues that Dr. Davidson repeatedly and deliberately submitted false information to ACC and should be disqualified from receiving investigational new animal drugs.

C. History of this Proceeding

The Center formally began its investigation of Dr. Davidson’s studies in 1990 when, in response to information CVM had received questioning the validity of studies submitted in support of the Cygro application, investigators from the Bioresearch Monitoring division of CVM (BIMO) inspected HMS. At the conclusion of the inspection, the investigators issued Dr. Davidson a Form FDA-483 Inspectional Observations form noting several deficiencies in Dr. Davidson’s conduct of five studies, including the studies in question in this proceeding. The deficiencies included unexplained changes to raw data and a variety of poor documentation and
recordkeeping practices. Only in 1995, however, did the Center issue a warning letter to Dr. Davidson, proposing to disqualify him from receiving investigational drugs and providing him with an opportunity to respond to the charges against him. On November 7, 1997, more than two years after sending the warning letter, CVM initiated this proceeding by sending Dr. Davidson a Notice of an Opportunity for a Hearing (NOOH). Dr. Davidson responded in a letter dated November 19, 1997, requesting a hearing under 21 C.F.R. Part 16.

Following several delays, the presiding officer, with the agreement of the parties, scheduled a motions deadline of May 28, 1999. During a flurry of activity in a matter otherwise characterized by long periods of stagnation, the parties filed nine briefs:

Dr. Davidson’s Motion to Dismiss and Response and Reply Briefs

1. May 28, 1999. Dr. Davidson’s Motion to Dismiss the Proceedings.
2. June 18, 1999. CVM’s Response in Opposition to Davidson’s Motion to Dismiss the Proceedings.
3. July 3, 1999. Dr. Davidson’s Reply to CVM’s Response to Davidson’s Motion to Dismiss.

CVM’s Motion for Summary Decision and Response and Reply Briefs

6. July 2, 1999. CVM’s Reply to Davidson’s Opposition to CVM’s Motion for Summary Decision.

Dr. Davidson’s Motion for Summary Decision and Response and Reply Briefs

8. June 18, 1999. CVM’s Response in Support of its Motion for Summary Decision and In Opposition to Davidson’s Motion for Summary Decision.

According to CVM, the Center only learned of the scope of data falsification in Dr. Davidson’s four Cygro studies after criminal proceedings against ACC’s study monitor, Dr. David Sharkey, concluded with Dr. Sharkey signing a plea agreement. See United States v. American Cyanamid Company (CR 94-067, United States District Court for the District of Maryland).

The first presiding officer, Peter H. Rheinstein, M.D., J.D., M.S., was appointed to preside over this matter on April 9, 1998. Linda Sherman, M.D. was appointed as the presiding officer on July 26, 1999, following reorganization of the Office of Health Affairs, the Office within FDA that formerly presided over disqualification proceedings. The current designation of a presiding officer was issued on July 31, 2008.

On October 8, 2008, an Order was issued requiring the parties to Show Cause whether this matter should, or should not proceed to hearing, due to the fact that a decision on these motions had been pending for over nine years. The parties filed responses on October 27, 2008, arguing that this matter should be decided on the outstanding motions. Below are the findings on the arguments presented in the two Motions for Summary Decision followed by the recommendation on the Motion to Dismiss.

I. FINDINGS ON MOTIONS FOR SUMMARY DECISION

A. The Standard for Summary Decision

Section 16.26(b) of 21 C.F.R. Part 16 provides:

After a hearing commences, the presiding officer may issue a summary decision on any issue in the hearing if the presiding officer determines from the material submitted in connection with the hearing, or from matters officially noticed, that there is no genuine and substantial issue of fact respecting that issue. For the purpose of this paragraph, a hearing commences upon the receipt by FDA of a request for hearing submitted under § 16.22(b).

The language of this provision is similar to that of Rule 56 of The Federal Rules of Civil Procedure, which provides for summary judgment when “the pleadings . . . and admissions on file, together with the affidavits, if any, show that there is no genuine issue of material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c). Case law under Rule 56 provides the appropriate standard for deciding motions under 21 C.F.R. § 16.26. See, e.g., Report of the Presiding Officer, In the Matter of Huibert M. Vriesendorp. M.D. (2000) at 12 (“the presiding officer may be guided by the body of law developed under Rule 56 in determining whether summary decision is warranted”); see also John D. Copanos and Sons, Inc., 854 F. 2d 510, 523 (D.C. Cir. 1988) (finding that principles in case law under Rule 56 “apply with equal force in the context of administrative judgment”).

Under Rule 56, “[t]he mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement
is that there be no genuine issue of material fact.” Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986) (emphasis in original). In granting summary judgment, the decision maker must find that even if all reasonable factual inferences are drawn in favor of the nonmoving party, no issues appropriate for trial remain unresolved by the parties’ submissions that could affect the case’s outcome. This standard applies to motions for summary decision in a Part 16 hearing. See Commissioner’s Decision, In the Matter of Eugen O. Grecu (1998) at 9.

B. Repeated or Deliberate Conduct

In its Motion for Summary Decision, CVM argues that its briefs and supporting materials demonstrate overwhelmingly that Dr. Davidson repeatedly and deliberately submitted false information in studies [redacted] and [redacted]. Although in his reply to CVM’s motion, Dr. Davidson argues that CVM has not shown that the data was false in all instances, briefs filed by Dr. Davidson in support of his Motion for Summary Decision and responsive to CVM’s Motion for Summary Decision primarily take issue with the Center’s assertion of deliberate action. CVM is correct in asserting that the language of section 511.1(c) should be given its plain meaning and that an investigator may be disqualified for repeated or deliberate submission of false information to a study sponsor. See Commissioner’s Decision, In the Matter of James A. Halikas (2001).

The interpretations of the terms “repeatedly” and “deliberately” in 21 C.F.R. § 312.70(b), FDA’s regulation governing disqualification of clinical investigators of new drugs, are well-established and inform my reading of those terms in 21 C.F.R. § 511.1(c)(2). The term “repeatedly” means, simply, more than once. See Commissioner’s Decision, In the Matter of William H. Ziering, M.D. (2008) at 7. Further, multiple violations within a single study constitute repeated violations sufficient to support disqualification from receipt of new
investigational drugs. See, e.g., Commissioner’s Decision, In the Matter of James A. Halikas (2001) at 23 (“[T]o interpret repeatedly to mean transgressions in more than one study would permit an investigator to commit as many violations of the regulations as he/she wished without possibility of disqualification as long as that investigator limited his/her violations to one study. Such a result ... would be absurd.”) See also Commissioner’s Decision, In the Matter of Layne O. Gentry (2008) at 23.

Decision makers in Part 16 proceedings have interpreted the term “deliberately” in 21 C.F.R. § 312.70(b) as roughly synonymous with the “deliberate indifference” or “willful” standard of intent. See, e.g., Commissioner’s Decision, In the Matter of William H. Ziering, M.D. (2008) at 8 (“[a] clinical investigator may be found to have acted ‘deliberately’ ... if he or she knowingly or willfully engaged in conduct that violates FDA’s regulations or if the investigator engaged in conduct that demonstrated a reckless disregard for compliance with FDA’s regulations.”) This standard does not require specific knowledge that behavior, such as submission of false data to a study sponsor, violates the law, but reckless disregard for what the regulations require. The decision in the Gentry disqualification provides a useful discussion of the standard for “deliberate” behavior in a disqualification proceeding:

the term “deliberate,” when used to describe a category of violations that might lead to legal consequences, does not necessarily require a showing of subjective intent on the part of the person in question....The purpose of [disqualification] is to protect the safety of patients and preserve the integrity of the data needed to assess the safety and effectiveness of drugs before being sold to the general public through disqualifying investigators who do not fulfill the responsibilities imposed on them.

In the context of such a remedial, as opposed to punitive, scheme, an objective standard for “deliberate” or “deliberately” is a better fit because the inquiry should focus on preventing risk rather than imposing punishment for culpable conduct. Even if the investigator did not intend for the violations to occur, conduct demonstrating a reckless disregard for the regulatory requirements calls into question the investigator’s fitness for conducting clinical trials.
Commissioner’s Decision, *In the Matter of Layne O. Gentry* (2008) at 20-21. Although the charges in the *Halikas, Gentry and Ziering* proceedings were brought under 21 C.F.R. § 312.70(b), the language of the regulations governing disqualification from receipt of new drugs and new animal drugs are similar. Interpretations of the legal standard for disqualification under 21 C.F.R. § 312.70(b), then, are appropriate guides in the interpretation of the standard for disqualification under 21 C.F.R. § 511.1(c)(2). Under this standard, to sustain a finding of repeated or deliberate submission of false information, the Center must show that Dr. Davidson submitted false information to ACC two or more times, whether in a single study or in multiple studies, or did so with reckless disregard for the truthfulness of the data he submitted.

C. **Dr. Davidson Repeatedly and Deliberately Submitted False Information**

1. Dr. Davidson Repeatedly Or Deliberately Submitted False Information In Study

   a. **Reports A and B.** The Center argues that Dr. Davidson submitted to the sponsor at least twenty-six pieces of false information in Study, either by submitting two reports with discrepant data or by submitting pen cards containing falsified values. The two reports, Report A and Report B, plainly contain different data for five values: The Adjusted Feed Efficacy (AFE) for Pen; the Total Feed Consumed (TFC) for Pen; the Adjusted Feed Efficacy (AFE) for Pen; the Total Feed Consumed (TFC) for Pen; and the Mortality Weight for Pen. According to CVM, these five discrepancies demonstrate repeated

5 The regulation governing disqualification of new drug investigators provides for disqualification from receipt of new investigational drugs “if the Commissioner determines that the investigator has … deliberately or repeatedly submitted false information.” 21 C.F.R. § 312.70(b).

6 The values in the two reports are as follows:

<table>
<thead>
<tr>
<th></th>
<th>REPORT A</th>
<th>REPORT B</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFE: Pen</td>
<td>1.927</td>
<td>1.866</td>
</tr>
</tbody>
</table>
submission of false information to ACC. Dr. Davidson does not specifically address each of these five discrepancies in his Motion for Summary Decision, Response to CVM’s Motion for Summary Decision, or Reply brief. Instead, Dr. Davidson argues that Report A was a draft report reflecting uncorrected pen card data and data entry mistakes and that only Report B was intended as a final report.

Dr. Davidson concedes, then, that he submitted inaccurate data but argues that CVM has not made the case for his disqualification for several reasons. These reasons include: Dr. Davidson’s contention that changes to Report B were corrections rather than falsifications and such corrections do not provide a basis for disqualification; Dr. Davidson’s assertion that

| TFC: Pen | 253.90 kg | 245.90 kg |
| AFE: Pen | 2.044 | 2.010 |
| TFC: Pen | 242.60 kg | 239.60 kg |
| Mortality Weight: Pen | 2030 g | 2530 g |

See CVM Motion for Summary Decision at 9.

Ordinarily, one would expect parties in a Part 16 proceeding to present their complete factual and legal case for summary resolution in their initial memoranda supporting their motions for summary decision and to use their responsive pleadings only to address arguments raised in the opponent’s brief. CVM has requested that responsive arguments presented in the Reply brief corresponding to Dr. Davidson’s Motion for Summary Decision be disregarded. See CVM’s Reply Brief, fn.4. The failure of Dr. Davidson’s attorneys to limit responsive arguments to the appropriate brief complicates what is already a vast and conflicted set of facts. For over 200 pieces of data alleged by CVM to be false, reaching a recommendation on CVM’s Motion requires not only consideration of the allegation of falsification for the data related to each charge, but also of Dr. Davidson’s evidence disputing the falsification, CVM’s calculations intended to show that the falsifications skewed data, and Dr. Davidson’s various rebuttals to CVM’s arguments concerning the effect of falsifications. Nonetheless, in the interests of fairness, all arguments presented in all pleadings have been considered in crafting this recommendation. See 40 Federal Register 22950 (1975) (noting that many of the usual “legal technicalities” of court proceedings do not apply to Part 16 actions.)

According to Dr. Davidson, pen’s pen card value for feed weighback at the grower stage reflected a failure to add feed remaining in the pen to feed remaining in the feed sack and the inaccurate original value was used to calculate the pen AFE and TFC values in Report A. By his own admission, Dr. Davidson changed this value on the pen card after the card was submitted to the study sponsor and used the new value to calculate relevant values in Report B.

Dr. Davidson argues that the values in Report A for pen AFE and TFC reflect a computer data entry error in recording the starter feed weighback value from the pen card for pen. According to Dr. Davidson, the pen card contained the appropriate value for starter feed weighback but, in calculating the values for Report A, he relied upon information that had been gathered from pen cards and entered into a computer database. He claims the values in Report B reflect the correct value gleaned directly from the pen card. Similarly, Dr. Davidson argues that the mortality weight for pen in Report A corresponded to a value inaccurately transcribed from the pen card into a source called the Mortality and Necropsy Records.
although the sponsor’s study monitor alerted him to data anomalies, Dr. Davidson made corrections on his own initiative and not at the direction of the study monitor; and Dr. Davidson’s argument that he had no intent to manipulate the data in favor of approval for ACC’s NADA. These arguments are misdirected. The standard under 21 C.F.R. § 511.11(c)(2) of repeated submission of false information is met when an investigator has submitted multiple pieces of inaccurate data, even in a single study. See Commissioner’s Decision, In the Matter of Layne O. Gentry (2008), at 23. Further, an investigator’s submission of two reports containing conflicting data suffices to show a violation of 21 C.F.R. § 511.1(c)(2) without the need for a hearing to determine which report is false. See Commissioner’s Decision, In the Matter of Carey L. Quarles, M.D. (2002), at 12-13. It is clear that Dr. Davidson repeatedly submitted false information in Study ___ by submitting inaccurate values for Pen’s adjusted feed efficacy and total feed consumed and for Pen’s adjusted feed efficacy, total feed consumed, and mortality weight.

b. Altered Data on Pen Cards Corresponding to Report B Values. In three instances, CVM argues that Dr. Davidson’s alteration of raw pen card data to yield the false calculations reported to the sponsor in Report B demonstrates that he acted deliberately. According to the Center, Dr. Davidson obscured the feed weigh-back value of 5.10 kg on pen card and wrote in 13.10 kg; similarly, the Center argues that Dr. Davidson altered the original feed weigh-back and male mortality weight values of 1 and 1325 on pen card and wrote in the values of 4 and 1825. Dr. Davidson does not dispute his alteration of the feed weigh-back value on pen card. According to Dr. Davidson, after the ACC study monitor alerted him to this “obvious outlier,” he revised the figure on the pen card, surmising that the figure was the product of an error in addition. Dr. Davidson explains in his Motion for Summary Decision that at the
end of a study phase leftover feed remained not only in the pens, but also in the feed sacks. Dr. Davidson claims to have calculated the figure of 13.10 kg by adding the weight of feed in the feed sack to feed leftover in the pens. However, Dr. Davidson has not produced his source for the weight of feed remaining in the feed sacks. Therefore, an issue of fact remains as to whether the feed weigh-back value of 13.10 kg on pen card is accurate.

Concerning the feed weigh-back and male mortality weight values on pen card, Dr. Davidson contends that no alteration took place because the figures 4 and 1825 - which correspond to the calculated figures in report B - are the original, accurate values. Regardless of whether a visual inspection of pen cards and would support CVM’s claim that the original values were altered or Dr. Davidson’s claim that 4 and 1825 were the original values, the question remains as to which set of values are accurate. CVM argues that because these values could only have been altered at the end of the study after Report A containing the original values had been submitted and when the raw data sources for the values were no longer available, the values must be false; Dr. Davidson, however, describes alternative sources for what he claims are the inaccurate Report A values. A question of fact remains therefore, concerning whether false information was submitted on the pen card for pen feed weigh-back and male mortality weight. The remaining questions of fact about the accuracy of the values for pens feed weigh-back and pen male mortality weight preclude granting summary decision on the question of whether Dr. Davidson deliberately submitted false data for these values.

c. **Altered Data For Body Weight And Feed Weigh-Back On Pen Cards.** CVM points to crossed through and overwritten values for body weight and feed weigh-back on multiple additional pen cards to support a finding of repeated or deliberate submission of false

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10 See supra footnote 8.

11 See supra footnote 9.
information. Excluding the three changes discussed above (to pen cards \[\text{and} \] feed weigh-back and to pen card \[\text{mortality weight} \], which correspond to values in Report B that the Center claims to be false, CVM alleges sixteen additional pen card revisions in this study. These revisions do not correspond to differences in Reports A and B or to allegations of false calculated values in the reports.

CVM argues that this widespread pattern of undated data revisions without explanation constitutes repeated submission of false information to the study sponsor. Further, CVM has attempted to show that these changes increased mean body weight and decreased mean adjusted feed efficacy, biasing the study results in favor of drug efficacy. According to CVM, this skewing of the data shows that the submission of false information was deliberate.

Dr. Davidson responds by contesting certain facts, conceding others, and disputing the inference that he made changes in an attempt to manipulate the data. First, Dr. Davidson argues that CVM has provided inaccurate numbers for the original male body weight and feed weigh-back values in several instances. (The significance of this argument is unclear, however, because the relevant legal question is not what the values were but whether they were falsified on the cards that were then submitted to the sponsor.) Second, Dr. Davidson concedes revisions were made to the original male body weight and feed weigh-back values\(^{12}\) in some instances, though he does not specify which pen cards were altered. Third, Dr. Davidson argues that only the revised feed weigh-back values yielded more approvable results, but that even these changes “had no statistically significant effect on the outcome of the study.” Davidson Motion for Summary Decision at 17.

\(^{12}\) Dr. Davidson provides no explanation for the changes to body weight. For his explanation of the revisions to feed weigh-back, see fn. 8.
In sum, in dispute are the original values on these sixteen pen cards, the effect of the revisions to those values, and whether the parties have presented adequate documentary evidence to support their sides of the dispute. Relying upon the Recommendation of the Presiding Officer, *In the Matter of Eugen O. Grecu (1998)*, which was adopted in full by the Commissioner, CVM argues that the revisions by themselves meet the burden to support a finding of deliberate submission of false information. Like Dr. Davidson, the investigator in *Grecu* conceded he had made revisions to original forms containing raw data collected from study subjects; unlike Dr. Davidson, however, the investigator in *Grecu* conceded that the revised figures were false.  

Dr. Davidson maintains that he corrected inaccurate values and the values on the revised pen cards are correct. By his own admission, Dr. Davidson’s recordkeeping practices would be considered inadequate under current standards and almost certainly under the standards of the late 1980’s, when the studies in question were being conducted. Section 511.1(c)(2), however, provides for disqualification upon a finding of repeated or deliberate submission of false information. The regulation does not seem to proscribe poor recordkeeping practices without falsifications on submitted documents.  

To sustain this charge concerning alterations to the body weight and

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13 Dr. Grecu attributed 17 instances of inaccurate information to “transcription errors” and acknowledged that blood glucose values from fingerstick samples were represented as being plebotomy venous samples. In the paragraph cited by CVM, the presiding officer states:  

> Whether the alterations were the result of “transcription errors” or of unauthorized repeat fingerstick testing, the original, accurate results of the required venous testing were absent from the case report forms when the sponsor’s representative reviewed them. Hence, Dr. Grecu submitted false information to the sponsor in the required case reports.

*See Recommendation of the Presiding Officer, In the Matter of Eugen O. Grecu (1998) at 28 (Recommendation adopted in full by the Commissioner, see Commissioner’s Decision, In the Matter of Eugen O. Grecu (1999)).* In this paragraph, the presiding officer concludes that the concededly false data submitted by Dr. Grecu constitutes the submission of false information under the disqualification regulation. Nothing in this language suggests that alteration of data constitutes such a violation regardless of the accuracy of the altered values.

14 Like 21 CFR 312.70, the drug investigator disqualification regulation, 21 CFR 511.1(c)(2) provides for disqualification of an investigator who repeatedly or deliberately fails to comply with the relevant regulations governing investigations. Compared to the requirements that apply to drug investigators, however, the regulatory requirements section 511.1 places on investigators of animal drugs are modest and do not include a rule, for
feed weigh-back on sixteen pen cards, CVM must, among other things, show that information submitted is false. A question of fact remains as to this basic showing.

2. Dr. Davidson Repeatedly Or Deliberately Submitted False Information In Study

   a. Discrepancies Between Pen Card Data And Feed Consumed Values In Final Report. CVM argues that the feed consumed values appearing in the Final Report for Study do not comport with the raw data appearing on eight pen cards for feed weigh-in and feed weigh-back values. Feed consumed is calculated by subtracting feed weigh-in from feed weigh-back, so although the feed consumed value does not appear on the pen card, CVM argues that the discrepancy between the reported value and the value yielded using the raw data on the pen cards constitutes the submission of false information. To support its argument, CVM notes disqualifications in which conflicting values in submitted reports was found to constitute evidence of the submission of false information.

Dr. Davidson concedes that the eight Final Report values CVM has called into question are inaccurate, but claims the values are the result of data entry errors. Further, Dr. Davidson example, that an investigator follow written procedures for making document changes or even general rules for recordkeeping. See 21 C.F.R. § 312.70(a) (authorizing disqualification for violations of Part 312, which includes investigator recordkeeping responsibilities.) Further, although the guidance referred to by Dr. Davidson, “Conduct of Clinical Investigations: Responsibilities of Clinical Investigators and Monitors for Investigational New Animal Drug Studies,” may contain the appropriate contemporary standards for the conduct of investigations of animal drugs, FDA’s regulations do not authorize disqualification for failure to follow that guideline.

CVM states in its Motion for Summary Decision:

Dr. Davidson repeatedly or deliberately submitted false information to the drug sponsor, American Cyanamid, for study . Dr. Davidson submitted the final reports and copies of the pen cards to the sponsor. For pens (Treatment Group 1); (Treatment Group 2); (Treatment Group 3); and (Treatment Group 5); and (Treatment Group 6) the feed consumption values derived from the pen card data differ from the feed consumption values listed in the final report for these pens. CVM MSD at 26 (citations to attachments omitted).

In its Motion for Summary Decision, CVM relies upon Report of the Presiding Officer, In the Matter of Ronald R. Fuller, D.V.M. (1987) and Commissioner’s Decision, In the Matter of Maurice Lippman, M.D. (1983) for the proposition that discrepancies between raw pen card data and the Final Report submitted by Dr. Davidson demonstrate the submission of false information. In its Response to Order to Show Cause, the Center relies upon the Commissioner’s decision, In the Matter of Carey O. Quarles as support for its argument.
states that the sponsor would not have relied upon the Final Report he submitted, but would have conducted its own calculations using the raw data figures, mitigating the consequences of inaccuracies contained in the Final Report. Dr. Davidson, then, has read a requirement of materiality into 21 C.F.R. 511.1(c)(2)’s proscription against the repeated or deliberate submission of false information, an interpretation that raises a legal issue appropriate for resolution on a Motion for Summary Decision if one accepts Dr. Davidson’s contention that the sponsor would not have relied on his Final Report. This contention is difficult to believe on its face but there is no need to address Dr. Davidson’s interpretation. Submission of eight false values in a Final Report meets any reasonable standard of materiality; thus Dr. Davidson repeatedly submitted false information to the sponsor by submitting eight false values for feed consumed in a report on study [redacted]. See Commissioner’s Decision, In the Matter of Layne O. Gentry (2008) at 23 (finding the standard for repeated violations met by multiple violations of regulatory requirements in a single study).

b. Altered Data On Pen Cards For Body Weight, Feed Weigh-In And Feed Weigh Back. CVM describes an additional 179 alterations to pen cards submitted for study [redacted] to support its argument of repeated or deliberate submission of false information in this study. These alterations are as follows:

- 12 changes to body weight;
- 123 changes to feed weigh-in at the grower stage and 13 changes to feed weigh-in at the withdrawal stage; and
- 11 feed weigh-back changes at the grower stage and 20 feed weigh-back changes at the withdrawal stage.
According to the Center, the “overwhelming number and similarity of such changes, without any
date or explanation for such changes, show a pattern and practice of deliberate alterations.”

CVM Motion for Summary Decision at 28. CVM also asserts that the changes improved the
study results, demonstrating that Dr. Davidson repeatedly and deliberately submitted false
information to the sponsor. Dr. Davidson concedes many of the alterations, but argues in all
cases that the changes were corrections to inaccurate data. Dr. Davidson’s arguments and
findings with respect thereto will be addressed according to the category of change:

**Body Weight Changes:** Concerning the changes to body weight, Dr. Davidson notes
explanations for the changes appearing on the back of seven of the pen cards and observes that
CVM has failed to show any pattern to the changes. As with many of the pen card alterations in
Study [redacted], CVM has presented no evidence of falsification, only that numbers appearing on
the pen cards were changed. Given Dr. Davidson’s argument that the revised numbers are
accurate, I find a question of fact remains as to whether the numbers submitted are false.

**Weigh-in Changes:** Birds received grower feed at two points in the study, so two grower
feed weigh-in values appear on each pen card. On 59 of 64 pen cards in the study, both of the
values were increased by 2 kg, reflecting an additional 4 kg total per pen in these 59 pens, or a
total of 118 changes. Five additional pen cards had variable changes to only the second grower
feed weigh-in value. Withdrawal feed weigh-in changes reflecting in each case values increased
by 2 kg appear on thirteen pen cards.

Dr. Davidson claims that during the grower feed phase of the study, he added feed to
each pen according to the amount that was needed. Thus, he concedes that the revised numbers
are estimates, reflecting the original amount of feed plus an approximated weight for the amount
added; he also seems to acknowledge that the amount of feed added would have varied from pen
to pen in explaining that “the amount added depended on the amount that Dr. Davidson or his employees judged each pen needed.” Davidson Motion for Summary Judgment at 31. Dr. Davidson does not explain the revisions to the thirteen withdrawal feed values, but argues that they reflect corrections to the original data.

That Dr. Davidson could have correctly estimated the weight of added feed 123 times – apparently without weighing the feed – and that the amount needed was the same for each pen, is not plausible. The standard for summary decision does not require the elimination of remote improbabilities, only that reasonable inferences are drawn in favor of the nonmoving party. See Report of the Presiding Officer, In the Matter of Layne O. Gentry (2001) at 7. CVM has met this standard concerning the 123 revisions to grower phase weigh-in data. Because Dr. Davidson has not provided an explanation for the thirteen changes to feed weigh-in data at the withdrawal stage, but has stated only that they were corrections, a question of fact remains concerning whether false data were submitted for these values.

Weigh-back Changes: No apparent pattern emerges to the numerous changes to pen card weigh-back values and, as elsewhere, CVM has shown only that revisions were made, not that the pen cards were falsified. The same issues of fact concerning Dr. Davidson’s method for calculating feed weigh-back in study ☐ ☐ apply to these thirty-one data.

In addition to arguing falsification, CVM attempts to show that revisions to these values skewed the data in favor of approval of ACC’s NADA and thus constituted deliberate submission of false data. Dr. Davidson acknowledges a pattern to the changes in feed weigh-in values but, because the consistent upward revisions affected control data as well as treatment data, Dr. Davidson denies that the pattern favored approval. Dr. Davidson denies that an intent to manipulate data motivated the revisions to any of the three data categories. Concerning
changes to the body weight, weigh-back, and withdrawal phase weigh-in data, an outstanding question of fact concerning falsification precludes a finding on whether the changes were deliberate. Concerning the altered grower phase weigh-in values, Dr. Davidson’s unverified method of estimating the added feed amounts to recklessness. Thus, Dr. Davidson repeatedly and deliberately submitted false information by submitting the 123 pen cards with revised figures for feed weigh-in to ACC in Study.

II. RECOMMENDATION ON MOTION TO DISMISS

Although CVM has shown repeated or deliberate submission of false information by Dr. Davidson, disqualification is not recommend because it is recommended that Dr. Davidson’s Motion to Dismiss should be granted. Part 16 authorizes a presiding officer to issue a dispositive order on a motion for summary decision, see 21 C.F.R. § 16.26(b); however, the regulation does not expressly address any authority on a motion to dismiss. No disqualification decisions addressing this authority have come to light. The decision in favor of dismissal is in the form of a recommendation to the Commissioner. This recommendation is based on two grounds: first, CVM has failed to make an adequate case that this disqualification would serve a remedial purpose; and second, delay in this proceeding has unfairly prejudiced Dr. Davidson.

A. Authority of the Presiding Officer

Dr. Davidson presents three propositions as legal bases to support his motion to dismiss:

1. Disqualification is intended to be prophylactic rather than punitive;
2. Disqualification cannot be proposed if lesser sanctions have been or would be adequate;
3. Disqualification is inappropriate where a clinical investigator has demonstrated compliance with regulatory requirements.
In its Reply to Dr. Davidson’s Motion to Dismiss, CVM argues that these matters are inappropriate for resolution by the Presiding Officer, and that the Presiding Officer’s role is limited to deciding questions of law and fact that pertain to whether an investigator has repeatedly or deliberately submitted false information. As Dr. Davidson points out, the preamble to the drug disqualification regulation acknowledges the propriety of considering discretionary factors in ruling on a Part 16 matter and disqualification decisions have consistently noted the propriety of exercising discretion not to disqualify under extraordinary circumstances. See Commissioner’s Decisions, In the Matters of James A. Halikas, M.D. (2001); William H. Ziering, M.D. (2008) (discretion not to disqualify exists where violations are truly insignificant, where disqualification would be truly unjust or would accomplish nothing). These authorities describe a role that encompasses consideration of fairness and justice, as well as law and fact.

The Center has largely sidestepped Dr. Davidson’s equitable arguments, focusing instead on the purported limitations of the Presiding Officer’s authority. For example, the Center has done little to address Dr. Davidson’s contention that disqualification is not intended to be punitive and the corollary question of what disqualification would accomplish in this case if we are not seeking to punish Dr. Davidson. The Center might have strengthened its position by

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17 CVM has overstated the limitations on the Presiding Officer in a Part 16 matter. Section 16.62(g) and (h) provides:

(g) The presiding officer has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct a fair, expeditious, and impartial hearing, and to enforce the requirements of this part concerning the conduct of hearings.

(h) the Commissioner or the presiding officer has the power under § 10.19 to suspend, modify or waive any provision of this part.

Under these regulations, principles of fairness may guide not only how a presiding officer conducts a Part 16 hearing but also how the presiding officer rules. The argument that such principles cannot be considered in this matter, where no hearing has been ordered overlooks the consistent finding in disqualification proceedings that discretionary or equitable factors may preclude disqualification under limited, extraordinary circumstances.

18 “[T]he Commissioner will exercise [] discretion and not disqualify an investigator if violations are insignificant, or if lesser sanctions would be adequate.” 52 Federal Register at 8826 (1987) (preamble to final rule governing disqualification of IND investigators).
addressing head on the equities of proceeding with a disqualification based on behavior that took place more than twenty years ago. If further factual development was needed to reach a decision on the legal standard, surely the passage of time and the difficulty of assessing the credibility of testimony concerning events so far in the past could justify a recommendation of dismissal. Other considerations justify such a recommendation here.

Thus, consideration of the equities in proceeding with a disqualification is not outside the scope of the Presiding Officer’s authority. If, as CVM concedes, disqualification is intended as a prophylactic measure, the Presiding Officer must be allowed to consider whether a particular disqualification proceeding serves any prophylactic purpose. Stated differently, the Commissioner may exercise discretion not to disqualify under extraordinary circumstances, such as “where the violations are truly insignificant, or where disqualification would be truly unjust or would accomplish nothing.” See Commissioner’s Decision, In the Matters of James A. Halikas, M.D. (2001). It is recommended that the Commissioner dismiss this proceeding because extraordinary circumstances justify the exercise of discretion not to disqualify. The extraordinary circumstances in this case are the absence of an adequate showing of remedial purpose in this action and the unfairness of disqualifying Dr. Davidson after depriving him of the opportunity to demonstrate corrective action.

B. CVM Has Failed To Show A Remedial Purpose To The Disqualification

CVM contends, however, that disqualifying Dr. Davidson would serve the remedial purpose of ensuring he does not again submit fraudulent data in investigations used by FDA to approve new animal drugs. Divorced from the particulars of this case, the Center’s contention seems reasonable; as CVM notes, the Quarles decision rejected the argument that an investigator’s age or infirmity precluded further drug investigations and found disqualification
was necessary to protect the public. Dr. Davidson has made no representations of his intention to forego investigations of animal studies should he remain eligible, nor would such representations be adequate to dispel CVM’s assertion of a remedial purpose. What is most difficult to square with CVM’s protestation of a public health need for this disqualification is the Center’s acceptance of data submitted by Dr. Davidson following the warning letter of 1995 and even after the NOOH of 1997 in a total of sixteen NADAs.\textsuperscript{20} The Center does not contest that it accepted these data in most cases without ordering BIMO inspections of the study facility and that the BIMO inspections ordered did not uncover violations. Under 21 C.F.R. 511.1(c)(3), the Center is required to undertake a review of all data submitted by an investigator following disqualification and determine whether the data is reliable. Nothing, however, prevented the Center from undertaking such a review \textit{before} disqualification.\textsuperscript{21} CVM’s refusal to explain its acceptance of these data or acknowledge an immediate responsibility to review them for reliability raise questions about the Center’s own view of the threat posed by Dr. Davidson’s eligibility to receive investigational animal drugs. More to the point, the Center’s actions undercut its position that it seeks disqualification for remedial purposes.

There are consequences to characterizing disqualification actions as remedial. The remedial nature of disqualification has been found to justify an interpretation of the term “deliberately” that captures not only intentional violations, but also reckless ones. \textit{See}

\textsuperscript{19} See Commissioner’s Decision, \textit{In the Matter of Carey O. Quarles} at 29

\textsuperscript{20} See supra, fn. 2.

\textsuperscript{21} Under 21 C.F.R. § 514.115(b)(1), FDA will withdraw approval of an NADA upon a finding that the application contains a false statement of a material fact. Either the Center has declined to review the data submitted by Dr. Davidson in the sixteen additional approved NADAs, or the Center has conducted such a review and has not found materially false data. A third possibility is that the Center has conducted reviews, found materially false data, but decided not to take action on the NADAs. All of these possibilities undermine CVM’s contention that disqualification is needed to protect the public. The Center states only that CVM “made appropriate determinations of safety and effectiveness under the new animal drug regulations for the product subject to the approvals.” CVM Response to Motion to Dismiss at 19.
Commissioner’s Decision, *In the Matter of Layne O. Gentry* (2008) at 18-22. Thus, the Center bears the burden of demonstrating a remedial purpose. The burden should not generally present difficulty; the showing made by CVM -- that unless disqualified the investigator could continue to submit false data that FDA will rely upon in reviewing product applications -- will be met by any investigator who does not expire during the pendency of a disqualification proceeding. This showing has generally sufficed. Dr. Davidson argues, however, that CVM has called its asserted purpose into question by continuing to accept, review, and approve NADAs containing investigations conducted by Dr. Davidson. CVM’s actions do not, as Dr. Davidson argues, demonstrate conclusively that Dr. Davidson achieved regulatory compliance after conducting the studies in question: perhaps CVM reviewers approved the subsequent NADAs only after the data submitted by Dr. Davidson was excluded; possibly, divisions within CVM that reviewed these NADAs were unaware of the warning letter and the NOOH issued to Dr. Davidson, and approval of the NADAs shows nothing more than that Dr. Davidson’s falsifications went undetected. The Center’s actions do, however, create certain inferences, including that Dr. Davidson’s data met the Center’s own standards for acceptance (particularly concerning those studies that were subject to BIMO inspections), and that the Center was not sufficiently concerned about Dr. Davidson’s studies after the Cygro studies to order inspections of most of them.\(^2^2\) The Center has failed to counter these inferences. Without an explanation from the Center for its continued acceptance of data from studies conducted by Dr. Davidson, this record does not provide an

\(^2^2\) CVM states that it became more concerned about Dr. Davidson in 1995, after prosecution of Dr. Sharkey uncovered the extent of data problems in the Cygro application. *See* CVM Response to Motion to Dismiss at 19-21 *and supra* fn. 3. CVM continued to approve NADAs containing data from Dr. Davidson, however, until 1999. The Center is correct that the regulations do not bar disqualification of an investigator whose data has been used to approve subsequent applications. *See* CVM Response to Motion to Dismiss at 19-21. The absence of such a bar does not mean that subsequent approvals are irrelevant to whether the intended purpose of disqualification will be served in a particular case.
adequate basis to overcome the inference that the public does not need to be protected because remediation has occurred. 23

C. The Failure To Decide This Action Has Unfairly Prejudiced Dr. Davidson

CVM also does not believe that equitable considerations related to the more than twenty year lapse between occurrence of the conduct that is the basis for this proceeding and now should influence my recommendation. In support of its view, the Center points to language from the Decision of the Commissioner, In the Matter of Carey O. Quarles, stating that “the mere passage of time” should not excuse an investigator from disqualification under 21 C.F.R. 511.1(c)(2) and that “there is no statute of limitations” for disqualification actions. 24 The Center argues that the Quarles disqualification is especially relevant to this proceeding, not only because that disqualification also arose from studies supporting the Cygro NADA, but because Dr. Quarles argued he had been prejudiced by delays in the proceeding to disqualify him.

It should be noted that CVM issued its NOOH to Dr. Quarles in 1998 -- after attempts to negotiate charges in a Warning Letter of 1995 failed-- and the Commissioner issued a decision disqualifying Dr. Quarles from receiving investigational animal drugs in 2002. CVM issued its warning letter proposing to disqualify Dr. Davidson in early 1995; fourteen years later, no

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23 CVM is correct that the current version of 21 C.F.R. 511.1(c) allows an investigator to demonstrate “adequate assurances” of future compliance only after disqualification. The subsequent compliance of an investigator, however, is relevant to whether a disqualification action serves a remedial purpose, an appropriate matter for consideration by the presiding officer in making his recommendation to the Commissioner.

Commissioner's decision has issued.\textsuperscript{25} On the basis of delay alone, this matter can be readily distinguished from the \textit{Quarles} matter and from all the disqualification decisions listed in Attachment B to CVM's Response to Order to Show Cause.

In any case, this recommendation of dismissal is not based on delay alone. It seems fairly clear that neither Part 16 nor section 511.1(c)(2) creates a statute of limitations for disqualification actions. However, the absence of an express time limitation does not preclude consideration of the equities of disqualifying an investigator who has been the subject of a pending action for twelve years\textsuperscript{26} without the opportunity provided by the regulations to provide "adequate assurance" of compliance. Specifically, section 511.1(c)(6) provides:

> An investigator who has been determined to be ineligible may be reinstated as eligible to receive investigational-use new animal drugs when the Commissioner determines that he has presented adequate assurance that he will employ such new animal drugs solely in compliance with the exempting regulations in this section for investigational-use new animal drugs.

The Center has consistently dismissed Dr. Davidson's argument that he has demonstrated adequate assurance of compliance in response to lesser sanctions and should not be disqualified, noting that the current regulation allows consideration of adequate assurances only \textit{after} an investigator has been disqualified.\textsuperscript{27} CVM's insistence that subsequent compliance can have no

\textsuperscript{25} The delays between submission of studies and issuance of the warning letter and NOOH are similar here and in \textit{Quarles}: in both cases, studies were conducted in the late 1980's, giving rise to warning letters in 1995. CVM issued an NOOH to Dr. Davidson in 1997 and to Dr. Quarles in 1998. Delay between initiation of a disqualification action and its conclusion, however, is particularly prejudicial to the investigator. An investigator remains eligible to receive investigational products during an action's pendency but the taint of the pending action and the possibility of having an approval overturned under the procedure described in 21 C.F.R. 511.1(c)(3) may deter sponsors from hiring an investigator who is the subject of a pending disqualification.

\textsuperscript{26} Dr. Davidson argues that he has suffered professional consequences during this time. According to letters written by Dr. Davidson's counsel, Dr. Davidson began withdrawing from participation in research conducted by HMS in 1995, after sponsors canceled their planned clinical investigations with the research organization because of the warning letter, and had sold his interest in HMS by 1997. \textit{See} Davidson Motion to Dismiss, Attachment 11 (Letter from Jess. H. Stribling and Mark S. Brown to Dr. Stuart L. Nightingale, Associate Commissioner for Health Affairs, FDA (Dec. 1, 1995)), \textit{and} Letter from Jess. H. Stribling to Dr. James F. McCormick, Bioresearch Monitoring Program, FDA (November 19, 1997).
bearing on a disqualification decision seems questionable. For example, a conclusive demonstration of subsequent compliance might call into question the existence of any remedial purpose to a disqualification action and constitute the sort of extraordinary circumstance that would permit a decision against disqualification even when the standard for disqualification had been met. In any case, to the extent the regulatory change postpones consideration of subsequent compliance until after disqualification occurs, the change elevates a question of timeliness to one of fairness in a case that has been characterized by multiple delays, including the fourteen years between issuance of the 1995 warning letter and this recommendation.28

IV. CONCLUSION

In summary, CVM has met the legal standard to sustain a finding of repeated or deliberate submission of false information concerning several of its allegations.

Specifically:

- Dr. Davidson repeatedly submitted false information in Study by submitting inaccurate values for Pen’s AFE and TFC and for Pen’s AFE, TFC, and mortality weight;
- Dr. Davidson repeatedly submitted false information to the sponsor by submitting eight false values for feed consumed in a report on study ;

27 See CVM’s Response to Davidson’s Motion to Dismiss at 5. The previous version of 21 CFR 511.1(c) expressly authorized the consideration of “adequate assurances” of future compliance in determining whether to disqualify.

28 The Center concedes that the delay in this case has been unfair to Dr. Davidson, but states the delay “has been equally unfair to the public.” CVM Response to Order to Show cause at 4. This has not been demonstrated. Dr. Davidson has ceased conducting investigations of animal drugs during the pendency of this action, so, from CVM’s perspective, the delay has redounded to the public benefit by ensuring no approvals based on studies conducted by Dr. Davidson after 1995 occur. If Dr. Davidson’s investigations of other drugs pose any continued threat to the public, it is because CVM continued to accept those studies and review and approve applications based on those studies even after issuing its NOOH.
• Dr. Davidson repeatedly and deliberately submitted false information by submitting the 123 pen cards with revised figures for feed weigh-in to ACC in Study.

There are questions of fact remaining concerning the following:

**Study**

• whether the feed weigh-back value of 13.10 kg on pen card in study is accurate;
• whether false information was submitted on the pen card for pen feed weigh-back and male mortality weight.
• whether false information was submitted for a total of sixteen body weight and feed weigh-back pen card values.

**Study**

• whether revised body weight values on twelve pen cards are false;
• whether revised withdrawal feed weigh-in values on thirteen pen cards are false;
• whether 11 revised feed weigh-back values at the grower stage and 20 revised feed weigh-back values at the withdrawal stage are false.

These questions preclude a finding concerning these facts on summary decision.

Although the Center has shown that Dr. Davidson repeatedly or deliberately submitted false information in several instances, disqualification is not recommended here. The recommendation of dismissal is not based on the “mere passage of time” but on the extraordinary inequity of disqualifying Dr. Davidson when a remedial purpose has not been adequately demonstrated and the delay has denied Dr. Davidson the opportunity afforded by the regulations to show adequate assurance of future compliance after disqualification. It is therefore recommended that Dr. Davidson’s Motion to Dismiss be granted.
Dated this 16th day of March, 2009

/s/ Daniel J. Davidson

Daniel J. Davidson
Presiding Officer