



**sanofi aventis**

Because health matters

11 January 2011

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

Re: Docket No. FDA-2010-D-0319

**Comment Collection: Draft Guidance for Industry and Staff: Dear Health Care Provider Letters: Improving Communication of Important Safety Information**

Dear Sir/Madam:

Reference is made to the Federal Register notice of 12 November 2010 (75 FR 69449), announcing a request for comments on the **Draft Guidance for Industry and Staff: Dear Health Care Provider Letters: Improving Communication of Important Safety Information**

Sanofi-aventis U.S. Inc, a member of the sanofi-aventis Group, appreciates the opportunity to comment on this draft guidance, and offers the following comments:

**GENERAL COMMENTS**

Sanofi-aventis applauds the FDA for issuing this draft guidance and appreciates the Agency's effort to bring clarity and consistency to the content, format, and rationale for issuing Dear Health Care Provider (DHCP) Letters, as well as its openness to sponsor consultations in the development of these important communications to health care providers.

**SPECIFIC COMMENTS**

Reference text: Lines 66-81

Regarding the section titled, "FDA CONSULTATION ON DEVELOPMENT OF DHCP LETTERS," sanofi-aventis believes it would be helpful for this section to specify how the recommended consultations should be requested. Given the serious nature of the issues communicated in DHCP letters, a consistent and formal method for requesting and obtaining consultations would be appropriate as opposed to more informal approaches such as telephone and e-mail requests. Otherwise, there is a risk that such interactions will not be given the prompt attention that they warrant.

Reference text: Lines 323-324 and 351

Among the information suggested for inclusion in the interior paragraphs of a DHCP letter, the draft guidance includes the following: "Discussion of additional research being done to better understand an adverse reaction." However, the draft guidance subsequently (Line 351) lists "A sponsor's plans to further investigate the problem" as a type of information that should generally not be included in a DHCP letter. Sanofi-aventis requests that this apparent

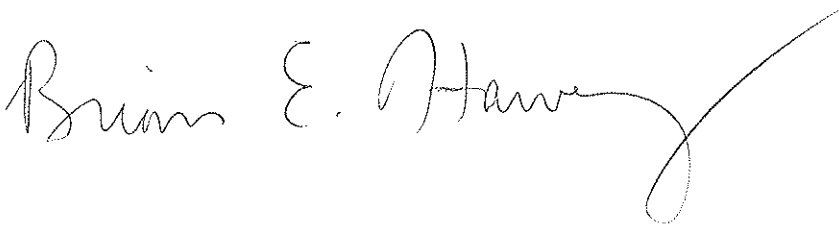
contradiction be clarified in the final guidance. Sanofi-aventis agrees that information regarding additional research to better understand an adverse reaction would be helpful in understanding the issue addressed by a DHCP letter, and we are concerned that Line 351 (“A sponsor’s plans to further investigate the problem”) could be interpreted in such a way as to exclude such information.

Reference text: Lines 374-380

The final section of the draft guidance recommends that sponsors monitor the extent to which the target audience received the letter and is aware of the information therein. The draft guidance also recommends that for letters that are intended to modify behavior in the target audience, ideally there would also be an evaluation of the extent to which the DHCP letter changed behavior in the manner described in the letter. While sanofi-aventis agrees that a sponsor should maintain a record of the recipients of a DHCP letter, and monitor those recipients who access the letter when it is sent electronically, via e-mail, we do not agree that it is the responsibility of a sponsor to obtain feedback on the effect of the letter in changing prescriber behavior. Since a sponsor is responsible for communicating product information that is consistent with FDA-approved labeling, and does not engage or interfere in the practice of medicine, a sponsor should not be held responsible for monitoring whether health care professionals have changed their behavior as a result of a DHCP letter. It is doubtful whether a sponsor would be able to accurately evaluate detailed changes in prescriber behavior since health care professionals may be reluctant to disclose this information because of potential liability. Moreover, it is unrealistic to believe that a sponsor could compel them to provide this information.

Sanofi-aventis appreciates the opportunity to provide feedback and hopes the comments provided are useful in the finalization of this draft guidance.

Sincerely,

A handwritten signature in black ink, reading "Brian E. Harvey". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

*Brian E. Harvey, M.D., Ph.D.*  
*Vice President*  
*U.S. Regulatory Policy*