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June 3, 2015

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

Re: Comments on FDA Draft Guidance for Industry on Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Prescription Drug User Fee Act Products. 80 *Fed. Reg*. 12822-12823 (March 11, 2015). Docket No. FDA-1999-D-1315 (formerly 1999-D-0296)

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA[1]) appreciates the opportunity to provide comments on the FDA's draft guidance for industry entitled "Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Prescription Drug User Fee Act Products" (draft guidance). This document was released on March 11, 2015 (80 *Federal Register* 12822-12823)[2,3]. CHPA members hope the Agency will find our suggestions useful as the final version of the guidance is developed.

IV. Meeting Requests

The March 2015 version of the draft guidance states that faxed or emailed meeting requests should be sent to the FDA during the official business hours of 8:00 am – 4:30 pm EST/EDT Monday through Friday with the exception of Federal holidays (see lines 196-198 of the draft guidance). This is consistent with the recommendations contained in the May 2009 final guidance entitled "Formal Meetings Between the FDA and Sponsors or Applicants"

[1] CHPA, founded in 1881, is a national trade association representing manufacturers and distributors of over-the-counter medicines and dietary supplements (www.chpa.org).
[2] FDA Draft Guidance "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products." Accessed at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM437431.pdf on 29 April 2015.
[3] *Federal Register* notice published 11 March 2015 (80 *Federal Register* 12822-12823). Accessed at http://www.gpo.gov/fdsys/pkg/FR-2015-03-11/pdf/2015-05523.pdf on 29 April 2015.

(guidance)[4]. Sponsors or applicants[5] from across the United States and from around the world may seek a meeting with the Agency based on the available options (*i.e.,* Type A, B or C meeting). CHPA members assume the basis for the proposed timeframe for when submissions should be completed is FDA's need to acknowledge receipt of the applicant's request and to initiate any applicable timelines listed in the draft guidance. We recommend the draft guidance be changed to state that meeting requests may be sent at any time but that documents faxed or emailed after 4:30 pm EST/EDT will be considered as received by the Agency on the next business day. FDA's official date of receipt would be used to initiate the timeframe to schedule the requested meeting (if granted) and the corresponding submission deadline(s). However, if the guidance is finalized as currently written, it would be helpful for the Agency to explain the rationale for requesting sponsors only make submissions Monday through Friday between 8:00 am and 4:30 pm EST/EDT.

VII. Meeting Package Content and Submission

C. Meeting Package Content

The May 2009 guidance and March 2015 draft guidance strongly suggest that, in addition to meeting packages provided in electronic format, sponsors also provide paper copies of their documents (see lines 397-398 of draft guidance[2]). Unless otherwise defined by an FDA Manual of Policies and Procedures (MAPP), CHPA members recommend the draft guidance be modified to reflect that the sponsor should speak with the project manager (or reviewer) to determine if submitting documents in electronic format only is acceptable or if paper copies are needed or preferred (alone or in addition to the electronic documents).

Electronic submissions have several advantages over submissions provided in paper format. First, electronic submissions allow applicants to easily link to references, table of content sections, and any data tables, charts, and/or graphs included in the background package. These links should allow for a more efficient review process because the reviewer can easily access the content in question without the need to manually search through large documents to find the relevant section or page. The ability to cross-reference information is obviously inactive or lost when the background documents are provided in paper format. Second, sponsors incur considerable expenses to prepare and ship multiple copies of paper submissions. Once the meeting has concluded, FDA becomes responsible for proper storage and/or the eventual destruction of the paper copies. Finally, by providing paper copies only when needed and in the quantity specifically requested for each review, sponsors can decrease their environmental footprint by using less paper, especially when the submission is voluminous.

VIII. Premeetings and Communications With Requesters

The May 2009 guidance indicates that FDA *may* (emphasis added) communicate preliminary responses to a sponsor's questions. However the March 2015 draft guidance now

[4] FDA Final Guidance "Formal Meetings Between the FDA and Sponsors or Applicants." Accessed at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm153222.pdf on 30 April 2015.
[5] For the purpose of this guidance, sponsors and applicants are used interchangeably.

reflects that the Agency has a *goal* (emphasis added) of communicating preliminary responses to the meeting requester no later than 2 days before the scheduled meeting date (see lines 469-471 of the draft guidance[2]). CHPA members support this subtle but important change to when sponsors should expect to receive preliminary feedback from FDA.

There may be instances when the Agency's preliminary responses fully resolve any outstanding issues or questions an applicant might have thus permitting the sponsor to advance its research & development (R&D) program accordingly. The sponsor can then initiate an official request for cancellation of the meeting (as outlined in the draft guidance) when appropriate. If the meeting cancellation is confirmed in a timely manner, sponsors may avoid unnecessary travel time and expenses while the affected FDA staff can attend to other regulatory matters.

In some circumstances the Agency's preliminary responses to the applicant's questions may not adequately address the issue(s) set for discussion. However advanced receipt of the preliminary responses will aid in the sponsor's ability to prepare for the subsequent meeting thereby ensuring meaningful dialogue on matters where clarification is needed or further discussion is warranted.

Summary

We applaud the Agency for releasing the revised draft guidance on formal meetings between the FDA and sponsors of Prescription Drug User Fee Act Products. While we agree with the majority of the points outlined in the document, CHPA members hope our suggested revisions will improve the final version of the guidance once released.

Thank you for your time and attention. My contact information is listed below should questions arise.

Sincerely,

Marcia D. Howard, Ph.D.
Senior Director, Regulatory & Scientific Affairs
Email: mhoward@chpa.org
Phone: 202.429.3532

Cc: Rachel E. Hartford, FDA Center for Drug Evaluation and Research
Stephen Ripley, FDA Center for Biologics Evaluation and Research