

December 22, 2008

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

**Re: Docket No. FDA-2008-N-0546, Electronic Data Collection Using MedWatch<sup>Plus</sup>  
Portal and Rational Questionnaire**

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the notice on electronic data collection using MedWatch<sup>Plus</sup> Portal and Rational Questionnaire. For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students.

ASHP commends FDA for implementing electronic data collection to improve adverse event reporting, and the Society believes the new format will greatly improve the agency's ability to utilize adverse event, product problem/consumer complaints, and medication use error reports submitted to FDA. ASHP encourages the agency to initiate a public education campaign to ensure potential users are aware of the new system, and use the system correctly, particularly those users who did not previously have access to or knowledge of the system. The Society would be pleased to assist FDA in these education efforts.

When implementing the new Web portal, FDA should ensure that the new system is interoperable with software that institutions currently use to document suspected adverse drug events internally, so both the institutions' internal systems and the Web-based portal are interoperable. FDA should also consider incorporating the Naranjo scale into the Rational Questionnaire.<sup>1</sup>

ASHP encourages FDA to provide an advanced method of submitting information to MedWatch, in addition to the Rational Questionnaire, that would allow individuals

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<sup>1</sup> Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA, Janecek E, Domecq C, Greenblatt DJ. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther. 1981 Aug;30(2):239-45. PMID: 7249508.

familiar with the system to more quickly and efficiently input the information. This process could be included with a physician or hospital's electronic medical record to more accurately complete and automate the data fields required for submission. The FDA may wish to consider developing a pilot project with electronic medical record software vendors to assess the functionality, determine the impact on the practitioner's time to complete the submission, and ensure interoperability utilizing HL7 or other appropriate standards.

The Society recommends that FDA continue to allow the submission of adverse event reports via paper. Most pharmacies permit Internet access on workstation computers, but some pharmacies restrict access. Additionally, in some rural facilities, information technology is limited or entirely absent. In order to ensure complete adverse event and medication use error report information is submitted to FDA, ASHP encourages the agency to ensure the option of submitting via paper continues once the portal is operational.

ASHP also encourages FDA to enable the system to document who (e.g., pharmacist, physician, patient) submits the information, since the type of submitter provides a good indication of the accuracy of and reasons behind the information provided.

Finally, ASHP encourages FDA to utilize standards (e.g. RxNorm, SNOMED-CT, or other nomenclature standards deemed appropriate by FDA), and allocate resources to codify the free text contained in the responses that are submitted through the portal.

The Society appreciates this opportunity to present its written comments on the notice. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at [jcoffey@ashp.org](mailto:jcoffey@ashp.org).

Sincerely,

A handwritten signature in cursive script that reads "Justine Coffey". The signature is written in black ink and is positioned below the word "Sincerely,".

Justine Coffey, JD, LLM  
Director, Federal Regulatory Affairs