NDA 217294

NDA 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) received March 15, 2023, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lasix ONYU (furosemide injection), for subcutaneous use.

We acknowledge receipt of your amendment dated August 7, 2025, following our October 18, 2024, tentative approval letter.

This NDA provides for the use of Lasix ONYU for the treatment of edema in adult patients with chronic heart failure.

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.

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.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, Quick Reference Guide, carton and container labeling) 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.*[2]

The SPL will be accessible via publicly available labeling repositories.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] 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.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 217294**." Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for furosemide injection shall be 24 months from the date of manufacture when stored at 20°C to 25°C.

The expiration date for the packaged product, furosemide injection plus the starter kit, treatment kit, and reusable unit and charger box shall be dependent on the shortest expiration date of any component.

ADVISORY COMMITTEE

Your application for Lasix ONYU was not referred to an FDA advisory committee because outside expertise was not necessary; there were no controversial issues that would benefit from advisory committee discussion.

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 this product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients and is unlikely to be used in a substantial number of pediatric patients.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

4701-1 To evaluate the post-market occurrence rate for (b) (4) provide the following:

a. The occurrence rate for [redacted] (b) (4) for the combination product. The occurrence rate should be provided as raw data per quarter (i.e., the number of occurrences in Q1, Q2, etc.) and cumulatively (i.e., total occurrence rate and number over all quarters) in addition to the total number of devices distributed at the time of the report (segmented into quarters). These data should include [redacted] (b) (4) observed both internally throughout the manufacturing process (e.g., release testing) and from devices distributed in the field presented separately from one another.

b. Updates on the investigation including root causes and corrective actions implemented to reduce the occurrence rate for [redacted] (b) (4)

The post-market reports as outlined above should be submitted quarterly starting from start of distribution of the final finished combination product through 5 years.

The timetable you submitted by email on October 6, 2025, states that you will conduct this study according to the following schedule:

First Quarterly report:	01/2026
Quarterly Report:	04/2026
Quarterly Report:	07/2026
Quarterly Report:	10/2026
Quarterly Report:	01/2027
Quarterly Report:	04/2027
Quarterly Report:	07/2027
Quarterly Report:	10/2027
Quarterly Report:	01/2028
Quarterly Report:	04/2028
Quarterly Report:	07/2028
Quarterly Report:	10/2028
Quarterly Report:	01/2029
Quarterly Report:	04/2029
Quarterly Report:	07/2029
Quarterly Report:	10/2029
Quarterly Report:	01/2030
Quarterly Report:	04/2030
Quarterly Report:	07/2030
Quarterly Report:	10/2030
Final Report Submission:	01/2031

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.*[3]

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.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

REPORTING REQUIREMENTS

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

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.[6]

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website[7].

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf
[6] https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products
[7] https://www.uspnf.com/

If you have any questions, please contact Christine Sadr, Senior Regulatory Health Project Manager, at (240) 402-6554 or christine.sadr@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Selena DeConti, PharmD, MPH
Deputy Director for Safety
Division of Cardiology and Nephrology
Office of Cardiology, Hematology, Endocrinology, and Nephrology
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Instructions for Use
  - Quick Reference Guide
  - Carton and Container Labeling

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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