NDA 210922/S-001

SUPPLEMENT APPROVAL

Alnylam Pharmaceuticals, Inc.
Attention: Holly Maier
Director, Regulatory Affairs
300 Third Street
Cambridge, MA 02142

Dear Ms. Maier:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 9, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ONPATTRO (patisiran) Lipid Complex Injection, 2 mg/mL.

This "Changes Being Effected" supplemental new drug application provides for updates to the carton and immediate container label to increase the prominence of the established name and to add "Do not freeze. Discard vial if it has been frozen." (emphasis added).

APPROVAL & LABELING

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

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your November 9, 2018, submission containing final printed carton and container labels.

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 Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Branch Chief, BI
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research