DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Redactions made by FDA

The Honorable Charles E. Grassley
Chairman
Committee on Finance
United States Senate
Washington, D.C. 20510-6200

OCT 20 2005

Dear Mr. Chairman:

Thank you for the letter of August 24, 2005, a follow-up to our July 20, 2005, correspondence to you providing information pertaining to the Food and Drug Administration's (FDA or the Agency) regulatory actions concerning Viagra (sildenafil) and non-arteritic anterior ischemic optic neuropathy (NAION), a condition related to low blood flow to the eye.

This response includes trade secret, commercial confidential or other privileged information protected from disclosure to the public under the Freedom of Information Act (Title 5, United States Code [U.S.C.] section 552), the Trade Secrets Act (18 U.S.C. section 1905), and FDA regulations. The Committee should not publish or otherwise make public such information. We would be glad to discuss with the Committee staff the protected status of any specific information.

In your August letter, you expressed concern that our methods of communicating the information regarding the small number of men that have lost eyesight in one eye after taking an erectile dysfunction drug should be improved to better inform the consumer. The Agency acknowledges that we are unable to reach every consumer who uses a product that FDA regulates, and unfortunately, we do not have the resources for this type of intensive patient education. As Viagra, Cialis, and Levitra are all prescription drug products, the Agency relies a great deal on the health care providers who prescribe these products, manage and oversee the care of their patients, to discuss the risks and benefits of the products before deciding whether the patient is an appropriate candidate to use an erectile dysfunction drug.

However, in addition to the posting of the Patient Information and Healthcare Practitioner Sheets for each drug to our website, there were several other communication tools that were utilized in regard to the July 8, 2005, update to the labeling of the three marketed erectile dysfunction drugs. Although perhaps it was not made clear in our last communication, a revised Patient Package Insert also was approved on that date. This information, written specifically for the patient, includes information on the potential sudden loss of vision. In addition, Pfizer sent a "Dear Health Care Practitioner" letter to all physicians that prescribed Viagra at least once in the last year and to ophthalmologists, regardless if they had prescribed or not.

As we mentioned in our July 20, 2005, communication, the Agency disseminated the safety information by FDA's MedWatch program via the E-list notification system, which includes over 50,000 individual subscribers and 170 partner organizations. As a brief background, there are over 170 organizations - health care professional groups and specialty societies representing doctors, nurses, and pharmacists, hospital and managed care organizations, retail and wholesale pharmacy organizations, public health agencies, and consumer groups now participating in the MedWatch Partners program. Partner groups work with FDA to spread the message about reporting, often provide links from their websites to the MedWatch site, and receive notification of all safety updates, public health advisories, and recalls; this information may be shared with their members through newsletter, on their websites, and by their own e-mail distribution lists. In essence, they are the amplifiers of FDA's message. As an example of the risk communication activities concerning the information specific to the erectile dysfunction drugs, one of our partners, *Medscape* from *WebMD,* posted the information pertaining to reports of sudden vision loss to the home pages of many of their specialty pages, including ophthalmology and urology. These sites have a total membership of roughly (b)(4) physicians and (b)(4) nurses. About (b)(4) of *Medscape* members use their homepages to access *Medscape* and the others use their weekly e-newsletters (*Medpulses*). *Medscape* informed us that the link containing the updated safety information went out to at least (b)(4) physicians and as many nurses through the *Medpulses* and also was exposed to about (b)(4) health professionals on the specialty home pages. In addition to exposure on the home pages and *Medpulses,* the link was featured in the *Drug and Device Digest* e-mail, which is sent to approximately (b)(4) physicians each month. It was also published in their Erectile Dysfunction Resource Center.

To further increase the public's awareness of this potential safety issue, many media outlets also participate on our listserv and are recipients of FDA MedWatch alerts. FDA provided information or interviews to both local and National media outlets, including CBS Radio, National Public Radio, The Wall Street Journal, The Urology Times (a widely distributed trade journal), American Association of Retired Person's magazine, and a magazine entitled, *Family Doctor: The Magazine That Makes Housecalls*. In addition, FDA did a story on the revised labeling for the three drugs on its Patient Safety News, a monthly video news program for health professionals. Patient Safety News is shown through four different satellite education networks (e.g., Health Sciences Television Network). We estimate that we reach about 2,500 mostly large and academic hospitals through these networks. FDA also distributes the program directly to our 350 MedSun hospitals. However, our primary distribution vehicle is through our dedicated Patient Safety News website, *http://www.fda.gov/psn*. We receive about 5,000 hits to this website each month. From the website, users can read the program, watch the whole show, or watch or download a story. The Agency also maintain a dedicated email listserv - people sign-up for this and each month they receive a notice describing the stories in the current program. This list is very active – we currently have about 4,000 members and approximately 125 new members are added each month.

Further efforts to reach the patient directly to make them aware of safety concerns associated with the erectile dysfunction drugs are being accomplished through (b)(4) (b)(4) (b)(4) At present, there are no television or radio ads being broadcast for Viagra, (b)(4) (b)(4)

[redacted] The consumer and professional aspects of the *Levitra.com* website have been updated to include the safety information regarding NAION and although there are currently no Levitra print ads in use, [redacted] At present, there are no television or radio ads being broadcast for Levitra. [redacted]

In addition, FDA scientists who are collaborating on the NAION issue plan to submit an article on the subject to a peer-reviewed journal. The Agency anticipates that such an article will further enhance the awareness of health care providers.

Although we have outlined several methods that have been undertaken to communicate this potential safety issue associated with the erectile dysfunction drugs, FDA also acknowledges that there is more that we could do to facilitate the communication of information concerning drug products to both patients and health care providers. On October 3, 2005, the Agency announced our intent to hold a two-day public hearing in December to obtain public input on the Center for Drug Evaluation and Research's (CDER) drug risk communication tools, identify stakeholders for collaboration and implementation of additional tools and obtain understanding of the strengths and weaknesses of CDER's existing drug risk communication. The Agency believes it is critical that drug risk communication be timely, accurate, and easily accessible, and it must recognize health literacy limitations and include the needs of a multicultural population. The input that FDA receives will help us learn which tools are effective and how our risk communication efforts can be improved.

Finally, FDA appreciates and agrees with your concern regarding the delay in negotiating a revised label with the three companies who market the erectile dysfunction drugs. CDER's Office of New Drugs works in close collaboration with the Office of Drug Safety to evaluate post-marketing adverse events and initiates regulatory action when warranted and this was the procedure that was followed for the revision of the label of the three erectile dysfunction drugs. Additional steps have been implemented to focus on new and better ways to perform our mission of protecting and advancing the public health in the form of a major initiative intended to improve our ability to monitor and respond to emerging drug safety information. These steps will ensure both a better internal process of deliberation on drug safety issues that ensures appropriate and independent consideration of all issues, as well as a stronger ability to gather data about drug safety issues once a drug has been approved. Most importantly, FDA is moving to encourage more transparency and to ensure that patients and physicians have the most up-to-date and complete information necessary to inform their treatment decisions. This new Drug Information Initiative will give patients, health care professionals, and other consumers quick and easy access to the most up-to-date and accurate information on medicines and make FDA's drug review, approval, and monitoring programs as transparent a possible.

Thank you again for contacting us concerning this matter. If there are further questions, please let us know.

Sincerely,

Patrick Ronan

Patrick Ronan
Associate Commissioner
for Legislation