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US FDA should disclose more about site inspections, says taskforce

By Gareth Macdonald, 20-May-2010

Direct link to the News/Story:-

http://www.in-pharmatechnologist.com/Industry-Drivers/US-FDA-should-disclose-more-about-site-inspections-says-taskforce?utm_source=RSS_text_news

The US FDA should change its disclosure policy relating to manufacturing site inspections according to new draft recommendations by the Department of Health and Human Services (HHS) Transparency taskforce.

The proposal, part of a [list](#) published yesterday, calls for the agency disclose of the name, address and [drug](#) product made at facilities it inspects as well as any resulting recommendations and warning letters.

Currently the Food and Drug Administration (FDA) only “*posts inspection reports (Form 483s and EIRs) when a high level of public interest is anticipated*” or those that are “*frequently requested.*”

The [Taskforce](#) also advises that the [FDA](#) starts routinely publishing details of drugs and device review applications, including when such submissions are withdrawn or placed on hold.

The group, which was set up at the behest of the Obama administration, also recommends that the FDA publishes the findings of investigations of institutional review boards (IRB) overseeing clinical trials.

Recall powers and IRB

The Taskforce also want the FDA to play more of a role in communicating the information it receives from [pharmaceutical](#) companies when the initiate product recalls.

They explained that currently “[*the*] FDA does not have mandatory recall authority, except under limited circumstances, but a firm may initiate a recall at any time.

“*FDA issues a written notification that a recall is terminated to the recalling firm, but does not notify the public when a recall has been terminated.*”

Instead the group suggests that: “When a system is set up that provides FDA with authority to require companies to submit certain information to the Agency when they initiate [a recall, the agency] should disclose this information as soon as practicable.”

The group, which was set up at the behest of the Obama administration, also recommends that the FDA publishes the findings of investigations of institutional review boards (IRB) overseeing clinical trials.

Taskforce chair Joshua M. Sharfstein, said: “*We invite public comment on these draft proposals, including input on whether we have struck the right balance between disclosure and confidentiality in support of public health. Because FDA cannot implement all of the proposals at once, we are asking for input on how to prioritize.*”