DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Niravkumar Sevak
Senior Manager, Regulatory Affairs
Azurity Pharmaceuticals, Inc.
8 Cabot Road, Suite 2000
Woburn, MA 01801

RE: NDA 219293
DANZITEN (nilotinib) tablets, for oral use
MA 71

Dear Niravkumar Sevak:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communications, a professional and direct-to-consumer (DTC) TV Skin/Background (PP-DAN-US-0177) (background) and Video (PP-DAN-US-0172) (video) for DANZITEN (nilotinib) tablets, for oral use (Danziten) submitted by Azurity Pharmaceuticals, Inc. (Azurity) under cover of Form FDA 2253. FDA has determined that the background and video are false or misleading. Thus, the background and video misbrand Danziten and make the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The background and video are misleading because they include claims and presentations about the use and benefits of Danziten, but they omit important risk information associated with the drug. Specifically, the background and video completely omit information regarding the warnings and precautions for cardiac and arterial vascular occlusive events, tumor lysis syndrome, hemorrhage, fluid retention, and embryo-fetal toxicity. Additionally, the video fails to communicate that low blood cell counts are common but also severe. By omitting this important risk information, the background and video fail to provide material information about the consequences that may result from the use of Danziten and create a misleading impression about the drug's safety. We acknowledge that the video includes the statement, "Ask your doctor about Danziten™ and review the full Prescribing Information, including the Boxed WARNING." However, this does not mitigate the misleading impression created by the omission of important risk information.

Furthermore, the presentation of risk information in the video does not appear in a sequence that discloses risk information in the order of severity, and thus misleadingly minimizes the risks associated with Danziten. Specifically, the risk information pertaining to the ADVERSE REACTIONS section of the FDA-approved prescribing information (PI) (i.e. "high blood sugar") is presented prior to the risk information pertaining to the WARNINGS AND PRECAUTIONS section of the PI (i.e. "elevated liver enzymes, low blood counts, or pancreatitis"), thereby framing the subsequent risk information as less serious.

The background and video are misleading because they fail to provide material information regarding Danziten's full FDA-approved indication. Specifically, the INDICATIONS AND USAGE section of the PI states (in pertinent part, underlined emphasis added):

> DANZITEN is indicated for the treatment of adult patients with chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML) resistant or intolerant to prior therapy that included imatinib.

The background suggests that Danziten is for adult patients taking Tasigna, while the video suggests that Danziten is for patients in chronic or accelerated phase CML after intolerance or resistance to *any* prior therapy. Both the background and video do not specify that Danziten is indicated for patients who are resistant or intolerant to prior therapy that included imatinib. By failing to adequately communicate the indication for Danziten, the background and video create a misleading impression about the drug's FDA-approved indication.

Conclusion and Requested Action

For the reasons described above, the background and video misbrand Danziten and make the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that Azurity take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that are misleading as described above). Please submit a written response to this letter within 15 working days from the date of receipt, addressing the concerns described in this letter, listing all promotional communications (with the 2253 submission date) for Danziten that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Danziten.

If you believe that your products are not in violation of the FD&C Act, please include in your submission to us your reasoning and any supporting information for our consideration within 15 working days from the date of receipt of this letter.

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

Please direct your response to 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. Please refer to MA 71 in addition to the NDA 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. You are encouraged, but not required, to submit your response in eCTD format. All correspondence submitted in response to this letter should be placed under eCTD Heading 1.15.1.6.

Additionally, the response submission should be coded as an Amendment to eCTD Sequence 2069 under NDA 219293. Questions related to the submission of your response letter should be emailed to CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

George Tidmarsh, M.D., Ph.D.
Director
Center for Drug Evaluation and Research

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/

CARTER M BEACH
09/09/2025 05:10:10 PM
On behalf of George Tidmarsh, M.D., Ph.D