



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 20 2009

Certified Mail - Return Receipt Requested

Mark S. Brown, Esq.
King and Spalding LLP
1700 Pennsylvania Avenue, N.W., Suite 200
Washington, D.C. 20006-4706

Regarding: In the Matter of Jeffrey N. Davidson, D.V.M.; Commissioner's Decision

Dear Mr. Brown:

I have reviewed the administrative record of the regulatory proceeding proposing to disqualify Jeffrey N. Davidson, D.V.M., from receiving investigational new animal drugs. Based upon my review, I have determined that Dr. Davidson is no longer eligible to receive investigational new animal drugs. The reasons for this determination are set forth in the enclosed Commissioner's Decision.

By this letter, I am providing a copy of this Decision to counsel for the Center for Veterinary Medicine and to the Division of Dockets Management to be placed on display in the public reading room, and posted on FDA's website.

Dr. Davidson may seek to have his eligibility to receive investigational new animal drugs reinstated pursuant to 21 CFR 511.1(c)(6) "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 . . . for investigational-use new animal drugs."

Sincerely,

A handwritten signature in cursive script that reads "Norris E. Alderson".

Norris E. Alderson, Ph.D.
Associate Commissioner for Science

Enclosure

cc: Donald Beers, Esq.
Counsel for the Center for Veterinary Medicine, FDA

Division of Dockets Management

DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. FOOD AND DRUG ADMINISTRATION
REGULATORY HEARING ON THE PROPOSAL TO DISQUALIFY
JEFFREY N. DAVIDSON, D.V.M.
FROM RECEIVING INVESTIGATIONAL NEW ANIMAL DRUGS

COMMISSIONER'S DECISION

The purpose of this proceeding is to determine, pursuant to 21 C.F.R. § 511.1(c)(2) and 21 C.F.R. Part 16, whether Jeffrey Davidson, DVM, should be disqualified from receiving investigational new animal drugs. Administrative Law Judge Daniel Davidson wrote the Report and Recommendation of the Presiding Officer. Judge Davidson granted the Center for Veterinary Medicine's (CVM) Motion for Summary Decision, finding that no hearing was necessary to conclude that Dr. Davidson had repeatedly and deliberately submitted false information to the sponsor of a New Animal Drug Application (NADA) under 21 C.F.R. 511.1(c)(2), but did not recommend disqualification. Instead, Judge Davidson recommended dismissal of the disqualification action, finding dismissal to be justified by extraordinary circumstances. CVM submitted a timely response to the Report and Recommendation.

Under authority delegated to me by the Commissioner of Food and Drugs, I am issuing the Commissioner's Decision in this matter. Based on my review of the administrative record, including the Report and Recommendation of the Presiding Officer and CVM's Response, I conclude that Dr. Davidson repeatedly and deliberately violated the regulations governing

clinical investigations. I do not find that the circumstances of this case constitute “extraordinary circumstances” justifying a dismissal. Accordingly, I am disqualifying Dr. Davidson from receiving investigational animal drugs.

The background of this proceeding is discussed in the Presiding Officer’s Report and Recommendation (Report). Concerning the factual background and relevant legal standards, I adopt the discussion in the Report and incorporate that discussion here by reference. I also adopt and incorporate by reference the Report’s discussion of the Motions for Summary Judgment filed by CVM and Dr. Davidson, as well as the Report’s finding that Dr. Davidson repeatedly and deliberately submitted false information in two studies. Because I do not believe Dr. Davidson should be eligible to receive investigational new animal drugs, I do not adopt the Report’s findings on Dr. Davidson’s Motion to Dismiss nor do I adopt the Report’s Conclusion. Therefore, I write separately to note the arguments made in CVM’s Response and to address the Report’s recommendation of Dismissal.

I. CVM’s Response to the Presiding Officer’s Report

In its Response to the Report and Recommendation, CVM presents three arguments: (1) the Presiding Officer erred in considering information unrelated to the investigations at issue; (2) CVM’s acceptance of data from Dr. Davidson to support multiple other NADAs is not relevant to whether Dr. Davidson should be disqualified; and (3) CVM’s failure to review the data in these NADAs during the pendency of the disqualification is not relevant to whether Dr. Davidson should be disqualified. I am disqualifying Dr. Davidson because his violations are numerous and serious and, as I discuss below, protection of the public warrants his removal from eligibility to receive investigational animal drugs. My decision does not rely on the resolution of the arguments presented by CVM.

II. Extraordinary Circumstances

I do not agree with the Presiding Officer that dismissal is appropriate. As the Report notes, precedent has recognized the discretion of the Commissioner not to disqualify under “extraordinary circumstances,” such as “where the violations are truly insignificant, or disqualification would be truly unjust or would accomplish nothing.” See Commissioner’s Decision, *In the Matter of James A. Halikas, M.D.* (2001). The Report identifies two grounds for the exercise of this discretion here: first, in light of CVM’s acceptance of data from Dr. Davidson in support of multiple other NADAs, CVM has not presented an adequate case for a remedial need for the disqualification; and second, the delay in this matter has unfairly deprived Dr. Davidson of the opportunity to demonstrate compliance that the regulations provide only after disqualification. I disagree that these circumstances, individually or combined, constitute “extraordinary circumstances” that warrant an exercise of discretion here.

The proposition that a disqualification action is intended to be remedial has to my knowledge never been challenged. CVM’s position is that the remedial purpose of this disqualification action is to prevent Dr. Davidson -- an investigator found to have repeatedly and deliberately violated FDA’s regulations -- from submitting additional data in applications to the agency. This showing is a basic element of the Center’s case in any disqualification action. As the Report notes, unless the investigator expires before a decision is reached, establishing this element should present no difficulty. The Presiding Officer’s view was that CVM has undermined its case for a remedial purpose by continuing to accept data from Dr. Davidson, apparently without any special scrutiny. These questions about CVM’s motivations and diligence, however, do not overcome the record of repeated and deliberate submission of false data, a record sufficient to convince me that a remedial reason to disqualify Dr. Davidson exists.

