NDA 211996/S-001
NDA 212161/S-001

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Fold Rx Pharmaceuticals, a wholly owned subsidiary of Pfizer, Inc.
Attention: Seoan Huh, PhD.
Manager, Pfizer Global Regulatory Affairs, Rare Disease
235 E. 42nd St
Mailstop: 219/9/02
New York, NY 10017

Dear Dr. Huh:

Please refer to your supplemental new drug application (sNDA) dated and received December 20, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vyndaqel (tafamidis meglumine)(NDA 211996) and Vyndamax (tafamidis) (NDA 212161).

This Prior Approval sNDA provides for revisions to the approved labels for tafamidis to add information regarding breast cancer resistant protein (BRCP), based on a drug-drug interaction study, to sections 7.1 and 12.3.

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 the Patient Package Insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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

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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We also refer to your December 20, 2020 submission containing the final report for the following postmarketing requirement listed in the May 5, 2019 approval letter:

3576-2 Conduct a clinical drug interaction study to evaluate the potential interaction between tafamidis and a relevant BCRP substrate.

The timetable you submitted on April 1, 2019 states that you will conduct this trial according to the following schedule:

Draft Protocol Submission:	09/2019
Final Protocol Submission:	11/2019
Study/Trial Completion:	05/2020
Final Report Submission:	08/2020

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there is a postmarketing requirement listed in the May 5, 2019 approval letter that is still open.

[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.

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 Lori Anne Wachter, RN, BSN, RAC, Regulatory Project Manager for Safety, at 301 796-3975.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
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
  - Patient Package Insert

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/

MARY R SOUTHWORTH
06/01/2021 11:05:28 AM