U.S. FOOD & DRUG ADMINISTRATION

February 1, 2023

Robert A. Gatenby, MD
c/o David de la Parte
Executive Vice President/General Counsel
MOFFITT Cancer Center
12902 Magnolia Drive
Tampa, Florida 33612-9416
David.delaParte@moffitt.org

Re: Approval of Reinstatement Request under 21 CFR 312.70 Contingent on Reinstatement Agreement

Dear Dr. Gatenby:

Under the authority delegated to me by the Commissioner of Food and Drugs, I have determined that your request for reinstatement under 21 CFR 312.70 is granted, contingent upon your agreement to enter into a Reinstatement Agreement with FDA. The attached Agreement specifies the "Terms of Reinstatement," including your acceptance of the condition that failure to abide by the stated terms will, of itself, be a basis for disqualification, without further proof that you repeatedly or deliberately failed to comply with the regulations for investigational studies.

To enter into the enclosed agreement with FDA, you must, within thirty (30) calendar days of the date of this letter:

(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 David C. Burrow, Pharm.D., J.D., Director, Office of Scientific Investigations, Office of Compliance, Center for Drug Evaluation and Research (CDER).

If you have any questions, contact David Burrow. His contact information is as follows:

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
CDER-OSI-Communications@fda.hhs.gov

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

Sincerely,

Namandje N. Bumpus -S
Digitally signed by Namandje N. Bumpus -S
Date: 2023.02.01 18:09:48 -05'00'

Namandjé Bumpus, Ph.D.

Chief Scientist
Food and Drug Administration

Cc: CDER, Office of Scientific Investigations; David Burrow, CDER

TERMS OF REINSTATEMENT

The Center for Drug Evaluation and Research ("the Center") of the United States Food and Drug Administration (FDA) and Robert A. Gatenby, M.D., hereby agree as follows:

1. By agreement dated November 1988 (the "Disqualification Agreement"), Dr. Gatenby agreed to disqualification as a clinical investigator pursuant to 21 CFR 312.70 predicated on a violation of FDA regulations in 21 CFR Part 312 relating to initiating and conducting a clinical investigation of investigational drugs without having an IND in effect.

2. Dr. Gatenby has requested that he be reinstated to be eligible to receive test articles under 21 CFR 312 and to conduct clinical investigations of FDA-regulated products. The request is granted provisionally, subject to the terms of this Reinstatement Agreement ("Agreement").

3. Under this Agreement, for a period of three (3) years from the date of execution of this Agreement:

    a. If Dr. Gatenby serves as the clinical investigator for any FDA-regulated clinical investigation of an investigational article, Dr. Gatenby must notify and provide the Center (see paragraph 9) a copy of the study protocol prior to initiating the clinical investigation[1]. At the same time that Dr. Gatenby submits the protocol, Dr. Gatenby must also submit to the Center a plan that specifically describes the manner in which Dr. Gatenby will personally ensure adequate oversight of his study, including adequate oversight of research personnel in their conduct of activities related to the clinical study. This plan must provide for Dr. Gatenby's personal involvement in the clinical investigation and specify the name and credentials of each sub-investigator who has agreed to participate in the clinical investigation. The protocol and plan must contain sufficient detail to ensure that Dr. Gatenby's conduct of the clinical investigation will be in compliance with applicable laws and FDA regulations. Unless the Center notifies Dr. Gatenby within thirty (30) days following the Center's receipt of the plan and protocol that additional safeguards (e.g., independent monitor) must be implemented, the submitted plan will be deemed acceptable to the Center and the clinical investigation may be initiated.

    b. Dr. Gatenby must attend at least two (2) educational programs per year. These educational programs must be related to clinical investigations (i.e., dealing with

[1] This requirement to notify and provide the Center a copy of the study protocol prior to initiating any FDA-regulated clinical investigation of an investigational article is distinct and separate from any applicable requirement to submit an application to FDA prior to conducting an FDA-regulated clinical investigation of an investigational article.

Initialed and dated by clinical investigator when agreement signed:

_____ _____

initials *date*

clinical trials and complying with FDA regulations) and sponsored or conducted by organizations or individuals with recognized expertise in the area. Dr. Gatenby shall provide the Center with documentation of each educational program within 30-days of attending each such program. The educational program will be deemed acceptable to the Center unless the Center notifies Dr. Gatenby to the contrary within 30-days following the Center's receipt of the documentation. Dr. Gatenby may consult with the Agency's designated contact (see paragraph 9) before attending any such programs to determine whether the educational programs and the content thereof will be acceptable to the Center.

c. If Dr. Gatenby serves as the clinical investigator for any FDA-regulated clinical investigation of an investigational article, Dr. Gatenby shall arrange for training and education of his research personnel in the conduct of clinical trials and complying with FDA regulations, and specifically, training that is appropriate to ensure compliance with respect to the study(ies) in which they will be involved(which may include training programs offered by sponsors of these clinical studies), prior to the commencement of each clinical investigation.

d. Dr. Gatenby shall comply with all FDA regulations relevant to the initiation and conduct of clinical investigations, including but not limited to, 21 CFR Parts 50, 56, and 312.

e. Dr. Gatenby shall certify to the Center in writing (in accordance with paragraph 9), on an annual basis, no later than the anniversary date of the execution of this Agreement, that he is in compliance with all the terms of this Agreement. Such certification shall set forth the details of his compliance with subparagraphs 3(a)-3(e).

4. Dr. Gatenby will provide the Center with a “Final Report of Reinstatement” (Final Report), due 30-days after the third anniversary date of this Agreement. The Final Report will provide information about Dr. Gatenby’s compliance with the terms of the Agreement, including:

   a. A description of Dr. Gatenby’s participation in research with FDA-regulated products, if any, including Dr. Gatenby’s role in each study.

   b. A statement certifying that Dr. Gatenby has been in compliance with the terms of this Agreement throughout the entire period covered by the Agreement and setting forth the details of his compliance.

5. Dr. Gatenby’s reinstatement is contingent on his successful completion of his obligations under this Agreement. Failure to abide by the stated terms of the Agreement will, of itself, result in rescission of this Agreement and return Dr. Gatenby to disqualification,

without further information or further determination by the Commissioner that Dr. Gatenby has failed to comply with the requirements of part 312, part 50, or part 56, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report. Any such rescission will be under the procedures set forth in FDA Staff Manual Guide 7715 in effect at the time and will not be conducted as a separate disqualification proceeding under 21 CFR Part 312.70.

6. Upon execution of this Agreement, FDA will update the FDA Clinical Investigators Disqualification Proceedings webpage, which is available to the public pursuant to the Freedom of Information Act (5 USC 552) to change Dr. Gatenby's status from "Disqualified" to "Reinstated pursuant to Agreement." Prior to reinstating Dr. Gatenby, FDA may conduct an inspection or investigation of Dr. Gatenby to confirm the requirements of this agreement have been met. If FDA determines that all of the requirements of this agreement have been met, FDA will update the FDA Clinical Investigators Disqualification Proceedings webpage to change Dr. Gatenby's status from "Reinstated pursuant to Agreement" to "Reinstated."

7. FDA may notify sponsors, IRBs, and other interested parties that Dr. Gatenby is not eligible to receive investigational drugs, biological products, or medical devices except under the conditions provided for in this Agreement. FDA may make copies of this Agreement available to sponsors, IRBs, and other interested parties.

8. This Agreement constitutes the complete agreement between FDA and Dr. Gatenby, and may not be amended except by written consent of FDA and Dr. Gatenby.

9. All communications to the Center or FDA by Dr. Gatenby pursuant to this Agreement shall be directed to the Center at CDER-OSI-Communications@fda.hhs.gov and the following or his/her successor at:

    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

Initialed and dated by clinical investigator when agreement signed:

_____ _____
initials *date*

Agreed to:

Robert A. Gatenby, M.D.	Date
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	Date

NOTE TO ROBERT A. GATENBY: To enter into this Agreement, 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:

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

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

Initialed and dated by clinical investigator when agreement signed:

initials	*date*