



Oncology Nursing Society

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June 3, 2016

Ms. Leslie Kux
Associate Commissioner for Policy
c/o Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Submitted electronically via: www.regulations.gov

RE: Labeling for Biosimilar Products; Draft Guidance for Industry (Docket No. FDA-2016-D-0643-0001)

Dear Ms. Kux,

The Oncology Nursing Society (ONS) is pleased to provide input on the US Food and Drug Administration (FDA) draft guidance, *Labeling for Biosimilar Products*. This is an important issue for oncology nurses as key members of the cancer care delivery and treatment team.

Labeling for Biosimilar Products

As noted above, oncology nurses are responsible for all aspects of administering and monitoring chemotherapy and biotherapy agents. Their education, training and competencies for administering chemotherapy and biotherapy depend on current and evidence-based content regarding chemotherapy, biotherapy, immunotherapy, and biosimilars. Specific to biosimilar products, education, training and competency assessments must consider (a) the presence of similarities and differences to the reference product; (b) an evaluation of analytical, clinical, and non-clinical data conducted in a patient populations and if available similar to that of the intended recipient; (c) an evaluation of additional clinical data, if any, reported as a requirement to obtain approval; (d) the appropriateness of use for the patient's condition.

For these reasons, we have a significant interest in furthering accurate labeling for biosimilar products, which we maintain is critical to ensuring patient safety. Toward that end, we urge FDA to require manufacturers to include a biosimilarity statement on biosimilar products in its final guidance. Biosimilarity and interchangeability are different statutory standards. As such, these two different levels of similarity warrant distinction to avoid any misunderstandings about what products are being administered to cancer patients, and what products can be safely substituted for one another.

ONS is a professional organization of over 39,000 registered nurses and other health care providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. The growing demand for cancer care, from prevention to palliative care, requires oncology nurses to play a pivotal and increasingly important role in delivering high quality, safe, effective and efficient health care to people affected by, or at risk for, cancer.

Thank you for the opportunity to submit comments on the draft guidance. Should you have any questions regarding our perspectives on this issue, please contact Alec Stone, MA, MPA, ONS Director of Health Policy, at astone@ons.org. We look forward to engaging in an ongoing dialogue to address issues of importance to our cancer patients and, most importantly in this discussion, ways in which we can enhance cancer patient management.

Sincerely,

The Oncology Nursing Society