PhRMA

January 11, 2011

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. FDA–2010–D–0319 Draft Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information; Availability; 75 Fed. Reg. 69449 (November 12, 2010)

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to provide comments to the above noted docket intended to improve the quality of Dear Health Care Provider (DHCP) Letters. The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $45.8 billion in 2009 in discovering and developing new medicines. Industry-wide research and investment reached a record $65.3 billion in 2009.

PhRMA appreciates and applauds FDA's efforts to make DHCP Letters more effective communication tools for new information about medicines. We recommend the following improvements to the draft guidance:

- In section III, FDA recommends that companies are encouraged to "consult with the appropriate review division in the development of a DHCP letter to ensure that the letter clearly and accurately reflects both the manufacturer's and FDA's understanding of the issue and the action required to address the issue." PhRMA is concerned that in some instances, waiting for input from the review division might slow down provision of important safety information to healthcare professionals. PhRMA recommends that FDA work to ensure that review divisions provide timely input into emergent DHCP letters, such as a 24 hour response period, so as not to delay providing important safety information to healthcare professionals.

- In section IV, FDA lists several reasons a company may want to communicate using a DHCP letter, including to provide new warnings, new prescribing information, or corrective information. FDA should acknowledge that companies might provide other important information to healthcare professionals for reasons other than the three mentioned in the guidance.

- In section V.A., FDA recommends that DHCP letters not exceed two pages. PhRMA is concerned that a two page limit may not be adequate in all cases to capture critical safety and effectiveness information that may be necessary for

appropriate use of certain medicines. We recommend that FDA acknowledge that in some cases, additional length may be necessary to convey important information.

- PhRMA encourages FDA to consider the inclusion of the following additional content under Section V:
    - Product availability either by Rx or also OTC
    - Other names of the product
    - Other treatment options, if the drug is withdrawn, or suggestion to contact a healthcare professional regarding alternative treatments
    - Pertinent timelines by which actions should occur (*e.g.* how quickly changes need to be addressed, how long the medicine will remain available, how soon patients should see a healthcare professional)

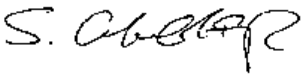
- In section VI, FDA recommends that companies "conduct an evaluation of the extent to which the target audience received the DHCP letter and is aware of the information that was communicated in the letter." We are concerned that asking for evaluations of DHCP letters would unnecessarily increase the number of correspondence regarding the letters and dilute the impact of the important information in the letters themselves. In addition, such a request appears to exceed FDA's statutory authority. We request that FDA reconsider this recommendation and instead perform a more systematic evaluation of the effectiveness the communication medium.

- Lastly, this draft guidance is heavily weighted toward communicating new information to health care practitioners in written form via the U.S. mail. Yet research has shown that mailings may not be the most efficient form in which to convey important safety messages to healthcare professionals. It would be beneficial if this guidance would acknowledge additional ways to communicate with healthcare professionals, such as through emails or password protected websites for health care providers. FDA should provide guidance regarding how these media may be used in a way that complies with applicable regulations.

PhRMA appreciates the opportunity to provide comments to FDA; we hope our comments will be useful to the agency in the development of Guidance for Dear Health Care Provider Letters.

If you have any questions, please do not hesitate to contact us.

Respectfully submitted,



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