FDA chief takes show on the road
Crawford to hear consumer concerns

By Diedtra Henderson, Globe Staff | August 16, 2005

WASHINGTON -- The new head of the Food and Drug Administration will hit the road, Oprah-style.

To find out what is on the minds of American consumers, FDA commissioner Lester Crawford will walk through smallish audiences, fielding questions.

Crawford picked the talk show format for "Vision 2006" public hearings the agency will hold in Massachusetts, Arizona, and Florida. The hearings will be Crawford's highest-profile event since his Senate confirmation. The first will be held Sept. 13 in Miami, followed by a Nov. 2 hearing at the Boston Marriott, in Cambridge, and a Nov. 30 session in Phoenix, according to an eight-page notice published in today's Federal Register. People interested in attending may register at www.graduate.usda.gov/vision.

Suzanne Trevino, an FDA spokeswoman, said the sessions will not be idle chatter.

"This is an opportunity for Dr. Crawford to shape his leadership and set the tone that we are very interested in what consumers have to say and will be responsive to what they have to say," Trevino said.

Trevino said public comments will influence FDA actions as the regulatory agency celebrates its 100th anniversary in 2006. Each 10 a.m. to 4 p.m. session will include at least 150 people, with time devoted to such hot-button topics as drug advertising, conflicts of interest among federal advisers, and drug safety.

The events lift a page from the playbook of Dr. David A. Kessler, who held similar information exchanges with the public while serving as FDA commissioner from 1990 to 1997.

Such sessions can serve triple duty, said William Vodra, a former FDA associate chief counsel for drugs. They balance the sessions the FDA holds with the drug industry, give a chance to hear what a large number of consumers have on their minds, and make the agency's top leaders and scientists accessible.

"This is a consumer-protection agency," said Vodra, a partner at Arnold & Porter in Washington, D.C. "If the consumers think they've bagged out to industry, that's a very bad thing. They've got to be open and available."

This fall's meetings come as the FDA faces unprecedented scrutiny from Congress and the public, as well as criticism from the drug industry. Last fall's withdrawal of the painkiller Vioxx due to heart risks triggered congressional hearings and fueled calls for major changes at the FDA. To fend off congressionally mandated changes, the drug industry has initiated voluntary restrictions on advertising to consumers.

"The FDA needs to step in to not only vet these drugs for safety, but also make them not so susceptible to consumer whim," said Lori Ehrlich, 42, a certified public accountant who lives in Marblehead with her husband and two daughters.

Ehrlich said television ads for erectile dysfunction drugs prompted her 9- and 13-year-old daughters to ask "a lot of questions." The conversations that followed were age appropriate, but remained uncomfortable. And the episode piqued her curiosity. A quick family survey showed nine of 13 advertisements during the evening news were for pharmaceuticals.

"They're just so in-your-face now," Ehrlich said.

In addition to drug advertising qualms, the FDA expects drug safety concerns to be on consumer's minds.

Few consumers balance the risks and benefits of prescription drugs, said Alan Sager, a professor of health services at Boston University.
"Most of us listen to our doctors and do what our doctor says because our doctor has actually been to medical school," Sager said. "Most of us haven't the time, ability, or willingness to make these complicated trade-offs."

The FDA chose locations around the nation to gauge consumer interest that can vary by region. Cambridge has a high concentration of drug and medical device companies whose profits are affected by the speed of FDA drug approvals. Arizona and Florida have high numbers of elderly residents, who use more prescription drugs than younger consumers. Trevino said Florida was selected for the diversity of its aging population, and Arizona because many seniors travel to Mexico to buy inexpensive prescription drugs.

The FDA has warned that prescription drugs purchased in Canada or Mexico could be made in far-flung countries and could be unsafe.

But elderly residents also hear from doctors that they should take prescription drugs to improve or lengthen their lives.

"Half the time, it's bad advice. But that's what they hear," said Arthur Levin, director of the Center for Medical Consumers. "The question is what message are you going to hear louder?"

Those who can't afford life-saving drugs trek across the border, despite the FDA warnings, he said.

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