



TRANSMITTED BY FACSIMILE

Sherrill L. Wagner
Regulatory Affairs Manager, Advertising and Promotion
Lantheus Medical Imaging, Inc.
331 Treble Cove Road
North Billerica, MA 01862

RE: NDA 017771
TECHNELITE[®] (Technetium Tc 99m Generator)
MA #11

Dear Ms. Wagner:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed a Generator Exhibit Panel (SYSGEN_ID42644) (exhibit panel) for TECHNELITE[®] (Technetium Tc 99m Generator) (TechneLite) submitted by Lantheus Medical Imaging, Inc. (Lantheus) under cover of Form FDA-2253. The exhibit panel is misleading because it omits important risk information associated with the use of the drug and presents unsubstantiated claims. Thus, the exhibit panel misbrands TechneLite in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 352(a) & 321(n). Cf. 21 CFR 202.1(e)(5); (e)(6)(i), (ii). Furthermore, the established name is not placed in direct conjunction with the proprietary name, where the proprietary name is featured, as required by 21 CFR 201.10(g)(1).

Background

Below are the indication and summary of the most serious and common risks associated with the use of TechneLite.¹ According to its FDA-approved product labeling (PI),

Sodium Pertechnetate Tc 99m Injection is used IN ADULTS as an agent for:

- Brain Imaging (including cerebral radionuclide angiography)
- Thyroid Imaging
- Salivary Gland Imaging
- Placenta Localization
- Blood Pool Imaging (including radionuclide angiography)
- Urinary Bladder Imaging (direct isotopic cystography) for the detection of vesico-ureteral reflux.
- Nasolacrimal Drainage System Imaging

¹ This information is for background purposes only and does not necessarily represent the risk information that should be included in the promotional piece cited in this letter.

Sodium Pertechnetate Tc 99m Injection is used IN CHILDREN as an agent for:

- Brain Imaging (including cerebral radionuclide angiography)
- Thyroid Imaging
- Blood Pool Imaging
- Urinary Bladder Imaging (direct isotopic cystography) for the detection of vesico-ureteral reflux.

TechneLite is associated with several risks, as detailed in the WARNINGS and PRECAUTIONS sections of the PI. The WARNINGS section states, “Radiation risks . . . are greater in children than in adults and, in general, the younger the child, the greater the risk These greater risks should be taken firmly into account in all benefit-risk assessments involving children.”

Furthermore, according to the PRECAUTIONS section, care should be taken to minimize radiation exposure to the patients as well as occupational workers. Since the eluate does not contain an antimicrobial agent, it should not be used after 12 hours from the time of TechneLite elution. After a nasolacrimal imaging procedure, blowing the nose and washing the eyes with sterile distilled water or an isotonic sodium chloride solution will further minimize the radiation dose. Only physicians appropriately qualified and trained in the use of radiopharmaceuticals should use TechneLite.

According to the ADVERSE REACTIONS section, allergic reactions, including anaphylaxis have been reported following the administration of Sodium Pertechnetate Tc 99m Injection.

Omission of Risk Information

Promotional materials are misleading if they fail to reveal facts that are material in light of representations made or with respect to consequences that may result from the use of the drug as recommended or suggested in the materials. The exhibit panel makes several efficacy claims for TechneLite, but omits material risk information for the drug. We note that the “Important Safety Information” section of the exhibit panel states, “Allergic reactions including anaphylaxis have been reported infrequently”; however, the exhibit panel fails to include **any** of the Warnings and Precautions associated with the use of this drug. By omitting this important risk information, the exhibit panel misleadingly suggests that TechneLite is safer than has been demonstrated by substantial evidence or substantial clinical experience. We note that the bottom of the exhibit panel includes the statement, “***Please see a representative in this booth for full Prescribing Information***” (emphasis in original); however, this does not mitigate the omission of risk information from the exhibit panel.

Unsubstantiated Superiority Claim

Promotional materials are misleading if they contain a drug comparison that represents or suggests that a drug is safer or more effective than another drug, when this has not been demonstrated by substantial evidence or substantial clinical experience. The exhibit panel includes the claim, “**TECHNELITE[®] THE PREFERRED CHOICE**” (emphasis in original). This claim misleadingly suggests that TechneLite is favored over other available generators for the indicated uses, when this has not been demonstrated by substantial evidence or substantial

clinical experience. The term “preferred” encompasses a variety of factors such as convenience, dosing, dosage form, efficacy, and adverse events. Generally, claims about preference must be supported by adequate and well-controlled, head-to-head clinical studies using well-developed instruments that can evaluate all determinants of preference. In the absence of substantial evidence or substantial clinical experience to support the assertion that TechneLite is “the preferred choice” for healthcare providers and/or patients, the above statement is misleading.

Unsubstantiated Claims

The exhibit panel makes the following claim regarding the use of TechneLite (emphasis in original):

- *“Simple, Hassle-free Use”*

This statement misleadingly suggests that TechneLite is easy to use and free of hassle, when this is not supported by adequate evidence. On the contrary, the TechneLite PI describes a complex series of steps that are required for proper preparation and administration. For example, the PI describes a thirteen-step procedure for eluting the Sodium Pertechnetate Tc 99m solution from the Generator. Additionally, there are several considerations depending on the type of diagnostic procedure performed. For example, imaging of the urinary bladder and ureters requires administration of the injection via a urethral catheter. Imaging of the nasolacrimal drainage system requires instillation via a device such as a micropipette. The dosage employed varies with each diagnostic procedure. If the oral route of administration is elected, the patient should fast for at least six hours before and two hours after administration. The PI also describes specific instructions for ensuring the safe use and disposal of radioactive material. In light of these extensive procedures and considerations, it is misleading to state that the use of TechneLite is “simple” or “hassle-free.”

Inadequate Presentation of Established Name

The exhibit panel fails to present the established name (Technetium Tc 99m Generator) in direct conjunction with the proprietary name (TechneLite) where the proprietary name is featured in the headline at top of the exhibit panel, as required by 21 CFR 201.10(g)(1).

Conclusion and Requested Action

For the reasons discussed above, the exhibit panel misbrands TechneLite in violation of the FD&C Act, 21 U.S.C. 352(a) & 321(n). Cf. 21 CFR 202.1(e)(5); (e)(6)(i), (ii). Furthermore, the established name is not presented in conjunction with the proprietary name when it is featured, as required by 21 CFR 201.10(g)(1).

OPDP requests that Lantheus immediately cease the dissemination of violative promotional materials for TechneLite such as those described above. Please submit a written response to this letter on or before November 9, 2011, stating whether you intend to comply with this request, listing all promotional materials (with the 2253 submission date) for TechneLite that contain violations such as those described above, 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, Division of Professional 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 Promotion (DPP) and the Division of Direct-to-Consumer Promotion (DDTCP). 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 #11 in addition to the NDA 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 promotional materials for TechneLite comply with each applicable requirement of the FD&C Act and FDA implementing regulations.

Sincerely,

{See appended electronic signature page}

James S. Dvorsky, PharmD
Regulatory Review Officer
Division of Professional Promotion
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/

JAMES S DVORSKY
10/25/2011