DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

TRANSMITTED BY FACSIMILE

Nascent Biotech, Inc.
Attention: Bruce Merchant, MD, PhD
Regulatory Contact for Nascent Biotech, Inc.
Merchant-Taylor International, Inc.
106 Camino Encantado
Santa Fe, NM 87501

RE: (b) (4)
Pritumumab
MA 1

Dear Dr. Merchant:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed Nascent Biotech, Inc's (Nascent) website[1] that discusses the investigational new drug Pritumumab, which is the subject of the above-referenced investigational new drug application (IND). You are receiving this letter as the authorized representative of Nascent, the sponsor of Pritumumab. The website represents in a promotional context that Pritumumab, an investigational new drug, is safe and effective for the purpose for which it is being investigated or otherwise promotes the drug. As a result, Pritumumab is misbranded under section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and is in violation of section 301(k) of the FD&C Act. The claims on the website are concerning from a public health perspective (b) (4)

(b) (4)

The statements on the website make conclusory representations in a promotional context regarding the safety and efficacy of Pritumumab, an investigational new drug, that has not been approved by the FDA and whose safety and efficacy has not yet been established.

Background

Pritumumab[2] is an investigational new drug for which there is no marketing authorization in the United States. (b) (4)

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[1] Available at https://www.nascentbiotech.com/ (last accessed October 31, 2019) and https://www.nascentbiotech.com/products/pritumumab (last accessed October 31, 2019)

[2] (b) (4)

Misbranding of an Investigational Drug

Under section 502(f)(1) of the FD&C Act, a drug shall be deemed to be misbranded unless its labeling bears adequate directions for use. Under FDA regulations, adequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended. 21 CFR 201.5. Your website describes the use of Pritumumab for treating brain cancer. This use is one for which a prescription would be needed because it requires the supervision of a physician and, therefore, for which adequate directions for lay use cannot be written.

Although 21 CFR 201.115(b) provides an exemption from the adequate directions for use requirement in section 502(f)(1) of the FD&C Act if a new drug "complies with section 505(i)…and regulations thereunder," your investigational drug fails to do so.[3] Among the requirements for this exemption for investigational drugs, 21 CFR 312.7(a) provides that, "[a] sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution."

The website includes claims and presentations that promote Pritumumab as safe and effective for the purposes for which it is being investigated or otherwise promote the drug, including the following examples (emphasis added):

- "Pritumumab has **cured a rare form of brain cancer**"
- "Delivering human antibodies for the treatment of cancer"
- "After 5 years, patients treated with pritumumab have an overall survival rate of 25-30%, compared to 3% standard therapy, **demonstrating antibodies are safe and effective**"

The above claims and presentations make numerous conclusory statements which suggest that Pritumumab has been established as being safe and effective in treating brain cancer. Because, however, Pritumumab is an investigational new drug, the product's indication(s), warnings, precautions, adverse reactions, and dosage and administration have not been established and are unknown at this time. These claims and presentations are extremely concerning given the lack of adequate safety and efficacy data for Pritumumab. Similarly, the suggestion that Pritumumab has established efficacy and has "cured a rare form of brain cancer" is especially troubling given that brain cancer in general is a disease associated with

[3] 21 CFR 201.100 offers another exemption from the requirement for adequate directions for use for prescription drugs provided certain requirements are met; however, Pritumumab does not fall within that exemption because it is an investigational new drug for which there is no marketing authorization in the United States.

a poor prognosis (i.e., decreased overall survival).

The benefit/risk profile associated with Pritumumab is not currently known. The conclusions reflected in the above claims create a misleading impression regarding the safety and effectiveness of the product. These claims are concerning given the seriousness of this disease and the relatively few available treatment options.

Additionally, we note that the website does not include information to clearly indicate that Pritumumab is an investigational new drug that has not been approved for commercial distribution in the United States. In summary, the above cited claims on the website represent the drug as having an established role in the treatment of brain cancer, when Pritumumab has not been proven safe and effective within the meaning of the FD&C Act and has not been approved as a drug under that authority for any use.

Conclusion and Requested Action

For the reasons discussed above, Pritumumab is misbranded under section 502(f)(1) of the FD&C Act and in violation of section 301(k) of the FD&C Act. The claims on the website are concerning because they make representations in a promotional context regarding the safety and efficacy of an investigational new drug that has not been approved by the FDA.

OPDP requests that Nascent immediately cease violating the FD&C Act, as discussed above. Please submit a written response to this letter on or before November 15, 2019, stating whether you intend to comply with this request, listing all promotional materials for Pritumumab that contain violations such as those described above, and explaining your plan for discontinuing use of such violative materials. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

Please direct your response to the undersigned at the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. To ensure timely delivery of your submissions, please use the full address above and include a prominent directional notation (e.g. a sticker) to indicate that the submission is intended for OPDP. Please refer to MA 1 in addition to the IND number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for Pritumumab comply with each applicable requirement of the FD&C Act and FDA implementing regulations.

Sincerely,

{See appended electronic signature page}

Emily M. Dvorsky, PharmD
Regulatory Review Officer
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

{See appended electronic signature page}

Susannah O'Donnell, MPH, RAC
Team Leader
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

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/

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