US looks to reboot nonprescription drug system

February 21 2014, by Matthew Perrone

The U.S. Food and Drug Administration is seeking to revamp its system for regulating hundreds of over-the-counter drugs, saying the decades-old process is not flexible enough to keep pace with modern medical developments.

In a federal posting Friday, the agency announced a two-day meeting next month to discuss overhauling the system known as the over-the-counter monograph.

The system was put in place in 1972 as a way to set dosing, labeling and other standards for hundreds of nonprescription drug ingredients, everything from aspirin to anti-bacterial hand scrubs.

But regulators acknowledged that the process has proven extremely time-consuming, requiring multiple rounds of scientific review, public hearings and comments before a final monograph can be published. As a result, many common pain relievers and cough medicines are still technically under review.

In its announcement, FDA regulators detail the numerous flaws of the current cumbersome system, including the inability to quickly add warning labels about emerging safety risks.

The monograph process was originally set in place by Congress in 1972 as a way for the FDA to review hundreds of nonprescription drugs that predated modern drug safety regulations. Initially a panel of FDA

experts went through the entire list of medications and determined whether they were "generally recognized as safe." These findings were published as "tentative" rules for various drug classes, though many have never moved beyond that phase.

The decade-spanning review process has increasingly come under fire from scientists, consumer groups and members of Congress.

Last year the FDA said for the first time that there was no evidence that common anti-bacterial soap cleansers, including triclosan, were more effective than regular soap. The agency issued that statement only after a three-year court battle with the Natural Resources Defense Council, an environmental group that sued the FDA to jumpstart its stalled review of the cleansers, which had been in regulatory limbo since 1978.

The FDA said Thursday it wants to design a new system that will "allow for innovative changes to drug products" and "provide FDA with the ability to respond promptly to emerging safety or effectiveness concerns."

But the leading industry group for nonprescription drugmakers says it supports the current monograph system.

"The system ensures consumers have access to a wide variety of safe and effective medicines, while at the same time providing FDA with access to important information on safety and quality," said Elizabeth Funderburk, spokeswoman for the Consumer Healthcare Products Association." We welcome the opportunity to provide input to FDA and hope they will use the input received to improve the rule making process to enable innovation and to update labeling in a timely manner."

The group represents companies like Johnson & Johnson, Bayer, Procter & Gamble and many others.