Boehringer Ingelheim

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

Boehringer Ingelheim
Pharmaceuticals Inc.

Docket Number 2010-D-0319 Draft Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information

December 20, 2010

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Dear Sir or Madam,

Boehringer Ingelheim Pharmaceuticals, Inc. is submitting comments on the **Draft Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information** as per the notice published in the Federal Register on 12-Nov-2010 (Vol. 75, No. 218).

Attached please find our tabulated comments which reference the corresponding line number of the draft guidance.

We wish to thank FDA for the opportunity to comment on the **Draft Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information.**

Sincerely,

for Joanne Palmisano, MD, FACP
Vice President, Drug Regulatory Affairs

Boehringer Ingelheim

1. **Draft Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information (2010-D-0319)**

Line number(s) of the relevant text ***(e.g. Lines 20-23)***	Comment and rationale; proposed changes
19-20	The first sentence of the guidance states that it "provides recommendations to industry and FDA Staff on the content and format of DHCP Letters". There also exists a CDER M.A.P.P. (NDAs: "Dear Health Care Professional" Letters) which addresses the policies and procedures CDER must follow in reviewing draft and final DHCP letters. Is the new guidance intended to replace or be an additional reference for FDA staff?
190-192	We agree with and support the inclusion of a statement in the heading or text of the letter that indicates that FDA has reviewed and agrees with the contents of the letter.
196-207	Regarding the dissemination of a DHCP letter to those who are "likely to administer" the drug and "others who would have a need to know the information", these could be quite broad large groups and thus clarity is requested regarding exactly how this would be determined and who this would be in certain settings. What is the expectation for how far to reach within these groups? Is it expected that a letter be specifically targeted to caregivers such as nurses and/or parents if they are assessed as "likely to administer" or "those who have a need to know"? Or, would distribution of a letter to a hospital or other healthcare institution with instructions to distribute to specific staff be adequate? Is there an expectation that DHCP letters be sent out to home caregivers? To alleviate some ambiguity, we believe the distribution should use reasonable calculation and justification, with certain audience targets considered on a case-by-case basis. This can be reviewed with FDA prior to distribution.
323 and 351	The bulleted descriptions of *The Interior Paragraphs* of the letter and the *Types of Information That Should Generally Not Be in a DHCP Letter* seem to include some contradictory information. Line 323 states that "discussion of additional research being done to better understand an adverse reaction" be included in the interior paragraph of the letter while line 351 states that "a sponsor's plans to further investigate the problem" should not be included in the letter. If these points are intended to describe different things, please clarify this.

Line number(s) of the relevant text ***(e.g. Lines 20-23)***	Comment and rationale; proposed changes
376-380	Tracking the delivery of a DHCP letter to ensure receipt is a reasonable expectation, however, it is unrealistic to expect that sponsors evaluate the extent to which the DHCP letter has modified individual behaviors. Since most DHCP letters are sent to a large number of HCPs, the feasibility of assessing modification of individual behaviours is not practical nor likely to provide accurate data