U.S. FOOD & DRUG ADMINISTRATION

NOTICE OF INITIATION OF DISQUALIFICATION PROCEEDINGS AND OPPORTUNITY TO EXPLAIN (NIDPOE)

VIA UNITED PARCEL SERVICE

Martin Valdes, M.D.
(b) (6)

Dear Dr. Valdes:

On July 15, 2024, the Food and Drug Administration (FDA), Center for Drug Evaluation and Research, issued a Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) and sent it by United Parcel Service (UPS) to you at your former address of (b) (6). Given that we have not received a response from you, we are re-issuing this NIDPOE to you at this address which is different from the address the NIDPOE was originally sent to. Except for the change of your address, this NIDPOE is identical to the one dated July 15, 2024.

Enclosed you will find a copy of the NIDPOE.

Sincerely yours,

{See appended electronic signature page}

Brittany L. Garr-Colón, M.P.H.
Branch Chief (Acting)
Compliance Enforcement Branch
Division of Enforcement and Postmarketing Safety
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Building 51, Room 5352
10903 New Hampshire Avenue
Silver Spring, MD 20993

cc: Martin Valdes, M.D.
(b) (6)

U.S. FOOD & DRUG ADMINISTRATION

NOTICE OF INITIATION OF DISQUALIFICATION PROCEEDINGS AND OPPORTUNITY TO EXPLAIN (NIDPOE)

VIA UNITED PARCEL SERVICE

Martin Valdes, M.D.
(b) (6)

Dear Dr. Valdes:

The U.S. Food and Drug Administration (FDA) conducted an inspection at your clinical site between February 10, 2016, and May 5, 2016. Investigators Craig A. Garmendia and Angelica M. Chica, representing FDA, reviewed your conduct of the following clinical investigations of the investigational drug (b) (4), performed for (b) (4)

- Protocol (b) (4), "(b) (4)
- Protocol (b) (4), "(b) (4)

This inspection was conducted as a part of FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of research and to help ensure that the rights, safety, and welfare of human subjects have been protected.

At the conclusion of the inspection, Investigators Garmendia and Chica presented and discussed with you the items listed on the Form FDA 483, Inspectional Observations. We acknowledged receipt of your May 25, 2016, written response to the Form FDA 483. On July 31, 2018, FDA issued you its post-inspection correspondence regarding the findings of the 2016 inspection.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

Subsequently, in August of 2023, you were convicted in the United States District Court for the Southern District of Florida-Miami Division of one (1) count of False Statements in violation of 18 U.S.C. 1001(a)(2).

We have reviewed the Acceptance of Responsibility you signed on July 31, 2023, in the criminal case *U.S.A. v. Martin Valdes*, No. 1:21-CR-20106-RNS(1) (S.D. Fla. 2023), and the Judgment entered against you by the court in that case, dated August 18, 2023. Based on our evaluation of information obtained by FDA, we believe that you have repeatedly or deliberately submitted false information in required reports of clinical studies involving an investigational new drug, as published under Title 21, Code of Federal Regulations (CFR), Part 312.

This letter provides you with written notice of the matters complained of and initiates an administrative proceeding, described below, to determine whether you should be disqualified from eligibility to receive test articles as set forth under 21 CFR 312.70 (copy enclosed), and disqualified from eligibility to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs; biologics; devices; new animal drugs; food, including dietary supplements, that bear a nutrient content claim or a health claim; infant formulas; food and color additives; and tobacco products.

A listing of the violations follows. The applicable provisions of the CFR are cited for each violation.

You repeatedly or deliberately submitted to the FDA or to the sponsor false information in any required report [21 CFR 312.70(a)].

FDA has concluded that, during your conduct of Protocols (b) (4) and (b) (4) (that is, the (b) (4) trials) for which you were the clinical investigator, you repeatedly and/or deliberately submitted false information to FDA or to the sponsor in required reports. Specifically, as described in the Acceptance of Responsibility cited above, you falsely represented in subjects' case histories by your signature that you personally performed physical examinations. You then knowingly and willfully made a false statement and/or representation in an interview with the FDA investigator during the previously mentioned inspection that you personally performed a physical examination on each subject in the (b) (4) trials for which your signature appeared on the subjects' case histories, when you did not in fact conduct physical examinations on every subject in the (b) (4) trials for which your signature appeared. Repeated or deliberate submission of false information in any required report to FDA or to the sponsor is a violation of 21 CFR 312.70(a).

As the clinical investigator, it is your responsibility to ensure that the data collected from study subjects are accurate and can be relied upon in any analyses of the study endpoints. When you signed the Form FDA 1572, Statement of the Investigator, you agreed to provide accurate information to the sponsor and to ensure that you would comply with FDA regulations related to the conduct of the clinical investigations of the investigational drugs. Furthermore, your signature constitutes your written commitment to abide by FDA regulations in the conduct of the

clinical investigations. The submission of false information significantly compromises the study integrity, as well as the reliability and validity of the data.

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

Based on the previously mentioned Acceptance of Responsibility and Judgment, as well as the above-listed violations, FDA asserts that you have repeatedly or deliberately submitted false information to the sponsor or the FDA, which caused unnecessary risks to human subjects and jeopardized the integrity of data, and FDA proposes that you be disqualified as a clinical investigator. You may reply to the above-stated findings, including an explanation of why you should not be disqualified as a clinical investigator, either in a written response or at an informal conference in my office. This procedure is provided for by regulation 21 CFR 312.70.

Within fifteen (15) working days of your receipt of this letter, write to me at the address below or call me at 301-796-5632, to arrange a conference time or to indicate your intent to respond in writing.

Should you choose to respond in writing, your written response should be forwarded within thirty (30) days of your receipt of this letter.

Your reply should be sent to:

David C. Burrow, Pharm.D., J.D.
Director
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Building 51, Room 5348
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Should you request an informal conference, we ask that you provide us with a full and complete explanation of the above-listed violations. You should bring with you all pertinent documents, and a representative of your choice may accompany you. Although the conference is informal, a transcript of the conference will be prepared. If you choose to proceed in this manner, we plan to hold such a conference within 30 days of your request.

At any time during this administrative process, you may enter into a Consent Agreement with FDA regarding your future use of investigational products. Such an Agreement would terminate this disqualification proceeding. Enclosed you will find a proposed Agreement between you and FDA.

The FDA's Center for Drug Evaluation and Research (the Center) will carefully consider any oral or written response. If your explanation is accepted by the Center, the disqualification process will be terminated. If your written or oral responses to our allegations are unsatisfactory, or if we cannot come to terms on a Consent Agreement, or if you do not respond to this notice, you will be offered a regulatory hearing before FDA, pursuant to 21 CFR 16 (copy enclosed) and 21 CFR 312.70. Before such a hearing, FDA will provide you with notice of the matters to be considered, including a comprehensive statement of the basis for the decision or action taken or proposed, and a general summary of the information that will be presented by FDA in support of the decision or action. A presiding officer who has not participated in this matter will conduct the hearing. After this hearing, the Commissioner will determine whether you will remain entitled to receive test articles and to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

You should be aware that neither entry into a Consent Agreement nor pursuit of a hearing precludes the possibility of an administrative remedy or further judicial proceedings concerning these violations.

To enter into the enclosed Consent Agreement with FDA, thereby terminating this disqualification process, you must:

(1) Initial and date each page of this Agreement;
(2) Sign and date the last page of this Agreement; and
(3) Return this Agreement, initialed, signed, and dated, to the signer below.

A copy of the fully executed Agreement will be mailed to you.

Sincerely yours,

{See appended electronic signature page}

David C. Burrow, Pharm.D., J.D.
Director
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Enclosures:
(1) Consent Agreement
(2) 21 CFR 16
(3) 21 CFR 312.70

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DAVID C BURROW
07/15/2024 11:00:54 AM

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

RACHELLE M SWANN on behalf of BRITTANY GARR-COLON
07/26/2024 02:40:53 PM