FDA NEWS RELEASE

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Media Inquiries: Morgan Liscinsky, 301-796-0397, morgan.liscinsky@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA, EMA announce pilot for parallel assessment of Quality by Design applications

The U.S. Food and Drug Administration and the European Medicines Agency (EMA) have launched a new pilot program that will allow parallel evaluation of relevant development and manufacturing data components, known as Quality by Design (QbD), of new drug marketing applications that are submitted to both agencies.

The parallel evaluation within this voluntary pilot program means that reviewers from both agencies will separately assess the quality/chemistry, manufacturing and control (CMC) section of the new drug applications (NDAs) submitted to the FDA and marketing authorization applications (MAAs) submitted to the EMA. However, there will be regular communication and consultation between European regulators and their U.S. colleagues throughout the review process relevant to QbD aspects of the applications.

QbD in pharmaceuticals involves designing and developing pharmaceutical formulations and manufacturing processes to help ensure product manufacturing quality. Several guidelines have been developed by the International Conference on Harmonisation (ICH) to harmonize and facilitate the implementation of QbD. This pilot program began out of concern that certain ICH guidelines were being interpreted differently in Europe and the United States. Goals of the pilot program include:

Helping to ensuring consistent implementation of ICH guidelines for manufacturing quality in the application evaluation process

Increasing awareness of these regulatory concepts by staff that review marketing applications and inspect manufacturing facilities as part of the approval process

Defining the reviewer and inspector interaction for QbD applications

Creating a further way for EMA and FDA assessors/reviewers to share full knowledge about these applications

Developing and harmonizing regulatory decisions to the greatest extent possible.

“As the number of applications that follow the QbD approach steadily increases, collaborative assessments will enhance understanding of QbD concepts. The tools used by FDA and EU reviewers will increase information sharing and reduce redundancy,” said Janet Woodcock, M.D., director of FDA’s Center for Drug Evaluation and Research. “To fully implement QbD, we need to further harmonize the implementation of the guidelines, work collaboratively, and provide scientific, risk-based regulatory decisions in a timely manner.”

"This is another concrete example of the very collaborative working relationship we have with our European regulatory colleagues and how we can leverage the scientific resources we both have for the benefit of our agencies and our citizens," said Murray M. Lumpkin, M.D., Deputy Commissioner of FDA's Office of International Programs.

This pilot program applies to NDAs and MAAs, some supplements, and CMC meeting requests that include QbD elements submitted to both agencies at about the same time. The pilot will only include chemical entities and not biologically-derived products. Review of QbD applications does not change statutory deadlines. The pilot will end on March 31, 2014.

For more information:

International Conference on Harmonization - Quality Guidance[1]

European Medicines Agency[2]
(http://www.ema.europa.eu/ema/index.jsp?curl=/pages/home/Home_Page.jsp&jsenabled=true)

International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)[3]
(http://www.ich.org/home.html)

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