



25 February 2014

FDA Circular
No. **2014-007**

TO : ALL REGULATED ESTABLISHMENTS FOR MEDICAL DEVICE

**SUBJECT : ADOPTION OF THE KUALA LUMPUR PRINCIPLES DEVICE
SECTOR CODES OF ETHICS**

I. BACKGROUND

The Philippines is a founding member of the Asia Pacific Economic Cooperation (APEC) which is an association of economies sharing the boundaries of the Pacific Ocean. The association serves as a forum for 21 Pacific Rim member countries that aims to promote free trade and economic cooperation in the region. One of APEC's goals is to sustain the growth and development of each member's economy and eventually, contribute likewise to the growth of world economy.

In the 2011, Ministerial meeting in Honolulu, the leaders held a high level Dialogue on Open Governance and Economic Growth. The meeting representatives recognized that transparency and open governance a critical elements of long-term economic competitiveness for sustainable economic growth and prosperity, especially targeting small and medium enterprises (SMEs). Further, it was recognized then that SMEs can serve as catalysts of economic growth in an open and ethical business environment. In response to this, in 2010, the APEC SME ministers called for the development of business codes of ethics in key sectors- biopharmaceutical, medical device and construction/engineering amongst its member countries. Thus, in 2011-2012, Business Codes of Ethics were developed for the key sectors which were unanimously endorsed in November 2011 by both APEC foreign and trade ministers. The Codes of Ethics intend to considerably benefit APEC economies through the following: 1) provide a platform for effective industry self-regulation; 2) support government enforcement and anti-corruption efforts; 3) benefit resource-constrained SMEs by providing clarity and harmonization of rules and practices to allow competition at a reduced cost. Ultimately,




Thus, an Expert Working Group was convened in Kuala Lumpur in 2011, developed the APEC Principles for a Code of Ethics in the medical device sector.

In 2012, APEC ministers hailed the progress made in implementing the APEC Principles and declared their unstinting support for its adoption among its member economies and conducted an expanded implementation and compliance program with adequate funding 1) for capacity building, 2) to promote ethical business practices in interactions between government, business and other stakeholders, and 3) to fight corruption which imposes a significant market access barrier and high costs for SMEs.

II. DETAILS

In view of the foregoing, the Food and Drug Administration hereby adopts through this Circular, the Kuala Lumpur Principles for implementation. It is intended to ensure that marketing practices, notably promotions, adhere to the principles of Integrity, Independence, Appropriateness and Advancement among medical device manufacturers, distributors and other regulated establishments marketing medical technologies. Besides establishing ethical practices among industry, healthcare professionals and regulators, it assures that patient safety is the prime consideration in the selection and use of these products.

For information, guidance and compliance


KENNETH Y. HARTIGAN-GO, MD
Acting Director General