



**BEAT  
CHILDHOOD  
CANCER**

August 29, 2023

Dear Parents, Patients, Medical Professionals, Supporters, and Friends,

After almost twenty years of dedicated work by Dr. Giselle Sholler and the Beat Childhood Cancer Research Consortium, hundreds of children diagnosed with neuroblastoma have experienced positive outcomes from DFMO, a well-tolerated, oral medication. In fact, data has confirmed that DFMO can reduce the risk of relapse by 50% when used as a maintenance therapy following remission from standard of care therapies.

As a first step to ensuring DFMO is available to every child, everywhere, a New Drug Application was formally submitted to the FDA last year and remains under review. The next step in this review process includes a meeting of the FDA's Oncologic Drugs Advisory Committee (ODAC) on October 4 to discuss the DFMO application. This ODAC meeting presents a unique opportunity for families and their clinicians to provide perspectives in letter submissions that will be made available to ODAC members and FDA in advance of the meeting. These letters will also be accessible to the general public on the government [regulations.gov](https://www.regulations.gov) website.

***I am writing to humbly ask that you please consider submitting a letter of support for DFMO! Your contribution is important and could make a significant difference.***

If you are willing to participate, here are some suggestions:

- Be brief: we recommend you limit your letter to one page.
- Make it 'skimmable': Put your main messages in the first sentence(s) of each paragraph. Advisors will have much to read, so make it easy for them to quickly get your viewpoint.
- Focus: answer the following question – *Based on your experience, why is it important for children to have access to DFMO?*
- Post it: When ready, post your letter by copying it into the "comment" box on the <https://www.regulations.gov/commenton/FDA-2023-N-3329-0001> website specific to this ODAC. Under the Comment Category, select Individual Consumer (or another category as appropriate to your profession.)

Thank you, in advance, for sharing your perspective on DFMO. It is so important for all FDA advisors to hear from you. **The deadline for submission is September 20.** Should you have questions, please do not hesitate to reach out to: [hello@beatcc.org](mailto:hello@beatcc.org). It is with appreciation and pride that we partner together to beat childhood cancer for every child, everywhere.

Sincerely,

Sarah Bartosz  
Executive Director, Beat Childhood Cancer Foundation  
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