



NDA 214032

**NDA APPROVAL**

Telix Pharmaceutical, Inc.  
Attention: Mike Wardach  
VP, Global Regulatory Affairs  
12 Municipal Drive Suite 330  
Fishers, Indiana 46038

Dear Mr. Wardach:

Please refer to your new drug application (NDA) dated September 23, 2020, received September 23, 2020, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ILLUCCIX (kit for the preparation of gallium Ga 68 gozetotide injection).

We acknowledge receipt of your major amendment dated September 20, 2021, which extended the goal date by three months.

This NDA provides for the use of ILLUCCIX (kit for the preparation of gallium Ga 68 gozetotide injection), for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

### **APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

We note that your December 15, 2021, submission includes final printed labeling (FPL) for your Prescribing Information. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at

FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling text for the Prescribing Information as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

The SPL will be accessible via publicly available labeling repositories.

### **CARTON AND CONTAINER LABELING**

We acknowledge your December 15, 2021, submission containing final printed carton and container labeling.

### **DATING PERIOD**

Based on the stability data submitted to date, the expiry dating period for ILLUCCIX (kit for the preparation of gallium Ga 68 gozetotide injection) is up to 24 months from the date of manufacture when stored at 2 to 8 °C.

### **ADVISORY COMMITTEE**

Your application for ILLUCCIX (kit for the preparation of gallium Ga 68 gozetotide injection) was not referred to an FDA advisory committee because the application did not raise significant public health questions on the role of the drug in the diagnosis, cure, mitigation, treatment, or prevention of a disease.

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because the necessary studies are impossible or highly impracticable since prostate cancer rarely occurs in pediatric patients.

---

<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

**POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B**

We remind you of your postmarketing commitments:

- 4176-1 Provide additional data for (b) (4) to show consistency in the values reported and perform 100% sampling of the manufactured batches if inconsistencies are observed. Provide a validated method (b) (4)

The timetable you submitted on November 11, 2021, states that you will conduct this study according to the following schedule:

Final Report Submission: 02/22

- 4176-2 Provide additional sterility data for gallium Ga 68 gozetotide injection product batches made with Ga 68 chloride eluate from aged generators (within 1 month of expiry) to demonstrate that eluates from aged generators do not impact the sterility of the final radiolabeled product.

The timetable you submitted on November 11, 2021, states that you will conduct this study according to the following schedule:

Final Report Submission: 04/22

Submit chemistry, manufacturing, and controls protocols and all postmarketing final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled “**Postmarketing Commitment Protocol,**” “**Postmarketing Commitment Final Report,**” or “**Postmarketing Commitment Correspondence.**”

**PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-*

*Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*<sup>3</sup>

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.<sup>4</sup> Information and Instructions for completing the form can be found at FDA.gov.<sup>5</sup>

**METHODS VALIDATION**

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

**REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Diane Hanner, Regulatory Project Manager, at (301) 796-4058.

Sincerely,

*{See appended electronic signature page}*

Libero Marzella, MD, PhD  
Director  
Division of Imaging and Radiation Medicine  
Office of Specialty Medicine  
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
- Carton and Container Labeling

---

<sup>3</sup> For the most recent version of a guidance, check the FDA guidance web page at

<https://www.fda.gov/media/128163/download>.

<sup>4</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>5</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

-----  
**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/  
-----

LIBERO L MARZELLA  
12/17/2021 01:19:54 PM