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July 19, 2021

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted electronically via regulations.gov

RE: Cancer Clinical Trial Eligibility Criteria: Approach to Available Therapy in Non-Curative Settings; Draft Guidance for Sponsors (Docket No. FDA–2020–D–1802)

The Oncology Nursing Society (ONS) appreciates the opportunity to provide feedback on the aforementioned draft guidance that "*provides recommendations to sponsors of clinical trials of investigational cancer drugs regarding the inclusion of patients who have not previously received available therapy (commonly referred to as existing treatment options) for their cancer in the non-curative setting*" with the goal of "*facilitate[ing] increased clinical trial options for patients with non-curable cancers by recognizing that, with appropriate informed consent, it may be reasonable for patients to be eligible for inclusion in trials of investigational cancer drugs, regardless of whether they have received available therapy, in the non-curative setting.*"

ONS fully supports efforts to reduce barriers to clinical trial enrollment and participation and concurs with the FDA that "*eligibility criteria in which patients receive an investigational drug(s) in lieu of available therapy is reasonable in the non-curative setting (i.e., when there is no potential for cure or for prolonged/near normal survival) when patients have been provided adequate information to make an informed decision on trial participation*."

As the agency is aware, not all effective therapies are listed as "curative intent." We maintain that clinical trials may offer feasible options for prolonging disease-free survival or quality of life, outcomes that are just as important for patients living with a non-curable cancer.

Finally, results from clinical trials must be reflective of the broader population, not a highly select group. It is our contention that expanding access and eligibility will help with extrapolation of clinical trials data.

For these reasons, we encourage FDA to finalize this draft guidance.

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We appreciate the opportunity to comment on this draft guidance and look forward to additional opportunities to provide feedback on these issues. If you have any questions about our comments, please contact Alec Stone, ONS Public Affairs Director, at astone@ons.org.

Sincerely,

The Oncology Nursing Society

About ONS

The Oncology Nursing Society (ONS) is a professional organization of over 39,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. ONS members are a diverse group of professionals who represent a variety of professional roles, practice settings, and subspecialty practice areas. Oncology nurses are leaders in the healthcare arena, committed to continuous learning and leading the transformation of cancer care by advocating for high-quality care for people with cancer.