U.S. FOOD & DRUG ADMINISTRATION

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

VIA UNITED PARCEL SERVICE AND EMAIL

Angela Maria Giron, M.D.
(b) (6)

Dear Dr. Giron:

The U.S. Food and Drug Administration (FDA) conducted an inspection at your clinical site between February 20 and March 1, 2018. The investigator representing FDA reviewed your conduct of a clinical investigation (Protocol (b) (4), " (b) (4) ") of the investigational drug (b) (4), performed for (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.

Subsequently, in September 2023, you were convicted in the United States District Court for the Southern District of Florida-Miami Division, of one (1) count of Conspiracy to defraud the United States in violation of 18 U.S.C. 371.F.

We have reviewed the Plea Agreement you signed on January 9, 2023, in the criminal case *U.S.A. v. Angela Maria Giron, No. 1:22-CR-20471-KMW(1) (S.D. Fla. 2023)*; the Factual Proffer in Support of Guilty Plea in that case, which you signed on January 9, 2023; and the Judgment entered against you by the court in that case, dated September 11, 2023. Based on our evaluation of the information obtained by FDA, we believe that you have repeatedly or deliberately submitted false information in required reports of a clinical study 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

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

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.

The violation follows. The applicable provisions of the CFR are cited for the 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 Protocol (b) (4) for which you were the clinical investigator, you repeatedly or deliberately submitted false information to FDA and to the sponsor in required reports. Specifically, as described in the Factual Proffer in Support of Guilty Plea cited above, you created fraudulent and false study records, including electronic case report forms (eCRFs), which falsely represented that subjects completed the informed consent process, when you did not obtain written informed consent from any of the 22 subjects enrolled in the (b) (4) study. You also falsified the data of enrolled subjects whom you knew did not participate in the study. For example, you indicated that you conducted protocol-required clinical investigator assessments at visits 2, 4, and 5, when you did not in fact conduct the assessments. You also knew that false information and data were submitted in the case report forms and eCRFs, including false information representing that subjects had satisfied eligibility criteria to participate in the (b) (4) clinical trial, had received and taken the study medication, and had completed the required documents and journals. 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 investigation of the investigational drug. 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 integrity of the study, 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 Plea Agreement, Factual Proffer in Support of Guilty Plea, Judgment, and the above-listed violation, FDA asserts that you have repeatedly or deliberately submitted false information to the sponsor or to the FDA, which caused unnecessary risks to human subjects and jeopardized the integrity of study 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) calendar 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 violation. 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

Cc: Angela Maria Giron, M.D.
3661 S. Miami Avenue
Suite 1002
Miami, Florida 33133

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
01/22/2026 10:18:47 AM