Sunovion Pharmaceuticals Inc.
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January 7, 2011

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

Re: Draft Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information [Docket No. FDA–2010–D–0319]

Dear Sir or Madam:

The following comments are submitted on behalf of Sunovion Pharmaceuticals Inc. (Sunovion), formerly Sepracor Inc., a wholly-owned U.S. subsidiary of Dainippon Sumitomo Pharma Co., Ltd. Sunovion is dedicated to discovering, developing and commercializing scientifically advanced therapeutic products that are focused on helping patients suffering from central nervous system and respiratory disorders, as well as other illnesses.

Sunovion supports the Food and Drug Administration's (FDA) undertaking to provide recommendations to industry and FDA staff on the content and format of Dear Health Care Provider Letters in order to effectively communicate this important information to health care providers. We thank you for the opportunity to comment on this draft guidance. If you have questions regarding these comments, please contact me at 508-357-7628 or patricia.johnson@sunovion.com.

Sincerely,

Patricia M. Johnson

Director, Regulatory Compliance

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General Comments

1. We request that FDA provide additional guidance regarding the process for Division Review/Consult or coordination as well as any impact on existing FDA MAPPs, specifically MAPP 6020.10 (eff. 07/02/03) entitled "NDAs: Dear Health Care Professional Letters".

Specific Comments

Section I. Introduction

2. Lines 24-26: "...These recommendations are also intended to apply to DHCP letters distributed by electronic means (e.g. email) to the extent practical for the type of electronic communication used."

   Comment: It would be helpful if the FDA were to note in the final guidance those instances in which they believe a recommendation they have made for a letter would not be "practical" for an electronic communication, and what their recommendation would be instead for the electronic communication.

Section II Background

3. Lines 44-46: "...FDA regulations describe the process for mailing important new information about drug products (21 CFR 200.5), but do not provide criteria for the format and content of the actual letter."

   Comment: Although 21 CFR does not provide details concerning the format and content of the DHCP letter, we note that very specific details, inclusive of font size and color, for the three types of DHCP letter envelopes are provided. To maintain consistency with 21 CFR 200.5 and across the industry concerning such correspondence, we recommend that similar formatting descriptions be included in section V. Content and Format of DHCP Letters of this draft guidance.

Section III FDA Consultation on Development of [DHCP] Letters

4. Lines 75-81: "Therefore, FDA encourages manufacturers 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. In addition to providing a broader range of input into the content of the letter, such consultation could potentially avoid the need to send a corrective letter in the event that FDA determines, after a DHCP letter has been sent, that the content of the letter was somehow false or misleading."

   Comment a: Please elaborate on the Agency's proposal provided in this section of the draft guidance which encourages manufacturers to consult with the appropriate review division concerning development of a DHCP letter. We note the availability of FDA MAPP 6020.10

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entitled "NDAs: Dear Health Care Professional Letters" (effective date 07/02/03). This MAPP describes the Agency's responsibilities and procedures for two scenarios: 1) when FDA requests that applicants distribute a DHCP Letter; and 2) when FDA does not review a DHCP Letter before it is mailed. The MAPP, however, does not currently describe a procedure that is specific to manufacturers initiating a request for review of a DHCP letter.

Comment b: Time frames for review and comment are not provided. Will time frames differ by type of letter, or by initiator (FDA vs. manufacturer)?

Section IV When to Use a DHCP Letter/Which Types of DHCP Letter to Use

Important Drug Warning Letter

5. Lines 101-103: "...This type of DHCP letter should be used for information that is to be incorporated into one or more of the following labeling sections: BOXED WARNINGS, CONTRAINDICATIONS, or WARNINGS AND PRECAUTIONS."

Comment: We request that the final guidance clarify that not all changes to WARNINGS AND PRECAUTIONS would require a DHCP letter.

Important Prescribing Information Letter

6. Lines 117-121 "Important Prescribing Information DHCP letters should be used to convey important changes to the prescribing information other than those changes that should be described in an Important Drug Warning letter (section IV.A)."

Comment: We request that FDA provide guidance on which type of letter to use in the event that the content includes elements in more than one category (e.g., a modification to the indications and usage as a result of new safety information that concerns a significant hazard to health).

Section V Content and Format of DHCP Letters

The Interior Paragraphs

7. Line 322: "Whether an event is common to a drug class."

Comment: We recommend deleting this bullet as it has the potential to undermine the importance of the information in the DHCP letter. It also seems to contradict the spirit of lines 220-222 which discourage imprecise terms used to characterize the incidence of a reaction.

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8. Line 325: "Why a promotional claim was false or misleading"

Comment: This line appears to be redundant given it appears in ***section V.A.4.b The Body of the Letter – Correction of Drug information Letters***, line 300 "The information that is false or misleading and why it is incorrect". We believe this statement is best retained in section V.A.4.b and should be removed from section V.A.5.

Types of Information That Should Generally Not Be in a DHCP Letter

9. Line 352: " Promotional language or claims"

Comment: We recommend that this statement include brand logos such that it would read "Promotional language, claims or brand logos". Brand logos may at times include promotional messages that may also be a distraction from the important information disseminated in a DHCP letter.

Format Recommendations

10. Line 366 "Upper and lower case letters (e.g. avoid all caps)"

Comment: This recommendation appears inconsistent with guidance provided in section V. A.1 Letter Heading, lines 187-190 which state "The letter heading should repeat whichever statement appears on the envelope in the same format (a smaller font may be used, as needed). For a DHCP letter distributed electronically, the letter heading should be the statement that would have appeared on the envelope if paper distribution had been used."