

Abbott

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Docket No. 05D-0062
Draft Guidance for Industry, FDA's "Drug Watch" for Emerging Safety
Information**

Abbott Laboratories (Abbott) offers the following comments on the draft Guidance for Industry, The Food and Drug Administration's "Drug Watch" for Emerging Drug Safety Information, published in the Federal Register on May 10, 2005

Abbott supports the FDA's efforts to disseminate important emerging information regarding the safety of marketed drugs to healthcare professionals and patients via a special section on the Agency's website called the "Drug Watch." The Drug Watch can serve as an invaluable source of information about emerging safety concerns. However, it is critical that the FDA convey important drug safety information, even if preliminary, in the context of a medication's benefits and the potential for harm if serious conditions are not treated. Therefore, the following topics should be addressed prior to finalizing the Guidance and the terminology, standards, and content of the Guidance and the accompanying Questions and Answers should be consistent.

- Line 92 states, "Posting this information on the website will alert patients and healthcare professionals to potential safety risks...". We respectfully submit that posting information to the Internet is a passive communication channel that does not communicate a message unless users actively solicit the information by accessing the Drug Watch. Healthcare providers and patients must access the Drug Watch to be better informed and there is no guarantee that they will do so routinely. Only those persons accessing the website will be exposed to the information versus communicating the information to a wider audience in an active and consistent manner. Therefore, in addition to posting information to the Drug Watch, FDA should utilize alternative active communication channels to publicize Drug Watch postings and updates (e.g. mass Emails, press releases, news conferences, mailings, etc.). In addition, the Agency should operate a communication center to field questions regarding postings, as it is reasonable that the public and providers will expect answers from the source of the information directly.

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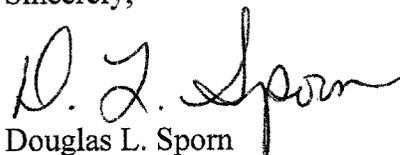
- The quality of the information to be posted is described as “the most up-to-date information possible on emerging safety issues to the public, even before FDA fully determines the significance of that information.” The posting of unevaluated and unvalidated information for the purposes of medical decision-making is a disservice to the healthcare community unless it is placed in the context of the risk/benefit profile of the product. Unsubstantiated safety information presented in isolation is of little use and may cause harm. Therefore, along with the preliminary safety information being posted, we suggest that the Drug Watch posting also include the benefits of continued use of the product, the risks from discontinuing the medication, and alternative treatments that may be considered, to place the safety concern in context.
- The timing of the information to be posted is described as “the most-up-to-date.” The value of quickly posting information when the significance of the information has yet to be determined may negatively impact the public health by driving patients to discontinue treatments and prescribers to switch medications prematurely. Therefore, it is important that the Drug Watch advise patients and practitioners what to do while FDA continues its evaluation. For example, patients could be advised, “Do not discontinue your medication and contact your physician to determine what is best for you.” Prescribers could be cautioned to, “Balance the safety concerns against the drug’s benefits when judging the needs of the individual patient.”
- The types of information to be posted to the Drug Watch should be clarified. Section III. A. *What information will be posted?* appears to distinguish only two categories of information rather than three: (1) emerging safety information, the significance of which has not been determined and for which a causal relationship has not been established, and (2) information about serious events that are deemed associated with the use of the drug and for which conclusions have been drawn. We suggest that the Drug Watch focus on the former, emerging safety concerns, during the period of uncertainty while FDA and sponsors evaluate emerging safety signals. And that MedWatch continues to be used to convey information about drug risks that are known with greater certainty. So that when an emerging signal is reasonably found to be associated with a drug and recommendations can be made to alter the product’s use, it should move from the Drug Watch to MedWatch.
- The criteria for posting drugs to and removing drugs from the Drug Watch should be clear. It is important that the Agency’s criteria for posting be elucidated in order for consistent decisions to be made and understood by healthcare community. Some posting factors to consider include:
 - Seriousness of the event – Will Drug Watch only include events that meet the regulatory definition of “serious” (21 CFR 314.80[a]) versus those that are clinically/medically serious? Could nonserious events be included?
 - Frequency of the event – Is the signal being seen more frequently in a labeled population or for the first time in a different population? How many cases will trigger a posting?

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- Measures taken to mitigate risk – Does this factor into posting a product on Drug Watch? As a signal is emerging, it will not be clear what, if any, actions can be taken to mitigate the risk. What if no clear actions that can be taken?
- Plausibility – Will pharmacologic activity, biologic plausibility, or class membership play a role in posting?
- The process by which postings are updated should be described. The Agency should establish a period in which to make a decision (e.g. no more than 6 months), so that the status of a safety concern is not left undetermined. If no definitive data emerges within a given period (e.g. no more than 1 year), the drug should be removed from the list.
- Sponsors should be advised by the FDA when the Agency has initiated its analysis of a safety concern with the potential to be posted to the Drug Watch, and given reasonable time (e.g. 5 working days) to provide any additional information to the FDA. In addition, sponsors should be notified that information about its drug will be placed on the Drug Watch at least 48 hours before the first posting and again at least 48 hours prior to each update that is made to the website. Twenty-four (24) hours is not sufficient time for sponsors to be prepared to respond to inquiries from providers and patients in response to Drug Watch postings.
- Information posted to Drug Watch that is deemed preliminary/emerging will not appear in the product's labeling. Therefore, there will be inconsistencies between what appears on the Drug Watch versus the information contained in the Investigator's Brochure, package insert, and patient package insert, as applicable. This has the potential for creating confusion between the information provided by pharmaceutical manufacturers to the healthcare community and in advertising and the information provided by the FDA. Hence, a disclaimer is needed on Drug Watch acknowledging this discrepancy.
- Given the preliminary nature of the information that may be posted to the Drug Watch, we recommend that the Guidance and the website include a statement reflecting that the posting of information to the Drug Watch does not reflect a conclusion by the FDA or the sponsor that the product caused or contributed to an adverse event.

Should you have any questions, please contact Ms. Lauren Hetrick, Senior Director, Regulatory Intelligence/FDA Liaison Office at (301) 255-0080.

Sincerely,


Douglas L. Sporn
Divisional Vice President