



September 28, 2015

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

Re: Comments of the Healthcare Supply Chain Association (HSCA) on FDA's Draft Guidance "Request for Quality Metrics: Guidance for Industry." Docket No.FDA-2014-D-2537

The Healthcare Supply Chain Association (HSCA) appreciates this opportunity to provide comment on the U.S. Food and Drug Administration's (FDA)'s draft guidance entitled "Request for Quality Metrics: Guidance for Industry."

HSCA's member group purchasing organizations (GPO) are crucial cost-savings engines for America's hospitals, clinics, nursing homes, and surgery centers. HSCA and its members are committed to lowering costs and increasing competition and innovation in the healthcare marketplace.

HSCA supports FDA's efforts to use quality metrics to monitor establishments involved in the manufacture, preparation, propagation, or processing of human drugs. By leveraging quality metrics to make critical decisions about risk-based scheduling and prediction of drug shortages, FDA will advance product quality and quality manufacturing facilities, and mitigate threats that could put patients, providers, and the broader healthcare market in jeopardy.

As regards risk-based inspection scheduling, HSCA recommends that all suppliers, foreign and domestic, be held to the same quality standards, and that FDA focus on suppliers that have not been inspected or that have a history of compliance problems.

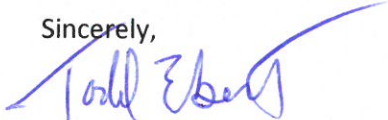
Regarding Section V.A entitled "Reporting of Quality Data and Calculation of Quality Metrics: Who Reports and Who May Contribute to the Report," HSCA recommends that quality metrics be provided by both foreign and domestic facilities. This helps ensure the safety of all drugs entering the U.S. market, and thus the safety of patients.

Regarding Section IV.B entitled "The Use of Quality Metrics and Effects of Non-Reporting: Effects of Non-Reporting," HSCA recommends that there be consequences for any organization manufacturing or distributing products for U.S. markets that chooses not to provide quality metrics. If a company is supplying drugs to the U.S. market, it is necessary that they comply with FDA standards.

Finally, HSCA recommends that quality metrics provided by manufacturers be made publicly available, after a grace period in which FDA reviews said metrics. These metrics should be made available by the company, with consistency in format of presentation. Making the quality metrics publicly available will increase transparency and accountability among drug manufacturers, spurring safety, innovation, efficiency, and competition throughout the healthcare supply chain.

We look forward to continuing to work with you as FDA explores guidance on quality metrics for the healthcare industry. Please do not hesitate to contact me directly should you have any questions. I can be reached at 202.367.1162 or tebert@supplychainassociation.org.

Sincerely,



Todd Ebert
President and CEO