CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

209988Orig1s000

Trade Name:	Furoscix
Generic or Proper Name:	Furosemide injection
Sponsor:	scPharmaceuticals, Inc.
Approval Date:	October 7, 2022
Indication:	Furoscix is indicated for the treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure.

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APPROVAL LETTER

NDA 209988

CORRECTED NDA APPROVAL

scPharmaceuticals, Inc.
Attention: Eric Kendig, PhD
Vice President, Head of Regulatory Affairs
2400 District Avenue, Suite 310
Burlington, MA 01803

Dear Dr. Kendig:

Please refer to your new drug application (NDA) dated August 23, 2017, received August 23, 2017, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Furoscix (furosemide injection).

We also refer to our approval letter dated October 7, 2022, which contained the following error: scPharmaceuticals, Services Inc. is listed as the name of the Applicant. The correct Applicant name is scPharmaceuticals, Inc.

This corrected action letter incorporates the correction of the error. The effective action date will remain October 7, 2022, the date of the original letter.

We acknowledge receipt of your amendment dated April 8, 2022, which constituted a complete response to our December 3, 2020, action letter.

This NDA provides for the use of Furoscix (furosemide injection) for the treatment of congestion due to fluid overload in adults with NYHA Class II/III 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 and Instructions for Use) as well as annual reportable changes

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

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]

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 *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 209988**." 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 Furoscix (furosemide injection) shall be 12 months from the date of manufacture when stored at 20 to 25 °C (68°F to 86°F).

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 ages 0 to less than 12 years of age or less than 42.5 kg body weight because you have demonstrated that reasonable attempts to produce a pediatric formulation necessary for this age group have failed. As required by section 505B(a)(4)(C) of the Federal Food, Drug, and Cosmetic Act/FDCA, the documentation you have provided that details why a pediatric formulation cannot be developed will be posted on the Agency's public website.

We are deferring submission of your pediatric study for ages 12 to 17 years or who weigh at least 42.5 kg, for this application because this product is ready for approval for use in adults and the pediatric study has not been completed.

[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.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act/FDCA is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(4)(C) of the Federal Food, Drug, and Cosmetic Act/FDCA. This required study is listed below.

4350-1 Perform an extrapolation analysis based on allometric scaling from adults with heart failure to support the efficacy for children with heart failure 12 to 17 years of age who weigh at least 42.5 kg.

Final Study Report Submission: 03/2023

Submit the Final Study Report to your IND 118919, with a cross-reference letter to this NDA. Reports of this required pediatric postmarketing study must be submitted as an NDA or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from this study. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

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).

[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

If you have any questions, please call Brian Proctor, Regulatory Project Manager, at (240) 402-3596.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiology and Nephrology
Office of Cardiology, Hematology, Endocrinology and Nephrology
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Instructions for Use
- 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/

NORMAN L STOCKBRIDGE
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