

Alan Goldhammer, PhD

Associate Vice President,
US Regulatory Affairs



December 6, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20857

Re: Docket No. 2006N-0464; Electronic Submission of Regulatory Information, and Creating an Electronic Platform for Enhanced Information Management; Public Hearing; 71 Federal Register 67356

Dear Sir/Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) requests time to present at the above-cited Part 15 meeting. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated \$39.4 billion in 2005 in discovering and developing new medicines. Industry-wide research and investment reached a record \$51.3 billion in 2005.

Two individuals from PhRMA's Electronic Regulatory Submission (ERS) Technical Group will be presenting on behalf of PhRMA. They are:

Ed Tripp
Program Director, eSubmissions
Abbott Laboratories
Dept. 03QD, Bldg. AP6C-1
100 Abbott Park Road
Abbott Park, IL 60064-6091
Phone: (847) 937-2021

Bill Rosen
Executive Director, eHealth Policy and Standards
Pfizer Global Research and Development
50 Pequot Avenue
New London, CT 06320
Phone: (860) 732-9244

PhRMA requests one hour for this presentation.

PhRMA and its member companies have been actively working with FDA and various standards organizations to further the technology and infrastructure that will facilitate electronic submissions. We are in the process of finalizing our presentation and have contacted Paula

Pharmaceutical Research and Manufacturers of America

950 F Street, NW, Washington, DC 20004 • Tel: 202-835-3533 • FAX: 202-715-7090 • E-Mail: agoldhammer@phrma.org

FDA Docket Management Branch
12/6/2006
Page 2

McKeever regarding the submission of the presentation in both electronic and paper format. PhRMA will provide the Agency with electronic and paper copies of the presentation on Monday, December 11.

Please do not hesitate to contact me if there are any questions on this request.

Sincerely,

A handwritten signature in cursive script, appearing to read "Alan Goldhammer".

Cc: Ms. McKeever (FDA), Mr. Rosen (Pfizer), Mr. Tripp (Abbott)