FDA NEWS RELEASE
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FDA seeks comment on proposed policy for diagnostic tests used with targeted drug therapies

Part of agency's efforts to promote development of personalized medicines and diagnostics

The U.S. Food and Drug Administration today issued a new draft guidance to facilitate the development and review of companion diagnostics – tests used to help health care professionals determine whether a patient with a particular disease or condition should receive a particular drug therapy or how much of the drug to give. The draft document is intended to provide companies with guidance on the agency's policy for reviewing a companion diagnostic and the corresponding therapy.

One common type of companion diagnostic looks for whether a patient has a specific gene amplification or protein over-expression that could predict whether a drug might benefit the patient or lead to harm. For example, the FDA in 1998 approved Herceptin (trastuzumab), a breast cancer drug designed to target HER2 gene amplification or HER2 protein over-expression. The drug was approved with a companion test and today testing is routinely performed on women diagnosed with breast cancer to help health care professionals determine whether or not the patient should receive Herceptin.

"These proposed guidelines support the development of innovative new targeted medicines and their corresponding diagnostic tests and are intended to provide manufacturers with greater predictability," said Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health. "It is the agency's goal to help stimulate early collaborations between drug and device makers so they can develop the best medical products for treating patients."

The draft guidance also:

- Clarifies the FDA's definition of a companion diagnostic;
- Recommends early engagement between the FDA and manufacturers so that the agency's expectations are included in development plans;
- Highlights the FDA's intention to conduct simultaneous reviews of a drug or biologic therapy and its corresponding companion diagnostic; and
- Identifies instances where the FDA may approve a targeted medicine in the absence of a cleared or approved companion diagnostic. In cases where the therapy is intended to treat a serious or life-threatening disease or condition for which there is no available or satisfactory treatment and when the potential benefits outweigh the risks of not having a cleared or approved companion diagnostic, the therapy could be approved first while the companion diagnostic may be approved or cleared later through the appropriate device submission process.

The FDA is seeking public input on the draft guidance for 60 days. Comments can be submitted online or in writing to: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

For more information:

Draft Guidance: In Vitro Companion Diagnostic Devices
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm262292.htm

FDA Basics Video: Alberto Gutierrez Interviewed on Diagnostic Tests and Personalized Medicine (video)
http://www.fda.gov/AboutFDA/Transparency/Basics/ucm195692.htm

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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