



NDA 217294

**TENTATIVE APPROVAL**

SQ Innovation, Inc.  
Attention: Pieter Muntendam, MD  
President  
20 Burlington Mall Road  
Suite 220  
Burlington, MA 01803

Dear Dr. Muntendam:

Please refer to your new drug application (NDA) dated March 15, 2023, received March 15, 2023, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for LASIX ONYU (furosemide injection) for subcutaneous use.

We acknowledge receipt of your amendment dated April 19, 2024, which constituted a complete response to our January 12, 2024, action letter.

(b) (4)

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105(a); therefore, this application is not approved and will not be approved until FDA issues an approval letter after any necessary additional review of the application. Enclosed are the tentatively approved labeling (b) (4)

This tentative approval determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

Final approval of your application is subject to expiration of a period of patent protection and/or exclusivity. Therefore, final approval of your application may not be granted before the period has expired.

To obtain final approval of this application, submit an amendment two or six months prior to the date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **“REQUEST FOR FINAL APPROVAL”**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or

judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not approved, and cannot be legally marketed and the use of the enclosed tentatively approved labeling is not permitted for marketing this drug product. If you believe that there are grounds for issuing the final approval letter before the expiration of the patent(s) and/or exclusivity protection, you should amend your application accordingly.

### **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 note that if this application is ultimately approved, you will need to meet these requirements.

### **POSTMARKETING COMMITMENTS**

(b) (4)



If you have any questions, contact Christine (Tina) Sadr, Senior Regulatory Health Project Manager, at 240-402-6554.

Sincerely,

*{See appended electronic signature page}*

Norman Stockbridge, MD, PhD  
Acting Deputy Director  
Division of Cardiology and Nephrology  
Office of Cardiology, Hematology, Endocrinology,  
and Nephrology  
Center for Drug Evaluation and Research

ENCLOSURE(S): (tentatively approved)

- Content of Labeling

(b) (4)



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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.**  
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/s/  
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