DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

TRANSMITTED BY FACSIMILE

Stanislaw R. Burzynski, MD, PhD
Burzynski Research Institute, Inc.
9432 Katy Freeway
Houston, Texas 77055

RE: IND # 43742
Antineoplastons A10 and AS2-1 Injections
MA #1

Dear Dr. Burzynski:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the websites for The Burzynski Research Institute, Inc.[1] and The Burzynski Clinic.[2] The websites, including the posted press releases[3] and embedded videos,[4] promote Antineoplastons A10 and AS2-1Injections (Antineoplastons or ANP), investigational new drugs, as safe and effective for the purposes for which they are being investigated. As a result, the websites violate the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and FDA implementing regulations. 21 CFR 312.7(a).

Background

Antineoplastons are investigational new drugs that do not have marketing authorization in the United States. An investigational new drug (IND) application was submitted to the FDA in (b) (4)

Promotion of an Investigational New Drug

Promotion of an investigational new drug is prohibited under FDA regulations at 21 CFR 312.7(a), which states, "A sponsor or investigator, or any person acting on behalf of a

[1] Available at http://www.burzynskiresearch.com/ (last accessed June 13, 2012).
[2] Available at http://www.burzynskiclinic.com/ (last accessed June 13, 2012).
[3] Press releases are posted on the homepage of the Burzynski Research Institute website at http://www.burzynskiresearch.com/ (last accessed June 13, 2012).
[4] "Tomorrow's Cancer Treatment Today" and "Treatment at the Burzynski Clinic-KHOU Part 2" videos are embedded on the Burzynski Clinic website at http://www.burzynskiclinic.com/youtube-channel.html (last accessed June 13, 2012).

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 websites, including the posted press releases and embedded videos, contain claims such as the following that promote Antineoplastons as safe and/or effective for the purposes for which they are being investigated or otherwise promote the drugs:

Press Releases posted on the homepage of the Burzynski Research Institute, Inc. website

Burzynski Research Institute Presents Positive Results From Phase II Trials of ANP for Inoperable Brainstem Glioma at the Congress (May 11, 2009)

- "ANP was well-tolerated with easy manageable side effects of fatigue, skin rash and electrolyte abnormalities and no chronic toxicities. . . . These results compared favorably to radiation therapy and chemotherapy (Mandell, et al. 1999, 7% overall survival at 2 years and 0% at 5 years), but should be confirmed in phase III trials scheduled to begin in 2009."

- "The remarkable response of one of the patients who was treated on the study protocol was the subject of the second presentation. . . . She achieved complete response in February 1999 and continues to be tumor free and lives a normal life since then."

Burzynski Research Institute Gets SPA Clearance from the FDA to Initiate Pivotal Phase III Trial of Combination Antineoplaston Therapy and Radiation Therapy (January 13, 2009)

- "Antineoplaston therapy (ANP) uses a synthetic version of naturally occurring peptides and amino acid derivatives found in the human body to target and control cancer cells without destroying normal cells."

Thought Leaders from Burzynski Research Institute Inc Present Encouraging Data on Antineoplastons for Treatment of Malignant Gliomas (November 20, 2008)

- "ANP was well tolerated, with just two cases of serious reversible toxicities."

Burzynski Clinic website

The top portion of the webpages includes a header with the claim, "**Success Stories**" and pictures of three young patients (bolded emphasis in original).

What are Antineoplastons? webpage

- "**How do Antineoplastons work?** (bolded emphasis in original)

  Antineoplastons act as molecular switches, which turn off life processes in abnormal cells and force them to die through apoptosis (programmed death of a cell). While they trigger the death of cancer cells, they do not inhibit normal cell growth. They specifically target cancer cells without harming healthy cells.

  It is generally known that the cancerous process results from increased activity of oncogenes and decreased expression of tumor suppressor genes. Antineoplastons 'turn on' tumor suppressor genes and 'turn off' oncogenes restoring the proper balance in gene expression."

Embedded Videos on Burzynski Clinic YouTube Channel webpage

"Tomorrow's Cancer Treatment Today" - Dr. Gregory Burzynski states the following:

- "Antineoplastons are a group of peptides and amino acid derivatives originally discovered by my father, Dr. S. R. Burzynski. These are present in our blood, and in healthy tissue they are elevated, much more so than in people suffering cancer. They're molecular switches. They play a role on activating genes that are involved in the cancerous process, and also protecting you with genes that are causing cancer, so in essence, they have been shown to attack cancer cells but protect the other cells, so it's the best of both worlds."

  SUPER: Gregory Burzynski, MD
  Senior Physician

  SCROLLING SUPER: "Antineoplastons are multi-targeted cancer therapy and are targeting a multitude of genes involved in cancer."

"Treatment at the Burzynski Clinic - KHOU Part 2" - In response to the interviewer's questions, Dr. Sonali Patil and Dr. Stanislaw Burzynski state the following in word or substance:

- "They're building blocks, and basically the ones that Dr. Burzynski is talking about exist normally in our system and that's the reason why the drugs work without causing side effects. It's just that cancer patients lack them, and so what he's is doing is putting it back into the system to help cure the cancer . . . . And we find that these particular compounds have multiple targets; they're not working on one particular pathway, but many pathways, which is what makes them a very effective anti-cancer medicine." - Dr. Sonali Patel

- "Glioblastomas, and it's even in the laboratory, we see that these cells respond very very well to the compounds and this is the main treatment that is being regulated by the FDA for the approval is the brain tumors, and, we have seen a lot of success with patients, as Dr. Burzynski will discuss, with this particular type of cancer." - Dr. Sonali Patel

- "Certainly, well, in FDA controlled clinical trials, we are limited to the patients who cannot be helped with any other treatment, and we place emphasis on the worst possible type of cancer. For instance, inoperable brainstem malignant tumors, everybody dies from these tumors regardless what kind of treatment is used, and most of the patients who are, mostly children, are dead within two years. Our survival for children in the age up to three years, is 50% at five years, which is remarkable. And, we have patients who are now surviving over twenty years without any sign of this type of cancer." - Dr. Stanislaw Burzynski

As stated above, some of the above-referenced claims suggest that the drugs are "well tolerated," "work without causing side effects," and have demonstrated "remarkable" results. The totality of these claims suggest that Antineoplastons, investigational new drugs, are safe and/or effective for the treatment of the various types of brain tumors indicated above, when they have not been approved for these uses.

Since Antineoplastons are investigational new drugs, the products' indication(s), warnings, precautions, adverse reactions, and dosage and administration have not been established and are unknown at this time. Promoting Antineoplastons as safe and effective for the purposes for which they are under investigation, by making representations such as those noted above, is in violation of 21 CFR 312.7(a).

Conclusion and Requested Action

For the reasons discussed above, the websites violate the FD&C Act and FDA implementing regulations. 21 CFR 312.7(a). These claims are concerning from a public health perspective because they make promotional claims about the safety and efficacy of investigational new drugs that have not been approved by the FDA.

OPDP requests that you immediately cease the dissemination of violative promotional materials for Antineoplastons such as those described above. Please submit a written response to this letter on or before November 1, 2012, stating whether you intend to comply with this request, and explaining your plan for discontinuing use of such violative materials.

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** or by facsimile at (301) 847-8444. Please note that the Division of Drug Marketing, Advertising, and Communications (DDMAC) has been reorganized and elevated to the Office of Prescription Drug Promotion (OPDP). OPDP consists of the Immediate Office, the Division of Professional Drug Promotion (DPDP) and the Division of Consumer Drug Promotion (DCDP). 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. In addition, OPDP recently migrated to a different tracking system. Therefore, OPDP letters will now refer to MA numbers instead of MACMIS numbers. Please refer to MA #1 in addition to the IND number in all future correspondence relating to this particular matter. OPDP reminds you that only written communications are considered official.

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

Sincerely,

{See appended electronic signature page}

Thomas Abrams, RPh, MBA
Director
Office of Prescription Drug Promotion

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THOMAS W ABRAMS
10/18/2012