SOPP 8216: Fast Track Development Programs - Designation and Management

Version: 3
Effective Date: February 27, 2023

Table of Contents

I. Purpose:

This Standard Operating Policy and Procedure (SOPP) serves as a guide for Center for Biologics Evaluation and Research (CBER) staff for processing and reviewing requests for fast track designation and for expediting the development and review of a fast track designated drug consistent with the requirements of section 506(b) of the Federal Food, Drug, and Cosmetic (FD&C) Act as added by section 112 of the Food and Drug Administration Modernization Act (FDAMA) of 1997 and amended by section 901 of the Food and Drug Administration Safety and Innovation Act (FDASIA) and as also explained in *Guidance for Industry: Expedited Programs For Serious Conditions – Drugs and Biologics*.

II. Scope:

A. This SOPP includes the procedures for:

- Review of a request for fast track designation submitted with an original Investigational New Drug Application (IND) or in an IND amendment,
- Procedures for rescinding a fast track designation under an IND submission, and

- Review of requests to withdraw a fast track designation or designation request.

B. This SOPP does not cover devices or device-led combination product designations. Please refer to the *Guidance for Industry and Food and Drug Administration Staff: Breakthrough Devices Program* and *Guidance for Industry and Food and Drug Administration Staff: Safer Technologies Program for Medical Devices* for information specific to expedited programs for devices.

C. This SOPP does not cover general administrative procedures for INDs. Refer to *SOPP 8217: Administrative Processing and Review Management Procedures for Investigational New Drug Applications* for such information.

D. This SOPP does not address the specific content of scientific reviews.

E. This SOPP does not cover breakthrough therapy or regenerative medicine advanced therapies (RMAT) designations.

F. This SOPP does not cover the review of new biologics license applications (BLAs), or new drug applications (NDAs) submitted for fast track designated products.

III. Background:

A. Section 506(b) of the FD&C Act as amended by section 112 of FDAMA and section 901(b) of FDASIA provides for the designation of a drug as a fast track therapy "… if the product is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life threatening disease and it demonstrates the potential to address unmet medical needs for such a disease or condition" OR "if the drug has been designated as a qualified infectious disease product."

B. The *Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics* provides information regarding the qualifying criteria for a fast track designation, and outlines at a high level, the features of a fast track designation.

C. Features of fast track designation include actions to expedite development and review and rolling review. Actions to expedite development include frequent interactions with the review team and the potential for eligibility for priority review. Information regarding priority review can be found in the G*uidance for Industry:* E*xpedited Programs for Serious Conditions – Drugs and Biologics*. For information regarding rolling review, refer to Appendix 2 of the *Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics* and Job Aid *JA 910.19: Procedures for Processing Rolling Review Submission.*

D. A fast track designation is not the same as a biologic or drug approval and does not change the statutory standards for demonstrating the safety and effectiveness needed for product approval. A fast track product development program must generate substantial evidence of effectiveness and sufficient evidence of safety to meet the statutory standard for approval.

IV. Definitions

N/A

V. Policy

A. Sponsors may make a request for fast track designation with the submission of an Investigational New Drug application (IND) or in an amendment to an existing IND, ordinarily not later than the sponsor's pre-BLA/NDA meeting with CBER because many of the features of fast track designation will not apply after that time.

B. Fast track designation, breakthrough therapy designation, and regenerative medicine advanced therapy (RMAT) designation are distinct designation programs with different programmatic requirements. Sponsors may apply for and receive more than one designation for a given product, but sponsors should apply for each designation separately, in separate amendments to their IND. In addition, if a sponsor's development program is granted fast track designation for one disease/indication and the product demonstrates the potential to address unmet medical needs for another disease/indication or condition, the sponsor should submit a request for fast track designation for that disease/indication or condition, in a separate amendment to their IND.

C. As noted in the *Guidance for Industry: Expedited Programs for Serious Conditions - Drugs and Biologics* features of fast track designation include actions to facilitate development and expedited review of the product. CBER intends where possible to review IND amendments that are related to product development in a timely manner. The guidance further indicates that there are opportunities for frequent interactions with the review team which include meetings. Such interactions can be more frequent than an IND without designation but generally not to the level of frequency for products with breakthrough therapy or RMAT designation(s).

D. CBER will notify the sponsor in writing, within 60 calendar days after receipt of the fast track designation request, as to whether the product has received fast track designation. If CBER determines that the product does not meet the criteria for fast track designation, CBER will include a written description of the rationale for the decision in the non-designation letter.

E. If a request for fast track designation was previously denied, and a sponsor submits new information, then that request will be considered a new designation request.

F. CBER will not grant requests for fast track designation for INDs that are inactive, on clinical hold, or placed on clinical hold if submitted with the original application. If the IND is on partial hold at the time the fast track designation request is received, the circumstances of the partial hold will be considered to determine how they may affect the review of the request for fast track designation.

G. The regulatory project manager (RPM), review team members, their immediate supervisors (laboratory or branch chiefs), and senior managers will follow the processes and procedures outlined in the *Draft Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants for PDUFA Products* and *SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products* when scheduling and conducting meetings for fast track designated products.

H. Review team members and supervisors will follow CBER's Managed Review Process when reviewing IND submissions for fast track designated products. These principles and practices include adhering to review timelines for IND amendments, and documentation of supervisory concurrence, when necessary, of written reviews.

I. Review team members and supervisors will follow the principles set forth in the *Guidance for Industry and Review Staff: Best Practices for Communication Between IND Sponsors and FDA During Drug Development*

J. When the criteria for fast track designation are no longer met, CBER may rescind the designation. CBER will notify the sponsor in writing of their intent to rescind the fast track designation. The Intent to Rescind Fast Track Designation letter will include the criteria for making such a determination and provide the sponsor with an opportunity to submit additional data and justification to support the continuing fast track designation and/or to request a meeting with CBER to discuss the fast track designation for the product.

1. If the sponsor does not submit additional justification or supportive data or request a meeting within 60 days of receipt of the Intent to Rescind Fast Track Designation letter, CBER may rescind the fast track designation.

2. If after review of additional information and meeting with the sponsor, if applicable, CBER decides to rescind the fast track designation, CBER will notify the sponsor in writing and will provide the rationale for this decision in the Rescind Fast Track Designation letter. The rescinding of a fast track designation does not necessarily mean that the product is not

promising or that the product may not receive marketing approval. It means that the criteria for fast track designation are no longer met.

K. Marketing applications for fast track designated products may be eligible for the accelerated approval pathway, priority review, and/or rolling review if the criteria are met as described in the *Guidance for Industry: Expedited Programs for Serious Conditions - Drugs and Biologics*. As stated in Appendix A of the guidance, rolling review should be discussed at the pre-BLA/NDA meeting (or sooner). Generally, a complete section (i.e., an eCTD module), such as the entire CMC section, toxicology section, or clinical section should be submitted, unless submission of an incomplete module was agreed upon. If a rolling review has been agreed upon, ideally, all portions of the application should be submitted no more than one year after the initial portion. Any review of portions already submitted may be suspended because our ability to conduct a meaningful review may be inhibited without the missing information. Efficacy supplements for products and indications with fast track designation are also eligible for rolling review.

VI. Responsibilities

Note: Refer also to *SOPP 8217: Administrative Processing and Review Management Procedures for Investigational New Drug Applications* for additional general responsibilities for IND review.

A. Review Team Member

1. Participates in all review team meetings

2. Participates in CBER-sponsor meetings when issues regarding their assigned areas of responsibility are being discussed

3. Consults with subject matter experts outside of the assigned review team, when necessary

4. Meets regularly with their supervisor to provide updates on the status and progress of the fast track product development program

5. Identifies issues with the fast track product development program, including when the criteria are no longer met for fast track designation, proposes potential solutions when appropriate, and communicates issues to their supervisor and the RPM as soon as possible.

B. RPM

1. Serves as the primary point of contact with the sponsor.

2. Stays up-to-date on the status of the fast track product development program, including planned and on-going clinical trials, product development plans, and discipline-specific information requests, meetings, and teleconferences with the sponsor to facilitate an efficient review of the development program.

3. Ensures the review team is kept up to date on all aspects, except scientific issues, of the product development program

4. Facilitates all review team and CBER-sponsor meetings (or designates a qualified staff member to facilitate, if unable to attend) and works to ensure that review team and CBER-sponsor meetings for fast track designated products are prioritized on the calendar

5. Communicates with the appropriate point of contact (e.g., RPMs) in other CBER offices and FDA Centers to exchange information, coordinate efforts, and request consults when the review team requires additional scientific expertise

C. Discipline Branch and/or Laboratory Chief

1. Meets with the discipline reviewer to stay up-to-date on the status and progress of the fast track development program.

2. Ensures the quality and consistency of discipline reviews

3. Attends critical IND milestone meetings, and subsequent review team and CBER-sponsor meetings when issues regarding their areas of responsibility are being discussed

4. Keeps the discipline Division Director up-to-date regarding the status of the fast track product development program

D. Discipline Division Director

1. Attends (or designates the Deputy Division Director to attend, if unable to attend) critical IND milestone meetings, and, any subsequent CBER-sponsor meetings, when issues regarding their areas of responsibility are being discussed

2. Meets with the discipline-specific branch or laboratory chief to keep apprised of the fast track product development status

3. Keeps their Office Director up-to-date on the status of fast track product development programs within the division

4. Resolves differences in scientific opinions between disciplines, as needed

E. Product Office Director

1. Stays informed of the status of fast track product development programs within the Office through the Division Directors

2. Attends critical IND milestone meetings, and review team and CBER-sponsor meetings, as appropriate

3. Addresses specific issues or policy questions brought to their attention through the discipline, or division management chain

4. Consults with the Discipline Office Directors, the Associate Director for Review Management (ADRM), the Center Director and appropriate groups as necessary regarding fast track product development issues, including rescinding fast track designation.

F. Office of Regulatory Operations (ORO), Division of Informatics (DI), Regulatory Information Branch (RIB)

1. Characterizes amendments as received.

2. Prepares monthly Fast Track Performance Report and a quarterly cumulative Fast Track Report.

VII. Procedures

A. Request for Fast Track Designation

1. Receive, digitally image (if applicable), process, and load into the CBER Electronic Repository (CER). Notify the appropriate Office through the load notification. **[DCC]**

2. Characterize the request in the appropriate regulatory system. **[RIB]**

3. Check to ensure that the request is not submitted to a pre-IND file, to an IND on clinical hold, or to an inactive IND. **[RPM]**

   a. If submitted to a pre-IND file, inform sponsor via telecon that a request for fast track designation cannot be made prior to the submission of an IND.

   b. If the IND is on clinical hold, deny the designation request using the appropriate letter template.

   c. If the IND is inactive, deny the designation request using the appropriate letter template.

d. If the IND is on partial hold the review team will consider the specific circumstances of the partial hold and whether this affects the review of the fast track request.

4. Verify that the designation request is specific to a single indication of a single product and is only for fast track designation.

a. If request is for multiple indications, inform sponsor that additional designation requests would be needed for each indication.

b. If sponsor also requested another type of designation (i.e., breakthrough therapy or RMAT) within the same amendment, inform sponsor that additional designation requests should be re-submitted in separate amendments.

c. Document communication in the appropriate regulatory system and ensure the amendment characterization reflects only the single request. **[RPM]**

5. Verify that the request has been characterized accurately in the appropriate system, update, if necessary, and inform RIB of any changes that have been made. **[RPM]**

6. Send the request to the IND review team members and provide the review timeline. **[RPM]**

7. Send acknowledgement of receipt of fast track designation request letter to sponsor no later than 14 calendar days after CBER receipt. **[RPM]**

8. Review request for designation and make decision based on criteria in the *Guidance for Industry: Expedited Programs for Serious Conditions - Drugs and Biologics* and available reviewer template *T843.01: CBER Fast Track Designation Determination Review*. **[Review Team members]**

a. Determine if consults are needed and if inter-center, follow *SOPP 8001.5: Inter-Center Consultative Review Process.*

9. Send letter to sponsor denying or granting designation within 60 days of receipt of request and upload the communication to the CER. **[RPM]**

B. Intent to Rescind a Fast Track Designation

1. Determine that the fast track product development program no longer meets the criteria for fast track designation. **[Discipline Reviewer(s)]**

2. Write a brief memo using *T 815.03: Intent to Rescind Fast Track, Breakthrough Therapy, or RMAT Memo,* route through supervisory chain for concurrence, and inform the RPM. **[Discipline Reviewer(s)]**

3. Return signed memo to discipline reviewer, with a cc to the RPM. **[Division Director]**

4. Notify senior management, the ADRM, and the Deputy Center Director when the product development program no longer meets the criteria for fast track designation and an *Intent to Rescind Fast Track Designation* letter will be issued to the sponsor. **[RPM]**

5. Draft Intent to Rescind Fast Track Designation letter and send letter for clearance to review team members, branch/laboratory chiefs, and senior management. **[RPM]**

6. Review letter and provide clearance to RPM. **[Review Team Members, Branch/Laboratory Chiefs, Senior Management]**

7. Finalize letter and circulate for final concurrence and sign-off. **[RPM]**

8. Sign Intent to Rescind Fast Track Designation letter. **[Division Director]**

9. Issue letter to sponsor and enter communication into the appropriate regulatory system and upload to the CER. **[RPM]**

C. Sponsor's Response to Intent to Rescind Fast Track Designation letter

1. Receive and send sponsor's response to review team. **[RPM]**

2. Review additional information, data, and/or rationale provided in the sponsor's response. **[Discipline Reviewer(s)]**

3. Schedule multidisciplinary internal meeting and sponsor meeting if the sponsor's response includes a request for a meeting. **[RPM]**

4. Attend pre-meeting and sponsor meeting. **[Review Team Members, Branch/Laboratory Chiefs (Discipline Division Director(s))]**

   Discussion topics should include:

   a. The additional information, data and/or rationale for maintaining fast track designation provided in the sponsor's response.

   b. Explanation of why the fast track designation should be maintained or rescinded.

c. If recommendation is to maintain fast track designation, plans for a path forward for the development of the product.

5. Make decision to maintain fast track designation. **[Review Team]**

a. If a decision is made to maintain fast track designation, document decision in a review memo and enter it into the appropriate regulatory system through CBER Connect. **[Discipline Reviewer]**

b. Draft an IND advice letter, modified to notify sponsor that fast track designation will be maintained and send to review team members, branch/laboratory chiefs, and senior management for review/clearance. **[RPM]**

c. Review letter and provide clearance to RPM. **[Review Team Members, Branch/Laboratory Chiefs, Senior Management]**

d. Finalize letter and circulate for final concurrence and sign-off. **[RPM]**

e. Sign advice letter. **[Product Office Director]**

f. Issue letter to sponsor, enter communication into the appropriate regulatory system, and upload into the CER. **[RPM]**

D. Rescinding a Fast Track Designation

1. Document rationale/findings using *T 815.04: Rescinding Fast Track, Breakthrough Therapy, or RMAT Designation Memo* and route memo through immediate supervisor to Division Director for concurrence. **[Appropriate Disciple Reviewer(s)]**

2. Return signed memo to the discipline reviewer and notify RPM. **[Division Director]**

3. Alert senior management (including the ADRM and the Deputy Center Director) when the product development program no longer meets the criteria for fast track designation and a *Rescind Fast Track Designation* letter will be issued to the sponsor. **[RPM]**

4. Draft Rescind Fast Track Designation letter and send it to review team members, branch/laboratory chiefs, and senior management for review/clearance. **[RPM]**

5. Review letter and provide clearance to RPM. **[Review Team Members, Branch/Laboratory Chiefs, Senior Management]**

6. Finalize letter and circulate for final concurrence and sign-off. **[RPM]**

7. Sign Rescind Fast Track Designation letter. **[Product Office Director]**

8. Issue letter to sponsor, enter communication into the appropriate regulatory system and upload into the CER. **[RPM]**

E. Request for Withdrawal

1. Receive request for withdrawal of fast track designation or fast track designation request. **[DCC]**

2. Forward to the request to the RPM. **[DCC]**

3. Characterize the request in the appropriate regulatory system. **[RIB]**

4. Verify that the request has been characterized accurately and update/correct as needed in the appropriate regulatory system. **[RPM]**

5. Route the request to the IND review team members. **[RPM]**

6. Inform IND review team members and office leadership that a request for withdrawal has been received. **[RPM]**

7. Acknowledge request for withdrawal by issuing Withdrawal – Fast Track Request letter no later than 14 calendar days after CBER receipt. **[RPM]**

8. Enter communication into appropriate regulatory system and upload into the CER. **[RPM]**

VIII. Appendix

N/A

IX. References

A. References below are CBER internal:

1. CBER Letter Template Page

2. T 815.03: Intent to Rescind Fast Track, Breakthrough Therapy, or RMAT Designation Memo

3. T 815.04: Rescinding Fast Track, Breakthrough, or RMAT Designation Review Memo

4. T843.01: CBER Fast Track Designation Determination Review

5. SOPP 8001.5: Inter-Center Consultative Review Process

B. References below can be found on the Internet:

1. Food and Drug Administration Safety and Innovation Act (FDASIA)
2. Draft Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products
3. Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics
4. Guidance for Industry and Review Staff: Best Practices for Communication Between IND Sponsors and FDA During Drug Development
5. Guidance for Industry and Food and Drug Administration Staff: Breakthrough Devices Program
6. Guidance for Industry and Food and Drug Administration Staff: Safer Technologies Program for Medical Devices
7. SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products
8. SOPP 8217: Administrative Processing and Review Management Procedures for Investigational New Drug Applications

X. History

Written/Revised	Approved By	Approval Date	Version No	Comments
M. Monser	Katie Rivers Acting Branch Chief, RABOB/DROP /ORO	February 23, 2023	3	Updated for change in signatory for intent to rescind letter and for 2023 CBER Reorganization.
M. Monser	Darlene Martin, MS, PMP ORO/DROP Director	November 16, 2022	2	Renumbered from SOPP 8414 to SOPP 8216; revised to current procedures and to remove SoPa procedures (moved to JA 910.19)

Written/Revised	Approved By	Approval Date	Version No	Comments
Bette Goldman, RN, MPH	Robert Yetter, PhD	November 16, 2001	1	First version– issued under SOPP 8414