DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Charles Garlisi, PhD
Senior Vice President, Regulatory Affairs
Altor BioScience, LLC, (an indirect wholly-owned subsidiary of ImmunityBio, Inc.)
25 DeForest Avenue, Suite 201
Summit, NJ 07901

RE: BLA 761336
ANKTIVA® (nogapendekin alfa inbakicept-pmln) solution, for intravesical use
MA 51

Dear Dr. Garlisi:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communications, the "Efficacy and Safety" webpage[1] (US-ANK-250071-v1.0) (webpage) on the ANKTIVA Healthcare Provider Branded Website (ANK-00079-US)[2] and the "Why ANKTIVA®" webpage[3] (US-ANK-250072-v1.0) (consumer webpage) on the ANKTIVA Consumer Website (ANK-00079-US)[2] for ANKTIVA® (nogapendekin alfa inbakicept-pmln) solution, for intravesical use (Anktiva) submitted by Altor BioScience LLC, an indirect wholly-owned subsidiary of ImmunityBio, Inc. (Altor) under cover of Form FDA 2253. FDA has determined that the webpage and consumer webpage are false or misleading. Thus, the webpage and consumer webpage misbrand Anktiva and make the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Prior Communications

OPDP notes that the Untitled Letter dated September 9, 2025, to Altor addressed similar claims and representations for Anktiva on the webpage addressed in this letter. In the correspondence, FDA requested that Altor take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that were misleading as described). OPDP is concerned that Altor appears to be promoting Anktiva using similar claims and representations in a misleading manner.

[1] The "Efficacy & Safety" webpage is accessed from the "Efficacy & Safety" sub-navigation menu of the website. See: https://anktiva.com/hcp/efficacy-safety. (last accessed January 7, 2026).
[2] The material ID referenced on the "Efficacy & Safety" webpage includes "v11."
[3] The "Why ANKTIVA®" webpage is accessed from the "Why ANKTIVA®" sub-navigation menu of the website. See: https://anktiva.com/why-anktiva. (last accessed January 7, 2026).

The "Efficacy and Safety" webpage includes the following efficacy representations regarding cystectomy avoidance and disease-specific survival (DSS) (in pertinent part, emphasis original, footnotes omitted):

- "**% Of Responders Who Were Cystectomy Free At 36 Months**
  - **84%**"

- "**Disease-Specific Overall Survival at 36 Months**
  - **99%**"

The "Why ANKTIVA®" consumer webpage includes the following efficacy representations regarding cystectomy avoidance and DSS (in pertinent part, emphasis original, footnotes omitted):

- "**84% of patients who responded to ANKTIVA were able to keep their bladders at 36 months** (n=100)"

- "**99% Disease-Specific Overall Survival at 36 Months**"

These representations on the webpage and consumer webpage misbrand Anktiva by misleadingly suggesting that QUILT-3.032 provided interpretable results regarding the effects of Anktiva on cystectomy avoidance and DSS, even though the design of the QUILT-3.032 study was not capable of establishing improvement on these time-to-event efficacy endpoints. Anktiva was approved based on an effect shown on complete response and duration of response in QUILT-3.032, a single-arm study. As a reference for these representations, you cite a presentation[4] by Chang S, which includes updated results from the QUILT-3.032 study. However, as QUILT-3.032 was designed as a single-arm study (i.e., with no comparator arm) and cystectomy avoidance and DSS are time-to-event efficacy endpoints, the reported cystectomy avoidance and DSS results are uninterpretable; absent an appropriate comparator, it is not possible to determine if the observed effect is attributable to Anktiva or to other factor(s), such as the natural history of the disease.

We acknowledge that the following text appears as a footnote on the webpage and consumer webpage (in pertinent part):

- "These data on time to cystectomy and disease specific survival represent prespecified secondary endpoints in QUILT-3.032. These results should be interpreted with caution and in the context of the study's limitations of a single-arm study."

However, including these statements in Anktiva's promotional communications, along with misleading representations about Anktiva's efficacy (i.e., cystectomy avoidance and DSS results from QUILT-3.032), does not render the promotional communication nonmisleading in light of the issues with QUILT-3.032 (explained above) that make the study incapable of supporting representations or suggestions that these results are attributable to the effect of Anktiva.

[4] Chang S. An update on QUILT-3.032: durable complete responses to NAI (ANKTIVA) plus BCG therapy in BCG-unresponsive CIS with or without Ta/T1 papillary disease and in papillary disease without CIS. Presentation at: AUA2025; April 26-29, 2025; Las Vegas, NV.

Conclusion and Requested Action

For the reasons described above, the webpage and consumer webpage misbrand Anktiva and make the distribution of the drug in violation of the FD&C Act.

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that Altor 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 Anktiva that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Anktiva.

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 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. Please refer to MA 51 in addition to the BLA 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 0214 under BLA 761336.

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}

Jeena Sun, PharmD, MBA
Regulatory Review Officer
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

{See appended electronic signature page}

Emily Dvorsky, PharmD, RAC
Team Leader
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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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01/07/2026 02:19:38 PM

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