Written Comment Guide for CAP-1002 FDA Review

Subject: Deramiocel (CAP-1002) for Duchenne Cardiomyopathy

To be submitted to: druginfo@fda.hhs.gov.

Introduction (Suggested Language)

> I am writing as a [person living with Duchenne / parent / sibling / caregiver] to express my support for the approval of deramiocel (CAP-1002), a cell-based therapy currently under FDA review for Duchenne cardiomyopathy. I am part of a community that lives every day with the relentless progression of this disease, and I believe deramiocel offers real hope, not just for more time, but for a better life.

Your Story (Please Personalize)

Use this space to share your personal experience. You can include:

- Who in your life is affected by Duchenne (name optional)
- What progression has looked like for you or your loved one
- Any cardiac issues, loss of function, or major health events
- What access to a treatment like deramiocel would mean to your family or the community

Why Deramiocel Matters (Suggested Language)

> Duchenne is a progressive and irreversible disease. Once function is lost, it cannot be regained. It is our understanding that Deramiocel has demonstrated the ability to slow cardiac decline and preserve upper limb strength. These benefits are life-changing and life-extending.
>
> The therapy has a significant? safety profile and addresses the underlying causes of muscle damage in Duchenne, fibrosis and inflammation. Families like mine do not view this as a minor improvement. We see it as essential.
>
> For older, non-ambulatory individuals who have very few treatment options, deramiocel could offer the benefit of time and the meaningfulness of independence, that they would not otherwise have.

Time Matters (Suggested Language)

> ***Every day without access to therapy is another day of decline***. In Duchenne, time is muscle lost. Families are asking for the chance to access a therapy that has already shown substantial and sustained benefit in the areas that matter most: cardiac health, arm function, survival, and quality of life.

Closing (Suggested Language)

> I urge the FDA to approve deramiocel for the treatment of Duchenne. Please hear the voices of families like mine who are doing everything we can to protect our children and loved ones from the worst outcomes of this disease.
>
> Thank you for your attention to our community and for considering the urgency and promise of this treatment.

How to Submit

- Email your comment to druginfo@fda.hhs.gov.
- You can send it in the body of your email or as an attachment.