

**BLA STN:** 125781/0

**Applicant:** Sarepta Therapeutics, Inc.

**Submission Receipt Date:** September 28, 2022

**Action Due Date:** May 26, 2023

**Proper Name:** delandistrogene moxeparvovec-rokl

**Proprietary Name:** ELEVIDYS

**Indication:** Treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene.

**The following officers or employees of FDA participated in the decision to approve this application and consented to be identified on this list.**

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