



December 20, 2005

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

Re: Docket 2005N-0394

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments to the Food and Drug Administration (FDA) on the Center for Drug Evaluation and Research's (CDER) current risk communication strategies for human drugs. As indicated in the Federal Register, this effort is to obtain public input on CDER's current risk communication tools and obtain greater understanding of the strengths and weaknesses of CDER's existing risk communication.

The Academy of Managed Care Pharmacy (AMCP) is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's 4,800 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

AMCP makes regular use of various FDA forms of communication to both educate internal staff on medication related announcements and to distribute information to the Academy membership. Therefore, AMCP comments focus on the effectiveness of FDA communications for health care professionals working to achieve positive patient outcomes.

FDA talk papers and news releases are regularly quoted or linked to in AMCP publications and have been posted on the AMCP website. The talk papers and news releases are written clearly and concisely and provide the appropriate information necessary for health care professionals to act on behalf of their patients. Appropriate amounts of information are provided on recent studies and the implications for patients. The information is provided in a manner that a health care professional can read and understand quickly and communicate to patients.

However, the structure of the FDA website, and the CDER information contained thereon, makes it difficult for a user to locate information once it is removed from the homepage. The Academy recommends that the FDA revamp the site to address this serious problem. Although a large quantity of quality information is

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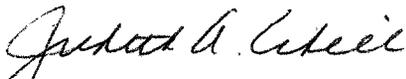
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contained on the website, the information is not easy to locate. Information contained on the CDER homepage is very accessible. Finding information no longer posted on the homepage is routinely difficult for health care practitioners to locate. For example, the most recent talk paper in the FDA News Release Archives is the FDA Talk Paper "FDA Awards Contracts on Databases of Adverse Effects of Marketed Drugs Ability to Monitor Approved Drugs Enhanced." This talk paper contains information that AMCP tried to locate on the FDA website while drafting comments for public testimony in November. Unaware that the information could be found in a talk paper, staff found it necessary to go to the web search engine Google to locate the information.

The Academy also recommends that FDA better promote the availability of various listservs for health care professionals. Both the MedWatch listserv and CDER daily and weekly updates can provide valuable information; however, many health care professionals learn of FDA announcements by relying on secondary sources like newsletter subscriptions because they are unaware of the listserv opportunities.

AMCP appreciates the opportunity to comment on this extremely important issue. If you have any questions, please contact Judith A. Cahill, AMCP Executive Director, at (703) 683-8416 or at jcahill@amcp.org.

Sincerely,


Judith A. Cahill
Executive Director