Society for Women's Health Research

July 29, 2015

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

Re: Docket # FDA-2015-P-0732-0001

To Whom It May Concern:

The Society for Women's Health Research (SWHR®) is the nation's leading non-profit organization dedicated to transforming women's health through advocacy, education, and research. We appreciate the opportunity to comment on Docket #2015-P-0732-0001and to provide our comments on needed regulatory policies that can facilitate innovative new treatments for diseases and conditions such as Alzheimer's disease, autoimmune disorders, and cancers, which may impact women disproportionately or differently than men.

Nanotechnology offers great promise for patients by developing medicines that have the potential to significantly improve their lives. Additionally, this technology has the capability to transform care and lead to new and innovative cures. Realizing the potential of nanotechnology, the National Cancer Institute (NCI) launched the NCI Alliance for Nanotechnology in Cancer in 2004 to advance basic scientific discoveries and translate them into viable clinical applications. Through this effort, NCI has set up nine Centers of Cancer Nanotechnology Excellence at leading universities and established the Nanotechnology Characterization Laboratory (NCL), which performs preclinical efficacy and toxicity testing of nanoparticles. Nanotechnology has transformed cancer treatment, with nanotechnology-enabled medicines allowing physicians to target therapies selectively at specific tumors while leaving healthy tissue intact.

Translating basic science into clinical application is only part of the solution. Recently, there has been a great deal of attention paid to the U.S. biomedical research enterprise and how the system can be improved to expedite cures to patients. These conversations have

1025 Connecticut Avenue, NW | Suite 601| Washington, D.C. 20036 Phone 202-223-8224 | Fax 202-833-3472 |SWHR.org

emphasized the integral role that the FDA plays in ensuring that innovative products reach patients. In the case of nanotechnology, SWHR believes that the current FDA approval standards and requirements for nanotechnology-derived drugs do not address the significant patient safety implications resulting from the uniqueness and complexity of these therapies. Therefore, a new framework that addresses these issues must be developed.

As explained in the Celgene Corporation and Abraxis BioScience LLC Citizen Petition; nanoparticles, due to their minute size, act differently than larger particles of the same drug, meaning that even small changes in the nanoparticles may result in the drug acting differently in the body, affecting patient outcomes and potentially compromising patient safety. SWHR encourages the FDA to implement comprehensive science-based regulatory standards that reflect the unique nature of nanoparticles when evaluating the safety, effectiveness and intended use of both new and generic cancer nanomedicines.

Along with many other organizations working to improve the delivery of health care, SWHR hopes that the recent emphasis and support for biomedical research and reducing regulatory burden to speed new and novel therapies to patients will result in a more targeted approach to medical practice, inclusive of new classes of highly targeted and more effective nanomedicines to detects and treat diseases. By implementing a strong regulatory framework for approving both new and generic cancer nanomedicines, FDA can play a key role in expediting these medicines to patients who desperately need them.

Thank you for taking these comments into consideration.

Sincerely,

Leslie Ritter
Vice President, Public Policy
Society for Women's Health Research
202-223-8224
Leslie@swhr.org

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