

FDA stresses need to modernize its science

October 6 2010, By MATTHEW PERRONE, AP Health Writer

(AP) -- The Food and Drug Administration must update its scientific tools for reviewing prescription drugs, medical devices and tracking food safety, according to a list of priorities laid out Wednesday by agency leadership.

An agency paper posted online says that improved scientific standards will help speed up the approval of important new products, while spotting safety problems sooner. FDA Commissioner Margaret Hamburg is expected to highlight the need to update the agency's methods in a speech at the National Press Club.

The FDA oversees the safety of nearly one-fourth of goods sold in the U.S., including processed foods, <u>prescription drugs</u>, <u>medical devices</u> and cosmetics.

The federal agency is looking to collaborate with outside universities on a host of projects, including efforts to predict the side effects of drugs based on the <u>genetic code</u> of individual patients, to reduce or eliminate drug testing on animals and to prevent the spread of salmonella and other bacteria in the <u>food supply</u>.

Modernization is a perennial theme for FDA leadership as the agency struggles to keep up with the evolving science behind the latest drugs, devices and even foods. Last month the agency held a three-day meeting on the safety of a genetically modified salmon that grows twice as fast as the naturally bred fish.



But federal funding for the agency traditionally has lagged behind the agency's budget requests, giving rise to a series of user fee programs in which drugmakers and medical device makers help pay for the agency's review of their products. If Republicans regain control of the House in November, the FDA's Obama-appointed leadership could face an even tougher time securing funding increases for the agency.

Hamburg, a former health commissioner for New York City, was nominated last year to bolster the agency's regulatory image after a string of food and <u>drug safety</u> scares under the previous administration. However, the recent recall of more than a half-billion eggs linked to salmonella has underscored the limits of the agency's powers.

"As in other areas, the effectiveness of FDA's food safety program depends on the strength and capacity of the science underlying it," the agency paper says.

In 2007, the agency's outside panel of science experts said the FDA was in danger of failing in its mission because of a lack of scientific expertise.

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