FDA/CDER
SMALL BUSINESS CHRONICLES
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Inside This Issue

Communicating with CDER

FDA promotes innovation through enhanced and timely interactive communication with sponsors during drug development. The ultimate goal: to facilitate the conduct of efficient and effective drug development programs. Let's take a look at some avenues of communication with the FDA:

CDER's Small Business Assistance Program: This is a great starting point. When you call or email, you will reach one of my colleagues or me and will generally receive guidance within two business days. You may contact us by emailing CDERSmallBusiness@fda.hhs.gov or by calling 301-796-6707.

Office of New Drugs and Enhanced Communication Team (ECT): For application-specific questions, communicate with your Regulatory Project Manager in the Office of New Drugs. ECT is a point of contact for general questions about the drug development process, for clarification on which review division to contact with questions, and a secondary point of contact for those who encountering difficulties in communicating with the review team. The ECT can be reached via phone (301-796-0319) or email (ONDEnhancedComm@fda.hhs.gov).

Formal Meetings with FDA: Formal meetings provide an important forum for you to present information, and for FDA to provide specific and targeted advice. Formal PDUFA meetings fall into one of three types – Type A, Type B, or Type C. The FDA determines the meeting type based on the nature of the request and the information in the meeting request.

A Type A meeting is a meeting which is necessary for an otherwise stalled product development program to proceed. Examples include dispute resolution meetings, certain meetings to discuss clinical holds, certain special protocol assessment (SPA) meetings, and a post-action meeting requested within three months after an FDA regulatory action other than approval (i.e. issuance of a complete response letter).

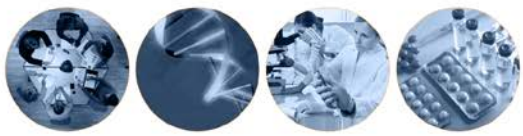
- Include a complete meeting package with Type A meeting requests, or the meeting may be denied.
- The response goal to grant or deny the meeting is 14 days. If granted, it should be scheduled to occur within 30 days of FDA receipt of a written meeting request.
- Before submitting a request, contact the Review Division to discuss the appropriateness of the request.

Type B meetings include the following meetings: pre-IND, pre-emergency use authorization, certain EOP1, EOP2 and pre-phase 3, pre-NDA/BLA, and post-action meetings requested three months or more after an FDA regulatory action other than an approval. Type B meetings also include meetings regarding risk evaluation and mitigation strategies or post-marketing requirements that occur outside the context of the review of a marketing application, and meetings to discuss the overall development program for products granted Breakthrough Therapy designation status.

- The response goal to grant or deny the meeting is 21days. If granted, it should be scheduled to occur within 60 days of FDA receipt of the written meeting request.
- In general, FDA will not grant more than one of each of the Type B meetings for each potential application or combination of closely related products developed by the same sponsor or applicant.

A Type C meeting is any meeting other than a Type A or Type B meeting regarding the development and review of a product.

- The response goal to grant or deny the meeting is 21 days. If granted, it should be scheduled to occur within 75 days of FDA receipt of the written meeting request.



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In the case of a pre-IND or Type C meeting, the sponsor may request a written response to questions instead of a face-to-face meeting. Sometimes, while the sponsor may request a face-to-face meeting, FDA may determine that a written response to the questions would be more appropriate. In either scenario, the FDA shall notify the requester of the date it intends to send the written response within the specified timeframe for assessing the meeting request. Before requesting a meeting, consider other sources of input applicable to the product development program. Submit meeting requests to your application. If there is no established application, the responsible point of contact in the review division will provide instructions on how to submit.

Meeting Request: This should include adequate information for the FDA to assess the potential utility of the meeting, such as:

1. Product name
2. Application number (if applicable)
3. Chemical name and structure
4. Proposed indication(s) or context of product development
5. Type of meeting being requested (If a Type A meeting, include the rationale and meeting package)
6. A brief statement of the purpose and objectives of the meeting
7. A proposed agenda
8. A list of proposed questions, grouped by discipline, and a brief explanation of the context and purpose
9. A list of sponsor or applicant attendees, affiliations, and titles
10. A list of FDA staff, if known, or disciplines asked to participate in the requested meeting
11. Suggested dates and times for the meeting. Also include non-availability dates and times
12. The format of the meeting (i.e., face to face, teleconference, videoconference, or written response)
13. The approximate date that the meeting package will be sent - at least one month in advance of the scheduled meeting for Type B and C meetings (including those for written responses only)

Meeting Package: A meeting package helps to ensure a productive discussion and information exchange with FDA, and allows FDA to prepare for the meeting. It should be submitted to the application at the time of request for a Type A meeting and at least one month before a Type B/C meeting. If there is no established application, the point of contact in the review division will provide instructions on how to submit. The content should be organized according to the proposed agenda and should include:

1. Product name and application number (if applicable)
2. Chemical name and structure
3. Proposed indication
4. Dosage form, route of administration, and dosing regimen
5. An updated list of sponsor or applicant attendees, affiliations, and titles
6. A background section that includes a brief history of the development program and the status of product development
7. A brief statement summarizing the purpose of the meeting
8. A proposed agenda
9. A list of the final questions, grouped by discipline, and a brief of the context and purpose
10. Data to support discussion organized by discipline and question

It is critical that the meeting package content support the intended meeting objectives. The meeting package should provide summary information relevant to the product and any supplementary information needed to develop responses. Full study and trial reports or detailed data generally are not appropriate. For additional information, please refer to the Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants, which is being revised to include PDUFA V.

Whether you are seeking general guidance on drug development, or are looking for guidance on data required to support a marketing application, we encourage you to take advantage of the available resources and communication options available.

Cheers! Until next year…

Renu Lal, Pharm.D.

CDER Small Business Assistance

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