FDA may disclose more details on drug, food safety (Update)

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(AP) -- The nation's top drug regulator proposed Wednesday to disclose more information about safety problems with the drugs and devices it rejects.

The effort is part of a broader plan to remake the public image of the Food and Drug Administration, which has come under fire for being too secretive.

An agency taskforce is suggesting 21 ways the FDA could release more information to the public in areas like drug evaluation and in food manufacturing inspections, another area in which it has oversight responsibility.

Agency leaders stressed that the FDA is merely considering the changes and that some would require legal changes by Congress to implement.

The FDA has long operated under strict confidentiality rules because its scientists handle reams of proprietary information from food, drug and device companies.

However, that operating style has come under fire in recent years from critics who have charge that the agency is too slow to disclose drug safety issues.

The changes suggested in the 67-page report would mark an about-face from current policies that allow manufacturers to control most public

information about products in development.

Deputy Commissioner Dr. Joshua Sharfstein said greater transparency would benefit both consumers and companies, who will be able to learn from the success and failures of competitors.

"The more people see how the agency approaches this the more they'll understand the kind of data they need and the more rapid and efficient approvals could be," Sharfstein said during a call with reporters.

Problems with FDA transparency were highlighted in 2004 when the popular painkiller Vioxx was pulled from the market five years after its approval, because of links to heart attack and stroke. Critics said lives could have been saved if the agency had opened up more to outside researchers and health advocates.

Half of the new suggestions are designed to give more information about experimental drugs and devices under review at the agency. Under current FDA regulations, communication about such products is extremely limited. In the initial months of review FDA spokespersons will not even confirm the existence of a new drug application. Additionally, when the FDA declines to approve a treatment it allows the manufacturer that make the announcement - which usually comes in the most vague, unspecific terms possible.

Under the proposals posted online, the FDA would begin publishing rejection letters to drug and device manufacturers, including any safety concerns that led to the decision.

The Pharmaceutical Research and Manufacturers Association said Wednesday it is reviewing FDA's proposal and generally supports increased transparency.

But the group's Senior Vice President Ken Johnson added that FDA must "ensure that the competitive development process remains intact to serve patients and the public."

Other recommendations from the task force include:

- publishing inspection reports of drug and food manufacturing plants online

- publicizing criminal cases against companies regulated by the FDA

- putting more documents online to relieve a massive backlog of document requests

One of the agency's toughest critics questioned that last strategy, pointing out that the FDA would actually need more time and money to redact thousands of documents to be posted online.

"There are some important steps forward here, but you can talk about transparency from here to eternity and if you don't have an actual mechanism to make that data available it becomes less meaningful," said Dr. Sidney Wolfe, of the consumer advocacy group Public Citizen.

The FDA's task force will take comments on the recommendations for 60 days and then submit a final list of changes for implementation.