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# Manual of Standard Operating Procedures and Policies

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## Regulatory - License Applications

### Fast Track Drug Development Programs: Designation and Review Programs

SOPP 8414

Version #1

Date: November 16, 2001

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#### 1. Purpose

This document describes procedures and policies for handling fast track designation requests. It also provides procedures for handling of requests for submission of portions of applications (SoPA).

#### 2. Background

Section 112 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) amended the Federal Food Drug and Cosmetic Act (FDCA) by adding section 506. Section 506 directs FDA to take actions appropriate to facilitating the development and expediting the review of applications for drugs that are intended to treat serious or life threatening conditions and that demonstrate the potential to address an unmet medical need for such a condition. The "Guidance for Industry: Fast Track Development Programs-Designation, Development and Application Review" was published on November 18, 1998, and is available on the CBER WEB Page at <http://www.fda.gov/cber/guidelines.htm>. To obtain designation as a fast track drug development program, a sponsor must submit a request to FDA in their Investigational New Drug Application (IND). FDA has 60 calendar days from the date of receipt to review the request and determine whether it meets the criteria as defined in the statute and further explained in the Guidance, and respond in writing. Section 506(c) provides for review of incomplete marketing applications for a fast track product in certain circumstances.

#### 3. Policy

The decision whether to designate the drug development program as Fast Track will be based on the criteria contained in the guidance mentioned above. The clinical reviewer of the IND, with concurrence from the branch chief and/or division director, will have primary responsibility for the decision. Responsibility for coordination of the response will be through the Regulatory Project Manager (RPM) in the Application division.

Section 506(c) of the FDCA provides that FDA may agree to submission of portions of a BLA application (SoPA) or efficacy supplement before the complete BLA is submitted. This provision only applies to a product and indication that has received Fast Track designation. FDAMA states that we will accept a SoPA only if the drug development program continues to meet the criteria for Fast Track designation (e.g., meets an unmet medical need) and preliminary evaluation of the efficacy data from the principal controlled trials

supports a determination that the product may be effective. In addition, CBER will consider the availability of staffing resources to initiate early review of the portions and whether accepting a SoPA is anticipated to increase efficiency of review or lead to an earlier approval action. Reviewers should tell sponsors that their entire SoPA should be completed within 4 to 6 months after their first portion is submitted. Sponsors should be told that at the time they submit their CMC section, their facility should be ready for inspection so that the scheduling of an inspection can begin.

#### 4. Responsibilities and Procedures

##### Procedures for handling designation requests

###### *Pre-submission communications with sponsors*

With regard to general inquiries on fast track policies, sponsors should be directed to the WEB site or to OCTMA for a copy of the Guidance. If there are remaining questions following their reading of the document they should discuss with the appropriate RPM.

The RPM should inform interested sponsors to submit a fast track request as explained in the guidance document. This will generally be 5 to 15 pages in length, and contain summaries of preclinical or clinical data that support the contention that their product has potential to address an unmet medical need.

- Potential for addressing an unmet medical need is supported by different types of data as drug development progresses.
- The level of detail required for documentation of the seriousness of the condition will depend upon generally accepted medical knowledge.
- The amount of information necessary to document an unmet medical need will depend on whether or not there are existing therapies for the condition.

At a sponsor's request, FDA will discuss details concerning a particular product and the fast track program at IND meetings and telecons if the sponsor includes this issue on the agenda, but FDA will not commit to decisions at such times. The actual decision will always be communicated in writing as a formal response to the designation request.

###### *Timeline for Review (calendar days)*

##### **Day 0     CBER Document Control Center (DCC) receives request**

Requests for fast track designation should be submitted as 3 copies with an appropriately labeled FDA Form 1571, as part of an Original IND Submission or an amendment to an existing IND. DCC will date stamp and route to the Application division for routine processing.

##### **Day 3     RPM conducts preliminary regulatory review and initiates routing**

The RPM will indicate Fast Track on the IND ORIGINAL SUBMISSION FORM or the PRELIMINARY IND AMENDMENT SLIP for a request received with an original submission or amendment, respectively. The submission will be routed to the clinical reviewer and CBER Fast Track Coordinator. The submission is returned to DCC with a priority processing slip. DCC will update BIMS with the FR (Fast Track Designation Request) code and route to the designated reviewers.

##### **Day 3-5     RPM conducts regulatory review and notifies team (concurrent with DCC processing)**

As part of the administrative/regulatory review, the RPM will determine whether the request contains information addressing each of the criteria of fast track (serious disease, unmet medical need, and potential to address the unmet medical need). If the application is clearly deficient, following consultation with the appropriate Office specific supervisory official, the RPM will inform the sponsor

by telecon that the request is materially incomplete and will not be considered a request for fast track designation. The RPM will identify the deficiencies so that the sponsor will have the opportunity to correct them in a subsequent submission.

If the request is materially complete, the RPM will notify all reviewers, clinical branch chief and division director, and the CBER Fast Track Coordinator of the arrival of the request by e-mail, along with target dates (e.g. day 40, 50) and the Fast Track check list attachment. The RPM will enter what the sponsor has identified as the condition for which the product is intended into the comment field of the amendment containing the request. If this is not clear in the submission, the indicated use will be entered.

#### **Day 5-40 Clinical review is completed**

Within 40 calendar days of receipt of the fast track request at CBER, the clinical reviewer should complete the review and submit a completed Fast Track check list ([Appendix 7](#)) or memo to the branch chief and/or division director for concurrence. The review should include "letter ready" comments. The decision will not be communicated by telephone.

The RPM receives signed off comments from Division Director by day 40.

#### **Day 40-50 RPM drafts fast track letter**

Using wording provided by the clinical reviewer, the RPM drafts the decision letter and E-mails it to the appropriate reviewers and the fast track coordinator for concurrence and to resolve wording issues within 3 working days. Non response is considered concurrence.

#### **Day 50-60 Letter finalized**

The letter is signed off by the appropriate Office specific official and designated in BIMS as FS (Fast Track Designation Granted) or FD (Fast Track Designation Denied), and the conditions entered into the BIMS letter comment field. The amendment screen is updated by the RPM to the exact wording used in the letter for indication/drug development plan.

### **Procedures for Submitting a SoPA**

#### *Pre-submission conversations with sponsors*

RPM should advise sponsors considering a SoPA to:

- include their proposal in the agenda for discussion at the pre-BLA meeting.
- present the preliminary analysis of data that supports a determination that the product is effective in the background package for the meeting.
- include a proposal for the SoPA including a description of the sections and a timetable for submission of each section of the SoPA in the background package for the meeting.

RPMs should document any discussion of the SoPA in their pre-BLA meeting minutes.

#### *Submission procedures:*

Subsequently RPMs should advise sponsors to submit a written request for a SoPA after consideration of issues discussed at the pre-BLA meeting, and at least 2 months prior to the proposed submission date for the first portion of the SoPA. The request should:

- be in triplicate with a Form 1571; the cover letter should clearly identify the amendment as a "Request for Submission of Portions of an Application."
- include a detailed schedule, a table of contents with brief description of the content of each

portion, and a statement of when facilities will be ready for inspection.

CBER will respond in writing, granting or denying the SoPA request. Sponsors should be told that changes to the submission schedule prior to starting the SoPA must also be submitted in writing and accepted by CBER.

Sponsors should be instructed that each portion of the SoPA should be in a form adequate to have been included in a traditional, complete BLA. Final reports, not draft documents, should be submitted. Generally, the review team will only agree to a SoPA if the portions are complete sections of a BLA, e.g. entire CMC section, toxicology section, clinical section, etc. Occasionally the review team may, at its discretion, agree to submission of portions that consist of a part of a section if they feel that such a subsection would constitute a reviewable unit and would be useful in facilitating the review process. Each portion, as well as the cumulative complete BLA, must be well organized to facilitate review.

#### *Handling of the SoPA*

Upon submission of the first portion of a SoPA, the RPM will ensure that a Submission Tracking Number (STN) is assigned in RMS-BLA with the Special Characteristics of "Fast Track Designation" and "SoPA Submission". ("Fast Track Designation" alone is used when the initial BLA submission for a designated program is a complete application.) A review committee is established, and the portion(s) routed for review. An acknowledgement letter is sent to the company at this time with their STN. No review schedule is entered in RMS-BLA for a SoPA until the final portion is submitted. Actual commencement of review will depend upon many factors including the submission schedule, workload, and other review priorities. Comments may be communicated to the sponsor in telecons, Information Request letters and Discipline Review letters. If application user fees and a Form 3397 do not accompany the first portion, or if the applicant is in arrears on user fees, the first portion will be considered "Unacceptable for Filing".

If the applicant deviates from the agreed upon schedule for the SoPA, CBER may consider the agreement to be void. The RPM will draft a letter informing the sponsor of the Center's decision. The letter will proceed through office specific sign off. The RMS-BLA tracking system should indicate "SoPA voided". Review will be restarted when the complete application is submitted.

Each partial submission to the SoPA should be designated with the Special Characteristic of "SoPA Submission" in RMS-BLA until the application is complete.

When the final portion of the SoPA is submitted, the applicant will indicate that the application is complete. Upon receipt of this notification, the RPM will ensure that the "Final SoPA Submission" Special Characteristic is assigned to the STN, the review schedule is established in RMS-BLA, and the review clock started. A filing review and decision will then be made within the usual timeframe. Generally, a BLA accepted as a SoPA will receive priority review status since the criteria for Fast Track at this stage of development are the same as those for priority review. There are cases where this would not be true, i.e., where another product has been approved since the first portion of the BLA was submitted that met the unmet medical need. In rare cases where multiple indications are submitted in a BLA and only some meet the Fast Track criteria, CBER may administratively unbundle the application and assign different review schedules as well as different Submission Tracking Numbers and possibly different review committees.

## 5. Appendices

Appendix 1: [Fast Track Granted Template Letter](#)

Appendix 2: [Fast Track Denied Template Letter](#)

Appendix 3: [SoPA Accepted Template Letter](#)

Appendix 4: SoPA Denied Template Letter (To be developed)

Appendix 5: STN assignment letter (Under revision)

Appendix 6: [Database tracking elements](#)

Appendix 7: Checklist template - [Review for Determining Fast Track Development Program Designation](#)

**6. Effective Date**

November 16, 2001

**7. History**

Comment / Revision	Approved By	Approval Date	Version Number	Comment
Bette Goldman, RN, MPH	Robert Yetter, PhD	11/16/2001	1	Original

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